PART 1: ADMINISTRATIVE

June 2014

TABLE OF CONTENTS

ADMINISTRATIVE CHAPTER 1: INTRODUCTION

Revised June 2014

Admin Chapter 1 Table of Contents

1.1 PPFA MANUAL OF MEDICAL STANDARDS AND GUIDELINES (MS&GS)

1.1.1 Development

I. The PPFA Manual of Medical Standards and Guidelines (PPFA MS&Gs) has been developed in conjunction with the PPFA National Medical Committee (NMC) in order to ensure the delivery of consistent, quality medical care by Planned Parenthood affiliates. It is not intended to create a standard of care. Because PPFA's belief in inclusion and diversity is a strongly held value, the PPFA MS&Gs promote delivery of culturally and linguistically competent services to the diverse communities we serve. The PPFA MS&Gs serve as the foundation for Affiliate MS&Gs.

II. Revisions to the PPFA MS&Gs are based on
   A. New evidence published in the medical literature
   B. Newly published guidelines from related professional organizations (e.g., CDC, ASCCP)
   C. Addition of new service(s)
   D. The need for clarifications
   E. Guidance from the NMC
   F. Input and feedback from affiliates, Affiliates Risk Management Services, Inc. (ARMS) and its legal counsel, national organizations, physicians, scientists, or health care professionals in the field of women's health care, primary care, or other related fields

III. The PPFA MS&Gs are designed for electronic use only. They are revised biennially. Individual sections may be revised more frequently if necessary. Affiliates **must** be able to easily access the most current version.

1.1.2 Terminology

I. The terminology used in the PPFA MS&Gs is critical, as certain terms denote mandatory Standards, while others denote optional Guidelines:
   A. Statements that direct by the words "shall" or "**must**" are required, and **must** be included in affiliate practice.
   B. Statements that direct by the words "could," "should," or "may" are Guidelines, and, while representing sound medical practice, may be included optionally in affiliate practice policies.

1.1.3 Non-Compliance

I. Non-compliance with any Standard found within the PPFA MS&Gs may result in actions that jeopardize the affiliate's ability to continue to use the Planned Parenthood trademark. In general, compliance with the PPFA MS&Gs is assessed through but not limited to the accreditation process.

1.1.4 Medical Waivers from the MS&Gs

I. Requesting a Waiver - If circumstances unique to the affiliate require an exemption or variance from a certain Standard(s), affiliates may request a medical waiver:
   A. A waiver may be granted only if doing so does not jeopardize the provision of quality medical care or the objectives of the Federation.
   B. Waiver requests **must** be submitted electronically to medicalservices@ppfa.org.
      1. The request **must** include the citation of the specific Standard for which the waiver is requested, rationale for the request, proposed alternative medical practice, and any supporting documentation.
      2. Medical waivers may be specific to an individual staff person or to an individual client. If a staff person, he/she **must** be identified by name in the request. Client names **must** not be used.
   C. Affiliates will be notified that their request was received within 2 business days.

II. Action on Waivers and Subsequent Review and Notification
   A. Waivers are reviewed and acted upon by PPFA Medical Services staff.
   B. Some waiver requests may require review and input from ARMS, NMC, expert consultants, and/or other divisions within PPFA.
      1. When ARMS is involved, the CEO of ARMS will determine its process.
   C. Some practices may be eligible for standardized or blanket waivers.
      1. A standardized waiver is issued by Medical Services when the same waiver requested is expected from numerous affiliates. This type of waiver provides affiliates with a sample request form and provides the Medical Services' administrative team with an approval letter template.
      2. A blanket waiver is issued by Medical Services presumptively to all affiliates, without requiring affiliate request. This occurs when it's determined that affiliates should have the option to update their protocols immediately. The most common reason for blanket waivers is the release of a new practice guideline or updating of a CIIC/CI between routine publications of the PPFA MS&Gs.

III. Review of proposed requests will focus on medical risks and benefits.

IV. Turnaround times
   A. Simple and standardized waiver requests — 5 business days
   B. Complex waiver requests — 6 to 8 weeks or longer. This depends on many factors including, but not limited to
      1. Adequacy of the documentation received
      2. Need for affiliate and/or PPFA Medical Services research into the issue
      3. Need for ARMS input, review and approval, if applicable (MedicoLegal Advisory Panel [MLAP] meets monthly)
      4. Need for NMC involvement

V. PPFA Medical Services will notify the affiliate of all decisions on waiver requests.

VI. The Accreditation and Evaluation Department and ARMS will be notified of waiver approvals.
VII. Affiliates may appeal decisions regarding medical waiver requests to the
   A. NMC for adverse decisions by PPFA Medical Services
   B. PPFA Board for adverse decisions by the NMC
   C. ARMS Board for adverse decisions by ARMS

1.1.5 Limitations of Use and Liability

I. The PPFA MS&Gs have been revised regularly since they were first published in 1977. Periodic updates are developed specifically for use by Planned Parenthood Federation of America, Inc. and its affiliates. The PPFA MS&Gs are not intended to be relied on by any other individual or entity except for informational purposes. The PPFA MS&Gs are not meant as a substitute for the development and adoption of specific standards, guidelines, and protocols that best meet the needs of other medical providers. Planned Parenthood Federation of America will not be responsible for any injuries or claims arising from the alleged use or non-use of this PPFA MS&Gs or any part of it by other individuals or entities.

1.2 AFFILIATE MANUAL OF MEDICAL STANDARDS AND GUIDELINES (AFFILIATE MS&GS)

1.2.1 Requirements

I. Each affiliate **must** maintain and periodically update Affiliate MS&Gs based on the most current PPFA MS&Gs and within the implementation period specified.
II. Affiliate medical policies and procedures **must** be consistent with the Standards contained in the PPFA MS&Gs.
III. Formatting of the Affiliate MS&Gs **must** include
   A. The affiliate implementation date on each page
   B. A cover sheet that includes the affiliate's legal name and statement that these are MS&Gs of the affiliate
   C. The affiliate's legal name and telephone number(s) on Client Information for Informed Consent (CIICs) documents
IV. If an affiliate chooses to write a protocol and adopt a clinical practice which is more restrictive than the current PPFA MS&Gs, the changes **must**
   A. Be evidence-based, with documentation provided within the affiliate's MS&Gs
   B. Cause no harm
   C. Not add additional barriers to care
V. The PPFA MS&Gs are evidence-based, and may include options that affiliates can choose from when developing their affiliate-specific protocols. In developing affiliate-specific protocols, the affiliate's infrastructure, staffing mix, and medical resources should be taken into account.

VI. Affiliates **must** develop policies for the archiving and destruction of their MS&Gs (this includes CIs and CIICs, consent and release forms) and other policies and procedure manuals. Affiliate MS&Gs **must** be archived for 7 years. Prenatal sections **must** be archived for an additional 18 years.

1.3 CITING AND SHARING PPFA OR AFFILIATE MS&GS

1.3.1 Citing the PPFA or Affiliate MS&Gs

I. The PPFA or Affiliate MS&Gs **must** never be cited in manuscripts, abstracts, or other documents without prior PPFA approval. Inquiries should be sent to medicalservices@ppfa.org

1.3.2 Sharing the PPFA or Affiliate MS&Gs

I. The PPFA MS&Gs are the confidential property of Planned Parenthood Federation of America. To the extent that a Planned Parenthood affiliate has developed its own version of the PPFA MS&Gs ("Affiliate MS&Gs") that Affiliate MS&Gs are deemed to be derived from the confidential materials contained in the PPFA MS&Gs and, as such, are subject to the same restrictions as the PPFA MS&Gs and are the confidential property of both PPFA and that affiliate. Any person, corporation, government entity, or organization outside PPFA or its affiliates is expressly prohibited from obtaining, reprinting, electronically or manually reproducing, or otherwise sharing or distributing the PPFA MS&Gs or Affiliate MS&Gs (referred to collectively as the "MS&Gs") in part or in whole unless prior written consent is obtained from PPFA Medical Services or the Office of General Counsel or under certain other limited circumstances, as described below.

1.3.3 Sharing the Affiliate MS&Gs with Regulatory Bodies

I. When a state or local regulatory body requests the Affiliate MS&Gs, in part or in whole, the following steps **must** be taken.
   A. Review the regulation to determine if the submission of the Affiliate MS&Gs, in whole or in part, is required under the regulation. This may require input from local legal counsel.
   B. If it is determined that submission is not required, the affiliate may
      1. Refuse to submit any portion of the Affiliate MS&Gs;
      2. Offer an alternate solution such as allowing regulators to review the Affiliate MS&Gs on site; or
      3. Produce the Affiliate MS&Gs according to the following guidelines
         a. Request that the regulatory body sign a confidentiality agreement
         b. If the regulatory body is unable or unwilling to sign a confidentiality agreement, attach to the Affiliate MS&Gs a cover letter stating its confidential nature

c. In all instances, produce only those portions of the Affiliate MS&Gs that are directly related to the request.

C. If it is determined that submission is required under the regulation, the affiliate **must**
   1. Submit only the portions of the Affiliate MS&Gs that are required; and
   2. Attach to the Affiliate MS&Gs a cover letter stating its confidential nature.

1.3.4 Sharing the Affiliate MS&Gs in the Context of a Title X Audit

I. When, strictly for audit purposes, there is a Title X request for sections of the Affiliate MS&Gs, the affiliate **must** take the following steps.
   A. Only submit those sections of the Affiliate MS&Gs relevant to the Title X audit
   B. A cover letter stating the Affiliate MS&Gs' confidential nature **must** accompany the produced Affiliate MS&Gs
   C. Neither approval from PPFA nor the use of a release is required

1.3.5 Sharing the PPFA or Affiliate MS&Gs outside of Planned Parenthood with Non-Regulatory, Non-Title X Bodies

I. Under most circumstances, the MS&Gs, either in whole or part, **must** not be shared with person, corporation, government entity, or organization outside of Planned Parenthood. In order for exceptions to be made, the following process **must** be followed:
   A. A written request **must** be submitted to PPFA Medical Services via medicalservices@ppfa.org.
   B. This written request **must** include:
      1. The name and address of requesting organization;
      2. A brief description of person, corporation, government entity, or organization (e.g., nonprofit, service provider offering xxx services, state health department, division of xxx, responsible for oversight and provision of xxx services, etc.);
      3. Contact information for person, corporation, government entity, or organization making the request;
      4. The specific section(s) of the MS&Gs being requested;
      5. The reason for the request;
      6. The affiliate contact person and his/her e-mail address.
   C. If approved, a disclaimer/release form provided by PPFA **must** be signed and the signed copy of the form received by PPFA Medical Services before the relevant section of the MS&Gs can be released.

1.3.6 Sharing the PPFA or Affiliate MS&Gs with Title X Regional Program Consultants, Direct Grantees and Delegate Agencies

I. Relevant section(s) may serve as a foundation for the development of
   A. Title X guidance by non-Planned Parenthood direct grantees and regional program consultants; and/or

B. Clinical protocols by non-Planned Parenthood delegate agencies. (See memo entitled "OPA Program Instruction Series, OPA 09-01: Clinical Services in Title X Family Planning Clinics – Consistency with Current Practice Recommendations," dated June 11, 2009, for requirements).

II. "Relevant sections" are defined as those addressing services supported under the Title X program (e.g., contraception, well-woman visits, cervical cancer screening, and preventive services).

III. Before any section(s) of the MS&Gs is shared, references to PPFA, the affiliate, and any relationship between the two **must** be removed.

IV. Contracts between Planned Parenthood direct grantees and their delegate agencies **must** include hold harmless, defense, and indemnification clauses.

V. The direct grantee or delegate agency receiving the MS&Gs **must** execute a release form that is kept on file (hard copy or electronic) at the affiliate.

1.3.7 Process for Approving Requests to Share the PPFA or Affiliate MS&Gs

I. Following receipt of a written request, PPFA Medical Services will evaluate the request according to the following criteria:
   A. In most instances, only specific sections of the MS&Gs, not the entirety of the MS&Gs, will be approved for sharing.
   B. The requestor **must** represent an organization — no approvals for individuals will be given.
   C. Request may be approved for, among others, the following reasons:
      1. Section(s) of the MS&Gs will be used as background to develop clinical practice guidelines for a specific agency, health center, or service (i.e., hospital-based surgical service, nonprofit health center [not Title X]);
      2. Section(s) of the MS&Gs will be used by a non-provider, public health, nonprofit organization as background in development of evidence-based guidelines on a specific subject (i.e., intimate partner violence, contraception, etc.).
   D. Stricter limitations will apply to requests for sections of the MS&Gs related to abortion. Requestor **must** be a known entity that already provides abortion services or can demonstrate that they are planning to provide abortion services.
   E. If the request is not approved by PPFA Medical Services, the affiliate or requestor (if submitted directly to PPFA) will be notified immediately.
   F. If approved by PPFA Medical Services, additional vetting and approval by Affiliate Risk Management Services (ARMS) and the PPFA Office of the General Counsel is required. Depending on the request, approval from Public Policy Litigation & Law may be sought. The final decision belongs to PPFA.

1.4 ADDITIONAL INFORMATION

1.4.a. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ Sharing the MS&Gs Outside of Planned Parenthood	Extranet

ADMINISTRATIVE CHAPTER 2: CLIENT CENTERED COMMUNICATION FOR SEXUAL AND REPRODUCTIVE HEALTH

Revised June 2014

Admin Chapter 2 Table of Contents

ADMINISTRATIVE CHAPTER 2: CLIENT CENTERED COMMUNICATION FOR SEXUAL AND REPRODUCTIVE HEALTH

Revised June 2014

2.1 STAFF-CLIENT COMMUNICATIONS

2.1.1 Effective Communication

I. Effective communication is an essential component of the sexual and reproductive health care visit.
II. It allows us to
   A. Inform client about all aspects of visit
   B. Provide opportunity for client to ask questions in order to fully understand what will happen during the visit and afterward
   C. Provide opportunity for client to make decisions about reproductive health choices
   D. Help allay anxiety and fear client may have about visit

2.1.1 Confidentiality

I. Confidentiality policies **must** be in place.
II. Assure client that confidentiality will be maintained. Explain any limits on confidentiality due to state/local laws or regulations at the beginning of the encounter.
III. Provide a private space for client to interact with staff.

2.2 COUNSELING IN A REPRODUCTIVE HEALTH CARE SETTING

2.2.1 Key Counseling Components

I. **Establish Rapport** — Greet client, establish purpose of visit, and clarify your role. Establish clients' expectations and build mutual trust and respect.
II. **Assessment** — Review medical history, ask questions, and allow client to ask questions. Establish what the client wants/needs to know to make decisions they have to make during the visit and feel comfortable about the purpose of the visit (Nonverbal behavior provides important information for the assessment).
III. **Interactive Communication** — Work with client interactively to develop plan.

✓ FYI - Client-centered Communication

IV. **Education** — Provide relevant, accurate, non-judgmental information and educational materials that can be understood and retained.
V. **Decision-making** — Allow client to express concerns so that they can make choices they need to make during visit. Determine risks for poor follow-up or coping after the visit.

VI. **Review** — Confirm that all information conveyed is understood. Clearly restate all decisions so that there is a shared understanding about what next steps are needed, including all the necessary information for any referrals that were given. The teach-back method may be used to confirm client's understanding by asking the client to repeat back significant messages.

2.2.2 Contraceptive Counseling

I. Ensure decision to adopt a method is voluntary, informed, and made by client.
II. Ensure client is fully informed about all methods that can be used safely.
III. Use a tiered approach to contraceptive method information (i.e., begin with the most effective methods first, before giving information on less effective methods).
IV. Ensure client understands
    A. Method effectiveness
    B. Correct use of the method
    C. Noncontraceptive benefits
    D. Side effects
    E. Protection from STIs / HIV

2.2.3 Medication Adherence Counseling

I. Provide simple explanations and education
    A. Medication dosage and schedule
    B. Management of common side effects
    C. Relationship of adherence to the efficacy of the medication
    D. Signs and symptoms of disease or worsening condition and recommended actions
II. Support adherence
    A. Tailor daily dose to client's daily routine
    B. Identify reminders and devices to minimize forgetting doses
    C. Identify and address barriers to adherence
III. Monitor medication adherence in a non-judgmental manner
    A. Normalize occasional missed doses, while ensuring client understands importance of daily dosing for optimal protection
    B. Reinforce success
    C. Identify factors interfering with adherence and plan with client to address them

D. Assess side effects and plan how to manage them

2.2.4 Behavioral Risk-Reduction Counseling

I. Establish trust and 2-way communication
   A. Provide feedback on STI and HIV risk factors identified during sexual and substance use history taking
   B. Elicit barriers to, and facilitators of, consistent condom use
   C. Elicit barriers to, and facilitators of, reducing substance abuse, if relevant
II. Support risk-reduction efforts
   A. Assist client to identify 1 or 2 feasible, acceptable, incremental steps toward risk reduction
   B. Identify and address anticipated barriers to accomplishing planned actions to reduce risk
III. Monitor behavioral adherence in a non-judgmental manner
   A. Acknowledge the effort required for behavior change
   B. Reinforce success
   C. If not fully successful, assess factors interfering with completion of planned actions and assist client to identify next steps

2.3 SPECIAL CIRCUMSTANCES AND CONCERNS

2.3.a. Table: Special Circumstances

Clients with special needs **must** be seen by personnel who are trained to manage these situations/conditions.

Special Circumstance	Action
Limited English Proficiency (LEP)	Every attempt **must** be made to provide an interpreter that is not a member of the client's family. This includes clients who need a sign language interpreter.
Intimate Partner Violence / Reproductive coercion	Assess per Clinical Chapter 11 Intimate Partner Violence and Reproductive Coercion
Sexual Abuse / Assault	Assess the need for referral, follow appropriate reporting requirements, and provide follow-up as mandated by state and local law.
Child Abuse / Maltreatment / Other abuse	Assess the need for referral, follow appropriate reporting requirements, and provide follow-up as mandated by law.

Special Circumstance	Action
Drug / Alcohol Use	Assess whether client's mental and/or physical state will interfere with the course of the visit or follow-up.
Psychiatric Conditions	Assess whether the client's mental and emotional state will interfere with the course of the visit or follow-up.
Physical Challenges	Assess whether the visit can adequately provide what client requires for their care.
Cognitive Challenges	Assess if client is competent to consent for their care or if there is a legal guardian for client other than parents.
Suicidal Ideation / Homicidal Threat or Behavior	**Must** seek assistance according to affiliate policy for immediate referral.

2.4 ADDITIONAL INFORMATION

2.4.a. Table: For Your Information

Section	Topic	Detail
2.2.1 III.	Client-centered Communication	Client-centered communication ▪ Means that all clients' rights to privacy, confidentially, respect, and dignity will be ensured ▪ Is a two-way process in which both clients and affiliate staff actively participate ▪ Is an ongoing process that must be part of every client-staff interaction during health care delivery Effective communication skills needed to promote effective communication include ▪ **Listening** — Be able to hear clients' concerns whether through language or non-verbal communication. ▪ **Assessment** — Be able to understand the unique circumstances of all clients and their individual cognitive, decision-making, and coping styles. ▪ **Supportive** — Be able to engage clients, and be empathetic and genuine to help them feel comfortable and at ease. Be able to assure clients of confidentiality. Be able to be sensitive to the individual cultures, values, and beliefs of our clients. ▪ **Communication** — Be able to use language that is easily understood by all clients, doesn't express bias, and has an appropriate balance between directive and non-directive statements, and between open-ended and closed questions.

2.4.b. Table: References

Section	Reference
Throughout	Centers for Disease Control and Prevention. "Providing Quality Family Planning Services, Recommendations of CDC and the U.S. Office of Population Affairs." 63, no. 4 (2014).
Throughout	Solter, Cathy. "Module 3: Counseling for Family Planning Services." Pathfinder International: Training Curricula, Guides, and Tools. 2000. http://www.pathfind.org/site/PageServer?pagename=Pubs_Training_Curriculum (accessed June 1, 2010).
Throughout	US Public Health Service. "Preexposure Prophylaxis for the Prevention of HIV Infection in the United States." A Clinical Practice Guideline. 2014. http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf (accessed May 20, 2014).
Throughout	US Public Health Service. "Preexposure Prophylaxis for the Prevention of HIV Infection in the United States." Clinical Providers' Supplement. 2014. http://www.cdc.gov/hiv/pdf/PrEPProviderSupplement2014.pdf (accessed May 20, 2014).

2.4.c. Table: Associated Resources for Staff

Type	Resource	Location
Training	**CAL Courses** Adverse Events: Communicating with Clients and Others Communicating with Adolescents Series Customer Service Series Customer Service – Instructor Led Training Expanding LGBTQ Cultural Competency Series Health Literacy Human Trafficking for Healthcare Workers Series Interpreter Services Series Interpreter Services Series - in Spanish Intimate Partner Violence (IPV) and Reproductive Coercion Series LGBTQ Healthcare for Clinicians - Series 1 - Health and Health Concerns of Lesbian and Bisexual Women and Gay and Bisexual Men Providing and Documenting Pregnancy Test Results Telephone Skills: Welcoming Callers to Planned Parenthood	

ADMINISTRATIVE CHAPTER 3: CLINICAL SERVICES

Revised June 2014

Admin Chapter 3 Table of Contents

3.1 STATE AND FEDERAL REGULATIONS

Affiliates must comply with all applicable current state and federal regulations as required by law — e.g., the most current Occupational Safety and Health Administration (OSHA) regulations, Clinical Laboratory Improvement Amendments (CLIA), Health Insurance Portability and Accountability Act (HIPAA) regulations, mandatory reporting requirements, National Standards for Culturally and Linguistically Appropriate Services in Health Care (CLAS), and Affordable Care Act (ACA).

3.2 ON-SITE AFFILIATE SERVICES

3.2.1 Service Requirements

I. Planned Parenthood affiliates provide a variety of services. Core services are required per the PPFA Bylaws and some services **must** be approved by PPFA prior to initiation. For non-core services, only affiliates with full accreditation may initiate a new service. Table 3.2.a. summarizes these requirements. The approval process is described below in 3.2.2.

3.2.a. Table: Service Requirements

	Must Provide Service	24/7 Coverage Required[1]	Staffing Requirements[2]
Core Services at Full Service Health Centers			
Well-Woman Exams (including cervical screening and CBE)	Yes	No	
1. All other periodic health screening and preventive services, as defined in "Periodic Well-Woman Visit"	Yes		
2. Breast Services			
o Basic[3]	Yes	No	
o Advanced[4] – MS&Gs available upon request from PPFA Medical Services	No	Yes	
Pregnancy Testing and Options Counseling	Yes	No	
Contraception: Education, Prescribing/Dispensing for all FDA Approved Methods — affiliate **must** be able to 1. Dispense affiliate-selected formulary of both combination and	Yes	No	

	Must Provide Service	24/7 Coverage Required[1]	Staffing Requirements[2]
progestin only oral contraceptives, emergency contraception, male condom 2. Provide for insertion of implant, CuIUC, LngIUC 3. Provide for injection of DMPA 4. Dispense or prescribe the following o Other oral contraceptives o Contraceptive vaginal ring o Contraceptive patch o FemCap or diaphragm o Female condom			
STI Screening, Testing, Treatment for Women and Men[5] (according to *CDC STD Treatment Guidelines*) 1. STI screening or testing for chlamydia, gonorrhea, trichomoniasis, bacterial vaginosis, HIV (point of service), syphilis, hepatitis B, hepatitis C, genital HSV 2. STI treatment or management for chlamydia, gonorrhea, trichomonas, bacterial vaginosis, genital HSV, EGW, scabies, pediculosis pubis	Yes	No	
HPV Vaccine	Yes	No	
Core Services at Affiliate			
Abortion Services – First-Trimester 1. Medication (up to 63 days) and / or 2. Surgical (up to 13 6/7 weeks) (Deadline 1/2015)	Yes	Yes	
Other Services			
Abortion Services – Second or Mid Trimester (14.0 to 24.0 weeks)	No	Yes	
Colposcopy, Cryotherapy and LEEP	No	No	

	Must Provide Service	24/7 Coverage Required[1]	Staffing Requirements[2]
Early Pregnancy Evaluation/Management of Early Pregnancy Complications	No	Yes	
Gynecological Services	No		
1. Basic Gynecology (Level I GYN) – Level I services include the initial diagnostic evaluation, including physical exam and/or diagnostic tests and provision of non-surgical management of the following conditions: o Abnormal uterine bleeding/ amenorrhea / PCOS / adenomyosis/ leiomyoma o Adnexal masses/Bartholin gland abnormalities/pelvic masses o Dysmenorrhea/endometriosis/pelvic pain o Hirsutism/galactorrhea o Conditions related to menopause o PMS/PMDD o Vulvar skin conditions (excluding VIN and VAIN)		No	
2. Expanded Office Gynecology (Level II GYN) - **Service approval is required.** Includes all conditions listed under Level I GYN as well as the provision of diagnostic evaluation and non-surgical management of hyperprolactinemia. And the following procedures o Fulguration of external genital warts o Marsupialization of bartholin abscesses o Diagnostic hysteroscopy, including retrieval of lost IUC		No	Providers who perform surgery **must** be o OB/GYN or o Family practice physician or o By waiver

	Must Provide Service	24/7 Coverage Required[1]	Staffing Requirements[2]
3. Expanded Gynecologic Surgery (Level III GYN) **Service approval is required**[6]. Includes entire scope of outpatient gynecological services as well as the performance of any procedures in a hospital or fully licensed surgical center for which the approved physician has the appropriate credentials and hospital privileges. These may include but are not limited to o Diagnostic laparoscopy o Operative hysteroscopy o Hysterectomy o Dilation and curettage o Removal/resection of benign ovarian neoplasms o Pelvic floor surgery o Endometrial ablation o Myomectomy o Management of ectopic pregnancies o Cold knife cone o Laser vaporization and laser cone – waiver required Once Expanded GYN services have been initiated, affiliate protocols, **must** be reviewed on a biennial basis to ensure compliance with MS&Gs and consistency with most up-to-date edition of the source(s) used.		Yes	Physicians who perform surgery **must** o Be board-certified or board-eligible OB/GYN or request a waiver o Have full hospital admitting and surgical privileges
4. Urinary Incontinence, Overactive Bladder and Pelvic Floor Disorders – MS&Gs available upon request from MedicalServices@ppfa.org.		No	

	Must Provide Service	24/7 Coverage Required[1]	Staffing Requirements[2]
Infertility Services 1. Basic Infertility o Infertility evaluation (male and female) o Treatment of anovulation and oligo-ovulation with clomiphene citrate and/or metformin o Intrauterine insemination with sexually intimate partner sperm. 2. Advanced Infertility[7] – MS&Gs available upon request from PPFA Medical Services	No	Yes	
Men's Reproductive Health Care – services include initial diagnostic evaluation, including physical exam and/or diagnostic tests and provision of non-surgical management or requirement for referral of the following conditions/findings/screenings: 1. Screening: Colorectal Cancer, Prostate Cancer 2. Balanitis 3. Epididymitis 4. Erectile Dysfunction 5. Hydrocele 6. Inguinal Hernia 7. Orchitis 8. Penile Cancer 9. Premature Ejaculation 10. Benign Prostatic Hypertrophy (BPH) 11. Prostatitis 12. Spermatocele 13. Testicular Torsion 14. Testicular Mass/Tumor 15. Urethritis 16. Urinary Tract Infection 17. Varicocele	No	No	

	Must Provide Service	24/7 Coverage Required[1]	Staffing Requirements[2]
Primary Care	No		
1. Limited Primary Care - Services are limited to assessment and management of: o Acute self-limited conditions such as URI, pharyngitis, contact dermatitis, acute gastroenteritis o Benign chronic conditions such as acne, irritable bowel syndrome, seasonal allergies o Medication management of previously diagnosed hypertension and hypothyroidism		No	
2. Expanded Primary Care - Services may include all limited primary care as well as diagnosis, initial, and ongoing management of the following chronic conditions o Asthma – limited to individuals ages 12 to 65 o Depression/Anxiety – limited to individuals ages 18 to 65 o Diabetes – limited to individuals ages 18 to 65 o GERD – limited to individuals ages 18 to 65 o Hypertension – limited to individuals ages 18 to 65 o Hypothyroidism – limited to individuals ages 18 to 65 o Lipid disorders – limited to individuals ages 18 to 65		Yes	
3. Comprehensive Primary Care – Service approval required**.** Includes entire scope of outpatient primary care including o Treatment of acute and chronic disease o Minor office procedures o Evaluations for referral to specialists o Authorization for hospital care		Yes	Clinicians **must** be o Family practice or internal medicine physician, PA, or family or adult NP o Family practice physician, pediatrician, PA or family or pediatric NP for pediatric conditions

	Must Provide Service	24/7 Coverage Required[1]	Staffing Requirements[2]
Once limited or comprehensive primary care services have been initiated, affiliate protocols **must** be reviewed on a biennial basis to ensure compliance with MS&Gs and consistency with most up-to-date edition of the source(s) used.			
4. Smoking Cessation		No	
5. Weight Management – components include o Eating Disorders — screening and referral for anorexia nervosa and bulimia nervosa. o Weight Loss Services — initial evaluation and provision of non-surgical management for overweight and obesity.		No	
Prenatal and Postpartum Care	No		
1. First Visit Only Prenatal Care – consists of initial screening (history, physical, laboratory testing), risk assessment, referral for continuing prenatal care to designated physicians or other prenatal programs in the community		No	
2. Comprehensive Prenatal Care - full prenatal and postpartum care for non-high risk clients only. Full prenatal care **does not** include the delivery. Once the transfer of care has been made to the delivery provider, the client **must not** be seen for further prenatal care on Planned Parenthood premises.		Yes	APCs providing comprehensive prenatal care **must** have 24/7 access to a physician experienced in obstetrical care. It may be provided by a Planned Parenthood Obstetrician (PPOB) or by referral to a high-risk obstetrician (HROB) ▪ The PPOB **must** be an affiliate-employed obstetrician-gynecologist or other physician trained and experienced in providing obstetrical care. Where specified, the PPOB's evaluation of the potentially high-

	Must Provide Service	24/7 Coverage Required[1]	Staffing Requirements[2]
			risk client may determine the need for transfer of care to the HROB. ▪ The HROB **must** o Be a practicing board-eligible or board-certified obstetrician-gynecologist with full obstetrical (including surgical) privileges at the hospital where deliveries will be conducted and whose practice includes the management of high-risk obstetrical clients. Alternatively, the HROB may be in the form of a "high-risk OB clinic" or similar hospital or community-based clinic associated with the hospital where deliveries are to be performed. o Be seen by the client off-site. In specified cases, telephone consultation with the HROB is an acceptable alternative to off-site evaluation. o Maintain a separate practice in addition to consulting for the affiliate If affiliate will manage diet controlled-GDM, a licensed nutritionist **must** be available for initial diet instruction and follow-up of dietary problems.

	Must Provide Service	24/7 Coverage Required[1]	Staffing Requirements[2]
Recovery Area Care	Yes, if surgical procedures are performed on site	N/A	**Where Sedation is Used** o **Must** be staffed by at least 1 licensed health professional with supervisory privileges who does not have duties other than client recovery or tasks that would compromise the continuous observation and monitoring of clients. o Other non-licensed staff may assist in the recovery area as allowed by state and local regulations. **Where Sedation is not Used** o Staff providing recovery area care **must** be trained in proper recovery for procedures performed. Licensed staff **must** be available at all times.
Sedation	No	Yes	A physician **must** be immediately available at all times during client treatment and recovery and until all clients are medically discharged. A least 1 staff person with training in advanced resuscitative techniques (e.g. ACLS) **must** be on site (in the building) until all clients are medically discharged.
Sterilization 1. Hysteroscopic Tubal Sterilization 2. Transabdominal Tubal Sterilization	No	Yes	

	Must Provide Service	24/7 Coverage Required[1]	Staffing Requirements[2]
3. Vasectomy			
Transgender Care 1. Well-Person Care 2. Cross-Sex Hormone Therapy - Services may include o Transfemale cross sex hormone therapy o Transmale cross sex hormone therapy	No	No	
Ultrasound Services[8]	No	No	
Vaccination Services	No[9]	No	

3.2.2 Service Approvals for On-Site Services for Which PPFA Medical Standards and Guidelines **DO NOT** Exist

I. Affiliates **must** seek approval to provide services for which there are no PPFA Medical Standards and Guidelines. In addition to approval by PPFA and ARMS, approval by the NMC and appropriate bodies of the PPFA Board may be necessary. For non-core services, only affiliates with full accreditation may initiate a new service. Examples of services that require an approval include, but are not limited to, Comprehensive Primary Care, Expanded Office Gynecology (Level II GYN), Expanded Gynecologic Surgery (Level III GYN), and Counseling Services.

A. Affiliate **must** submit a written request to initiate the service to PPFA for review and approval. E-mail request to accreditation.docs@ppfa.org.

B. If the request is for a new medical service that has not been offered previously by any affiliate, the medical protocols **must** be submitted for review and **must** be approved by the NMC or a designee, via a mechanism to be approved by the NMC Chair. Subsequently, requests containing substantially the same content may be evaluated and approved by PPFA Medical Services.

C. The following information **must** be submitted with a request to initiate the medical service:

1. A description of the medical services that will be provided and those conditions that will be referred out of the affiliate
2. Clinical protocols including a description of the development process, expertise of the authors and published evidence used
3. If 24/7 coverage will be provided and level of licensure of staff that will provide the coverage
4. plans for back-up coverage

D. There **must** be insurance coverage.

E. A self-assessment is recommended 6 months after initiation of a new service. A self- assessment tool is available on the Accreditation page of the Extranet.
F. If an approved service has not been instituted or has been suspended for 1 year or more, a new service approval **must** be requested before the service can be initiated or restarted.
G. Affiliates may appeal a disapproval of a new service to the PPFA Board of Directors.

3.3 MANAGEMENT OF EMERGENCIES

3.3.1 Policies and Procedures

I. Each affiliate **must** have a written plan and protocols for the management of medical emergencies that are appropriate and specific to the services provided, including
   A. A clear posting of emergency exit routes
   B. Emergency transfer of individuals needing additional care
   C. Vacating the premises, should the need arise (e.g., fire, bomb threat, power outage, flooding)
II. ARMS Emergency Manual or an equivalent resource **must** be used as the source of emergency protocols.

3.3.2 Staffing

I. There **must** be personnel with documented current certification in basic cardiopulmonary resuscitation (CPR) in the immediate area while medical or surgical services are being provided.

3.3.3 Emergency Call Systems

I. When 24/7 coverage is required, a licensed staff member trained in the identification and management of problems relevant to the specific service **must** be available for consultation on a 24-hour basis.
II. The emergency number **must** be provided on the client's written care instructions.
III. On-call staff **must** be aware of all clients who have made previous calls with significant complaints. If a client calls more than once with the same significant complaint, he/she should be instructed to return to the clinic to be assessed in person. If an emergency cannot be evaluated and managed in a timely manner, the client **must** be referred to an emergency department.
IV. There **must** be a system to follow up with a client who made an after-hours call to reconcile the after hour call(s) with client's original plan of care and follow up as needed.

3.4 CONTRACTS/WRITTEN AGREEMENTS WITH OUTSIDE ORGANIZATIONS

Whenever an affiliate engages outside agencies or individuals (i.e., educational affiliation agreement, residency rotation agreement, clinical services agreement, affiliation agreement), legally acceptable contracts **must** be in place. Affiliates **must** obtain approval from ARMS regarding the insurance and indemnification sections and their local counsel for the contract generally. PPFA's Office of General Counsel is available for guidance related to this requirement.

3.5 INFECTION PREVENTION

All affiliates **must** have an infection prevention program in place. The ARMS *Infection Prevention Manual* as well as other tools and resources are available at www.armsconnect.org to assist in developing affiliate programs.

3.6 CLINICAL QUALITY IMPROVEMENT (CQI)

Affiliates should have a CQI program in place to track, trend and improve clinical quality outcomes on a continuous basis. They should also set goals for at least 1 clinical quality measure and implement changes to improve performance.

3.7 RISK AND QUALITY MANAGEMENT

All affiliates **must** have a structured and permanent Integrated Risk and Quality Management Program in place. Required components of the clinical RQM program include assessment of staff proficiency, chart auditing, adverse events and complication tracking, incident reporting, practice drills related to emergencies, and continuous evaluation of programs and identification of deficiencies with corrective actions/interventions and monitoring for compliance. The ARMS manual, Risk Management: *The Path to Patient Safety,* as well as other tools and resources are available at www.armsconnect.org to assist in developing affiliate programs.

3.7.1 Medical Record and Follow-up Audits

I. At a minimum, medical record audits **must** be performed annually of charts from all health centers providing high-risk services such as abortion, colposcopy/LEEP (Pap results ≥ HSIL), sterilization, prenatal care, LARC, breast mass management, etc.
II. Affiliates are encouraged to use the STARS Audit tools available from ARMS. These tools contain audits for medical services that reflect current standards as found in the MS&Gs. If not using STARS Audits, audits with comparable criteria **must** be used. Each audit **must** have a corrective action plan and follow-up monitoring as indicated.

III. Agency-wide audits of the referral follow-up system involving all health centers **must** occur at least annually to ensure that clients requiring referrals are contacted in a timely manner, are provided appropriate information, and receive appropriate consultation/management. Audit tools are available at www.armsconnect.org.

3.7.2 Adverse Events and Complication Tracking

I. At a minimum, the affiliate **must** have a complication tracking system for each provider that is reviewed on a regular basis by the Program Director and affiliate's RQM Committee.

3.7.3 Incident Reporting

I. Any incident listed on www.armsconnect.org **must** be reported to ARMS.
II. Designated RQM affiliate staff in cooperation with the medical director is responsible for reporting incidents in AIMS.

3.8 PHYSICAL FACILITY, MEDICAL EQUIPMENT AND SUPPLIES, AND LABORATORY

3.8.1 Physical Facility

I. The physical facility, on or off-site, **must** satisfy applicable state and local regulations.

3.8.2 Medical and Surgical Equipment and Supplies

I. Medical and surgical equipment and supplies **must** be appropriate and adequate to provide the services offered (e.g., equipment necessary for required laboratory testing that complies with local CLIA standards **must** be immediately available)
II. Surgical equipment **must** meet FDA standards and be in adequate supply to permit individual sterilized instruments for each client.
III. Equipment **must** be checked/maintained at least annually for safety.
IV. Equipment and supplies needed to manage emergencies **must** be available per ARMS Emergency Manual.

3.8.a. Table: Required Supplies and Equipment by Service

Service	Supplies and Equipment
All services that use equipment that would require back up power, including but not limited to	A battery-operated power and light source (or other back-up system such as a generator or uninterruptable power supply (UPS)) to allow, in case of power failure, the completion of the procedure, appropriate monitoring of the client, and safe working conditions for staff.

Service	Supplies and Equipment
▪ Surgical Abortion ▪ Miscarriage management ▪ Hysteroscopic Tubal Sterilization	
Analgesia and Sedation	At a minimum, there should be a reliable source of oxygen, suction, monitoring and resuscitation equipment and emergency drugs.
Infertility	Maintenance of human cells, tissues, or cellular or tissue-based products relevant to infertility services **must** be in compliance with FDA regulations. For more information: ✓ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1271
IPV/RC	Reproductive coercion safety cards, Did You Know Your Relationship Affects Your Health?, produced by Futures without Violence. Available for free in English and Spanish from Futures Without Violence through the following link: ✓ http://www.futureswithoutviolence.org/plannedparenthood

3.8.3 Laboratory

I. Affiliate-run Pap laboratories - Any approval to initiate and continue Pap laboratories will be made in close consultation with the National Medical Committee.

II. Laboratory Tests

A. Unless otherwise stipulated, affiliates may only use FDA approved lab tests in the manner for which they were approved.

B. Affiliates may use laboratories using internally-validated STI (not HIV) testing practices. This applies to variations in testing site, media and the location of sample collection (inside vs. outside of the health center).

1. Rectal and pharyngeal specimens **must** use culture or an FDA-approved test that has been internally validated in accordance with applicable statutes

C. HPV Testing in Liquid-based Media

1. Labs contracted with Planned Parenthood affiliates **must** use FDA-approved HPV tests.
2. These tests **must** be performed in media approved by the FDA for HPV testing (ThinPrep is the only Pap test FDA-approved for HPV testing at this time).
3. When co-collecting an HPV test separate from the Pap, use the collection kit provided by the manufacturer to avoid confusion in the laboratory regarding the test being ordered.

3.9 ADDITIONAL INFORMATION

3.9.a. Table: For Your Information

Section	Topic	Detail
3.2.a. Footnote #5	Client-delivered Partner Therapy	Client-delivered Partner Therapy should be offered if permitted by state law(s). It consists of the following ▪ The partner is not seen at the affiliate. ▪ The clinician provides the client with medication for the partner **OR** a prescription in accordance with state laws/regulations. ▪ The client is given written information about the STI and medication (see Client Information sheets for partners for chlamydia, gonorrhea, and trichomoniasis) ▪ Clients deliver the treatment to their partners. Clients are responsible for giving their partners the appropriate medication and information sheets.

3.9.b. Table: Associated Resources for Staff

Type	Resource	Location
Training	**CAL Courses** Advanced Cardiac Life Support (ACLS) Adverse Events: A Step-by-Step Response for Managers and Clinicians Caring for the Caregiver Series: Assisting the Healthcare Provider After an Adverse Event CPR Refresher for Healthcare Workers How to Administer Intramuscular Injections How to Measure Blood Pressure, Pulse, and Respiration Infection Prevention and Control Laboratory Skills and Microscopy Performing Routine Laboratory Procedures in Compliance with CLIA Phlebotomy STARS Audit Working Together to Improve Patient Safety - Part I	
Sample Forms	Sample Lab Application Form	Part 3, Chapter 01_03

[1] When 24/7 coverage is required, a licensed **staff** member trained in the identification and management of problems relevant to the specific service **must** be available for consultation on a **24-hour** basis.

[2] There **must** be staff with documented current certification in basic cardiopulmonary resuscitation (CPR) in the immediate area while medical or surgical services are being provided

[3] Basic breast services include risk assessment, CBE, screening mammography recommendations with management of abnormal findings per MS&Gs, assessment of breast findings (including ordering of diagnostic imaging and/or breast biopsy) with management per MS&Gs.

[4] Advanced breast services include all components of basic plus additional management of abnormal findings.

[5] Client-delivered partner therapy should be offered if allowed per state law. FYI - Client-Delivered Partner Therapy.

[6] Approval for this service **does not** include surgical or non-surgical management of known malignancies, obstetrical procedures, conditions or services for which distinct PPFA Standards exist elsewhere in the MS&Gs, and/or laser surgery. Clients with known malignancies **must** be referred to a physician with cancer management skills. The PPFA Insurance Program does not include cancer management. Referral physicians with cancer management skills cannot practice those skills as a PP physician and/or employee.

[7] Advanced infertility services include all components of basic services plus treatment of anovulation and oligo-ovulation with gonadotropins, evaluation and treatment of recurrent pregnancy loss, intrauterine insemination with non-sexually intimate partner sperm, diagnostic or operative laparoscopy or laparotomy (**must** also be approved for Level III GYN), other advanced reproductive technology services (**must** also be approved for Level III GYN).

[8] Affiliates **must** maintain a consistent policy for how pregnancies are dated for all services they provide (i.e. abortion care or prenatal care.) (See Chapter 19 Ultrasound). All state and local regulations pertaining to pregnancy dating **must** be followed where applicable.

[9] HPV Vaccine is required.

ADMINISTRATIVE CHAPTER 4: CLIENT EDUCATION AND INFORMED CONSENT

Revised June 2014

Chapter 4 Table of Contents

4.1 CLIENT EDUCATION

4.1.1 General Information

I. All client education should be given both verbally and in writing. Clients **must** be given education/information and instructions regarding
   A. Conditions under evaluation and/or management
   B. Specific services to be provided, tests to be ordered, treatments and medications
   C. Referrals for alternative and/or additional providers or care options
II. Clients **must** demonstrate understanding of information provided.
III. Written Client Information (CIs) provided in the MS&Gs
   A. Are developed for educational/informational purposes — not specifically for obtaining informed consent
   B. Are available as samples and may be edited or altered by affiliates
      1. All the information included in the PPFA–provided CIs **must** be incorporated into the written information given to clients, but the CI supplied by PPFA need not be used.
   C. May be provided in electronic or paper format but **must** be available in paper if that is the client's preference
   D. Do not need to be signed
   E. **Must** be coded (including language of the document) and dated using a consistent system
IV. Staff involved in client education **must** be familiar with the content of the CIs.
V. Where PPFA CIs do not exist related to Pap/colposcopy, STIs and vaginitis, and well-person care, client education points should be addressed according to Table 4.1.a.

✓ For a complete list of CIs provided by PPFA and to access available CIs see Part 3: Required Documents and Additional Resources

4.1.a. Table: Client Education Points – for content not addressed by a PPFA CI

Section	Client Education Points
Pap and Colposcopy	▪ Avoidance of intercourse or the use of vaginal products for at least 24 hours before Pap and/or colposcopy
Sexually Transmitted Infections and Vaginitis	▪ Natural history, route of transmission, and possible sequelae of condition(s) ▪ Treatment options ▪ Partner notification and treatment, if applicable ▪ Prevention of reinfection ▪ When to call or return to health center

Section	Client Education Points
Well-Person Care	▪ Preventive care, positive personal behaviors and healthy lifestyle choices or guidance on how to obtain such information with particular focus on high-risk conditions specific to client

4.2 INFORMED CONSENT

4.2.1 General Information

✓ FYI – What is the Informed Consent Process?

I. The informed consent process **must** take place. Consent procedures for minors and others **must** be consistent with state law. It is the professional and legal duty of every affiliate to provide each client with adequate information regarding the nature of the proposed services including all of the following
   A. Anticipated benefits
   B. Medically recognized risks and possible complications
   C. Alternatives

II. Clients **must** be given education/information and instructions according to requirements in **4.1 Client Education**.

III. Information that the client needs to make an informed decision **must** be presented in an objective and non-judgmental manner and in language and terminology that the client can best understand. Whenever possible, family and friends should not be used to provide interpretation services. The client **must**
   A. Have the opportunity to ask questions and get answers at any time during the process
   B. Have the option of deciding not to undergo therapy or treatment
   C. Demonstrate understanding of information provided

IV. Written information should be provided as much as possible.

V. Clinician performing a procedure **must** ascertain that informed consent has been obtained and that all of the client's questions have been answered satisfactorily before providing that procedure.

4.2.2 Request for Services and Release Forms

I. All affiliates, including those with approval for Level III GYN, **must** use the request for services forms authorized by ARMS.

II. All requests to use substitute, altered, or combined request and release forms **must** be approved by ARMS.

III. Request for Medical Services

A. All clients **must** sign the Request for Medical Services before receiving any clinical services. A copy **must** be given to the client if requested.
B. Unless there are significant changes to the document, it only needs to be signed and dated once. Affiliates that provide training **must** include the following language in the Request for Medical Services: "Please note that [AFFILIATE NAME] is a teaching institution, and that persons in training, under strict supervision, may be involved in some aspects of your care." The phrase is available in additional languages in Part 3: Required Documents and Additional Resources.

IV. Request for Surgery or Special Procedures
A. A new form **must** be signed and a copy offered as stipulated in Table 4.2.a., below.
B. Clients receiving comprehensive prenatal care **must** sign the [PPFA] Request for Surgery and Special Procedures. The following two items **must** be added to that request form. The phrases are available in additional languages in Part 3: Required Documents and Additional Resources.

"I give my permission for the transfer of my medical records to _____ Hospital and to other medical providers, if necessary. I also consent to the transfer of laboratory reports and delivery records from the hospital back to Planned Parenthood."
AND
"I understand that [AFFILIATE NAME] does not provide delivery services. I am being referred to _____ Hospital for delivery. I also understand that the health care providers at the hospital who will provide delivery services are not acting at the direction of or as agents of Planned Parenthood."

V. When Test/Service/Consultation Will Not Be Obtained as Advised
A. A new release form **must** be signed once each time an advised test, service, or consultation is not obtained
B. The specific test, service, or consultation that will not be obtained **must** be checked off or written in. (See Administrative Chapter 8 Systems for Notification and Follow-up)

4.2.3 Client Information for Informed Consents (CIICs)

I. All affiliates, including those with approval for Level III GYN, **must** use the CIICs authorized by PPFA.
II. All requests to use additional, substitute, altered, or combined CIICs **must** be approved by PPFA Medical Services.
III. Affiliate's legal name and telephone number(s) **must** be included on all CIICs.
IV. CIICs **must** be coded ((including language of the document) and dated using a consistent system
V. CIICs **must** be read by the client before the treatment/service is given/prescribed
A. CIICs that do not require a signature do not need to be retained in the medical record, but it **must** be documented in the medical record that the client received them.
B. CIICs that require a signature **must** be signed before the treatment/service is given/prescribed.

1. Signed CIICs **must** be retained in the medical record in their entirety.
2. A copy **must** be given to the client.
3. A new CIIC **must** be signed each time a service/procedure is performed even if signed previously.

VI. Staff involved in obtaining informed consent **must** be familiar with the content of each CIIC.

4.2.a. Table: Client Information for Informed Consent Documents

CIIC	Client **Must** sign	Surgical Request Form Required	Notes
Abortion			
In-Clinic Abortion	Yes	Yes	
Preparing for an In-Clinic Abortion with Dilators and/or Pills	No	No	
When You Decide to Stop Your in-Clinic Abortion	Yes	No	
Digoxin	Yes	No	
The Abortion Pill	Yes	Yes	Danco Patient Agreement **must** be signed by medication abortion clients
Second Dose Misoprostol	Yes	No	
Reaspiration after In-Clinic Abortion/Aspiration after Using the Abortion Pill	Yes	Yes	**Must** be used whenever a reaspiration is performed following an in-clinic abortion.
Analgesia and Sedation			
Sedation	Yes	Yes	
Breast			
Breast Cyst Aspiration	Yes	Yes	
Cervical Cancer Screening and Evaluation			
Colposcopy and Cervical Biopsy	Yes	Yes	Request for Surgery or Special Procedures **must** be signed when ECS is performed without colposcopy,
Cryotherapy	Yes	Yes	
LEEP	Yes	Yes	

CIIC	Client **Must** sign	Surgical Request Form Required	Notes
Endometrial Biopsy	Yes	Yes	
Contraception (Reversible and Permanent)			
Pill, Patch, Ring	No	No	
Use of Hormone Birth Control By Women with Special Conditions	No	No	Required for the following conditions ▪ **Pill, Patch, Ring** – diabetes, chronic hypertension, elevated BP (140-259/90-99), hx of DVT with low risk recurrence, multiple cardiovascular risk factors, undiagnosed breast mass ▪ **Implant/POPS** – systemic lupus erythematosus (SLE), when antiphospholipid antibodies are positive or unknown, undiagnosed breast mass ▪ **DMPA** - osteoporosis, fragility fractures, blood pressure ≥ 160/100, multiple cardiovascular risk factors, SLE — when antiphospholipid antibodies are positive or unknown and/or severe thrombocytopenia, undiagnosed breast mass
Contraceptive Implants	Yes	Yes	
Removal of Implants	Yes	Yes	
DMPA	No	No	
Emergency Contraception	No	No	
Progestin-Only Birth Control Pills	No	No	
Intrauterine Contraception	Yes	Yes	Request for Surgery or Special Procedures form **must** be signed for removals that require intrauterine instrumentation.
Use of IUC By Women with Special Conditions	No	No	Required for the following conditions: ▪ Cu IUC – SLE only with severe thrombocytopenia ▪ LNG IUC – SLE only when antiphospholipid antibodies

CIIC	Client **Must** sign	Surgical Request Form Required	Notes
			are positive or unknown; undiagnosed breast mass
Pregnancy with IUC	No	No	**Must** be used for specific clinical situation
IUC Missing String	Yes	No	**Must** be used for specific clinical situation
IUC Use Beyond Recommended Date	No	No	**Must** be used for specific clinical situation
Preparing your Cervix with Misoprostol	No	No	**Must** be used for specific clinical situation
Diaphragm and Cervical Cap	No	No	
Vasectomy	Yes	Yes	
Transabdominal Tubal Sterilization	Yes	Yes	
Hysteroscopic Tubal Sterilization (HTS)	Yes	Yes	
Early Pregnancy Evaluation and Management of Complications			
CIIC Treatment of Miscarriage: The Abortion Pill	Yes	Yes	
CIIC Treatment of Miscarriage: Medication (Misoprostol)	Yes	No	
CIIC Treatment of Miscarriage: Suction Procedure	Yes	Yes	
CIIC Treatment of Miscarriage: Doing Nothing or "Wait and See"	Yes	Yes	
Gynecological Conditions			
Endometrial Biopsy	Yes	Yes	
Vulvar Biopsy	Yes	Yes	
Menopause			
Menopausal Hormone Therapy	No	No	
Men’s Sexual and Reproductive Health			
PSA	No	No	
Skin Biopsy	Yes	Yes	

CIIC	Client **Must** sign	Surgical Request Form Required	Notes
Prenatal and Postpartum Care			
Prenatal Care	Yes	Yes	
Screening for Birth Defects	Yes	No	
Genetic Counseling and Diagnostic Testing	Yes	No	
Sexually Transmitted Infections			
STI Treatment without Testing	No	No	
Post Exposure Prophylaxis (HIV)	No	No	
Pre-Exposure Prophylaxis (HIV)	No	No	
Treatment of Genital Warts	No	No	
Bartholin's	Yes	Yes	
Molluscum	No	No	
Transgender Care			
Feminizing (Male to Female) Therapy	Yes	No	
Masculinizing (Female to Male) Therapy	Yes	No	
Ultrasound			
N/A	N/A	Yes	Either the Request for Surgery or Special Procedures form OR Request for Medical Services form **must** be signed

4.2.4 Timing of Signing of Request for Services and CIICs

I. The "Request for Surgery or Special Procedures" and any CIICs that require a signature should be signed on the day a procedure is performed or initiated (if multi-day process).
II. Consent forms do not need to be re-signed if a single episode of care occurs over multiple visits due to medical protocol or local/state consent requirements. For example:
    A. If a client is seen for an abortion procedure that requires care over more than 1 day, consent forms are signed on the day the process is initiated.
    B. If a client is seen for sterilization counseling and the state requires a 30-day waiting period, both state and affiliate consents can be signed at the initial counseling visit.

III. If a client returns for unplanned care related to an earlier procedure, this is not the same "episode of care," and new consent forms **must** be signed. For example
   A. If a client is seen for a surgical procedure which cannot be performed that day (e.g., she does not meet NPO requirements for moderate sedation and wishes to receive it for the procedure), then that episode of care is over and new consents need to be signed when she returns.
   B. If a client is seen for hysteroscopic tubal sterilization and a device can only be placed in one side, then the episode of care is over. She would then need to sign new affiliate consents when she returned for the next attempt at placement.
   C. If a client returns to the clinic days after an abortion procedure and it is determined she requires reaspiration, she **must** sign a new "Request for Surgery or Special Procedures" form and the CIIC Reaspiration/Aspiration after Using the Abortion Pill.

4.2.5 Clients with Limited English Proficiency (LEP)

I. All written materials to be read or signed **must** be provided in the client's preferred reading language or an interpreter **must** be available to give the client the information in the documents (CLAS Standard #7).
II. In cases of illiteracy, client **must** be provided all appropriate information verbally.

4.2.6 Minors – clients younger than age 18 and not emancipated minors

Reproductive Health Services
   A. Minors **must** be encouraged to consult with their parents with respect to such services.
   B. Services **must** not be denied when consultation with parents is not feasible (unless prohibited by state law/regulations).
   C. Any person who signs the request for services form **must** sign the CIIC(s) for the corresponding procedure. For example, if the affiliate uses the "Request for Surgery or Special Procedure" to document compliance with a state's parental consent for abortion law, the parent(s) or guardian who signs the request should sign the CIICs relating to the minor's abortion procedure.
   D. Affiliates should consult local counsel on compliance with state laws on parental consent and notification.
   E. The parent or guardian who consents for a minor **must** be given the affiliate's notice of health information privacy practices

Non-Contraceptive or Non-STI Services
   A. Consent of a parent or guardian **must** be obtained when required by state law.
   B. Each affiliate **must** consult with local legal counsel to clarify state requirements.
   C. Any circumstances in which parental consent is not required (e.g., "mature" or "emancipated" minors) **must** be clearly defined in the affiliate's protocols.

4.2.7 Mentally Disabled Clients

I. A mentally incompetent person cannot legally request medical or surgical treatment.
II. Judicial Determination of Mental Incompetence
   A. The consent of the client's legal guardian **must** be obtained.
   B. The mentally incompetent person should also sign the request form if he or she understands the form and is capable of signing.
III. Not Adjudged Legally Incompetent/Clinician Doubts a Client's Capacity to Consent
   A. Consent of nearest relative should be obtained in addition to the consent of the client. Use the additional section provided at the end of the consent forms for the guardian's or relative's signature.
   B. If no relatives to consult, application should be made for a court order.
IV. Sterilization
   A. Consent of a parent or relative is not sufficient for sterilization.
   B. Each affiliate should check with local counsel as to the law of its state.

4.3 ADDITIONAL INFORMATION

4.3.a. Table: For Your Information

Section	Topic	Detail
4.2.1	What is the informed consent process?	The informed consent process consists of three basic elements: ▪ Written general request forms ▪ Written service-specific Client Information for Informed Consent sheets ▪ Staff-client interaction in the preferred language of the client (either through an interpreter or bilingual staff) to supplement and reinforce required written materials and ensure informed decision

4.3.b. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
Required Forms	Request for Medical Services Request for Surgery or Special Procedure Release Form When Test Not Obtained Items to Add to Request for Medical Services for Affiliates Who Provide Training Items to Add to Request for Surgery or Special Procedures Comprehensive Prenatal Care Clients	Part 3, Chapter 01_04

4.3.c. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	Contraceptive Effectiveness Chart	Part 3, Chapter 02_06
	Master List of PPFA CIs/CIICs Tools for Obtaining Informed Consent	Part 3, Chapter 01_04
	✓ You Decide: Making Informed Health Choices about Hormonal Contraception Tool Kit	
Training	**CAL Courses** Adverse Events: Communicating with Clients and Others Communicating with Adolescents Dos and Don'ts of Documentation and Informed Consent Health Literacy Interpreter Services Series Interpreter Services Series - in Spanish	

ADMINISTRATIVE CHAPTER 5: MEDICAL RECORDS, DOCUMENTATION, AND REPORTING REQUIREMENTS

Revised June 2014

Admin Chapter 5 Table of Contents

5.1 MEDICAL RECORDS

5.1.1 Required Components

I. Affiliates **must** maintain a complete medical record for each client in accordance with accepted professional standards and any applicable laws/regulations.

II. The active medical record/database **must** be updated at least annually and reviewed and signed by a staff member. The medical record **must** include
   A. Identification of client
   B. A unique client number
   C. Birth date
   D. Contact information (e.g., address, e-mail, phone numbers)
   E. Emergency contact person and contact information
   F. Documentation of client's preferred method of notification
   G. Dating of all visits and contacts
   H. Documentation of all services and information provided, including
      1. Diagnostic and therapeutic orders, observations, clinical findings, and action(s) taken
      2. Justification of diagnosis or clinical impression and treatment
      3. Referral(s)
      4. All follow-up
      5. All client contacts made either by or to a client

III. Medical records **must** be
   A. Readily accessible
   B. Systematically organized to facilitate retrieving and compiling information
   C. Designed so that the client's name and unique identifier
      1. Appear on both sides of every paper chart form
      2. Are displayed on every electronic template
   D. Maintained for every client encounter with staff
   E. As confidential as possible
      1. Safeguards against loss and use by unauthorized persons **must** be maintained.
      2. Affiliates **must** have policies that ensure medical record safety and that are in compliance with HIPAA.

IV. Released according to HIPAA regulations and state law/regulation
   A. Written consent should be obtained whenever possible when there is no state requirement
   B. In some circumstances written consent is not needed, for example when
      1. Requiring written consent may result in a delay in the client's care (e.g., when the client is admitted to an emergency room)
      2. Client requests a copy of a lab or ultrasound report

5.1.2 Maintaining Medical Records

I. Affiliates **must** develop policies to ensure appropriate retention and destruction of medical records that are beyond the retention date.
II. Records **must** be retained according to the following:
   A. Inactive clients — for a minimum of seven years, or longer if required by state law or regulations
   B. Minors — until they reach the age of majority, plus seven years, or longer if required by state law or regulations
   C. Clients who received prenatal care — until the offspring reaches the age of majority plus seven years, or longer if required by state law or regulations

5.2 DOCUMENTATION IN THE MEDICAL RECORD

5.2.1 Required Components

I. Master signature log
   A. Affiliates **must** maintain an up-to-date master signature log that contains the name, full signature, title, if applicable, credentials, if applicable of every staff person that makes entries in the client's record.
II. Documentation **must** be performed in accordance with accepted professional standards and any applicable laws/regulations. It **must**
   A. Be legible, factual, complete, concise, and professional
   B. Include a record of all written materials given to client. Signed CIICs **must** be retained in the medical record in their entirety. The documentation of other written materials may be accomplished by
      1. Maintaining a copy in the record OR
      2. Notating in the record
   C. Include operative and recovery notes for all surgical procedures
   D. Include a description of any abnormal areas and/or injuries observed in physical exam and a map that indicates the location of the abnormal areas and/or injuries and any biopsy site(s), if relevant.

E. Be signed with the full name of the signer including credentials for licensed staff and titles for non-licensed staff. Abbreviated signatures, initials or scrawls are acceptable only if appropriately identified in an up-to-date master signature log.

5.2.2 Documentation by Service

5.2.a. Table: Specific Additional Documentation Requirements by Service

Service	Documentation Requirements
Abortion – medication	Documentation **must** include ▪ Package serial number for Mifepristone
Abortion - surgical	**Must** include ▪ For first and second trimester procedures, gestational age and type of abortion technique used o For first trimester procedures, whether abortion was completed by manual vacuum aspiration or electromechanical suction o For second trimester procedures, whether the uterus was evacuated entirely with suction, or if instruments were also used in the evacuation o For procedures using osmotic dilators, number of dilators inserted and number of dilators removed ▪ For mid-trimester procedures o Documentation of the Federal Abortion Ban at 2 stages • Prior to abortion procedure, **must** document intent to comply with Federal Abortion Ban ◊ By use of fetocide ◊ By umbilical cord interruption ◊ By plan to evacuate the uterus using multiple passes to remove the fetus in multiple parts ◊ By plan to evacuate uterus entirely with suction ◊ Other (describe) • After completion of the abortion procedure, **must** document that fetal demise occurred before the procedure or before passage of the anatomical landmarks outlined in the Federal Abortion Ban and technique employed - options include: ◊ Ultrasound prior to the procedure confirmed absence of fetal cardiac activity ◊ Umbilical cord was transected and lack of pulsation was confirmed prior to procedure (by palpation or

Service	Documentation Requirements
	ultrasound) ◊ Multiple passes were used to remove the fetus in multiple parts ◊ The uterus was evacuated entirely with suction ◊ Other (describe) o If digoxin was used, date, time, dose and route of digoxin administration (intraamniotic, intrafetal, intracardiac) and client response (i.e., well tolerated, injection without difficulty) **must** be documented in medical record o If osmotic dilators were used, number of dilators inserted and number of dilators removed ▪ For all procedures o Estimate of blood loss o Post procedure tissue evaluation findings
Breast Care ✓ FYI – Sample Breast Mass Documentation	Documentation **must** include ▪ Normal CBE findings ▪ Abnormal CBE findings including o Findings of inspection and lymph node exam o Location of any palpable mass found depicted by both a drawing and a narrative description • Description – **must** include ◊ Side (right or left breast) ◊ Clock face location ◊ Distance from the areolar edge ◊ Two measurements of the mass in two dimensions • Description – should include additional characteristics such as ◊ Shape (round, oval or irregular) ◊ Tenderness ◊ Margins (well-defined or ill-defined) ◊ Consistency (soft, firm, or rubbery) ◊ Mobility (fixed/immobile or mobile) o Color of any nipple discharge found and whether single or multiduct

Service	Documentation Requirements
Colposcopy	Documentation **must** include ▪ Adequacy of colposcopic evaluation including whether satisfactory or unsatisfactory ▪ Notation if squamocolumnar junction (SCJ) is within the endocervical canal and of possible influence on management ▪ Description of abnormal patterns seen, e.g., leukoplakia white epithelium, punctation, mosaic, or atypical vessels ▪ A "map" to include specific location, e.g., quadrant or clock position, and relative size of each abnormal area ▪ Colposcopic impression
Contraceptive Implant	Documentation **must** include ▪ Insertion date ▪ Which arm it was placed in ▪ Lot number of implant inserted ▪ Post-insertion confirmation of placement
Cryotherapy	Documentation **must** include ▪ Technique (freeze-thaw-freeze vs single freeze) ▪ Time ▪ Anesthesia: type, quantity used
HIV Screening	Documentation **must** include that tests were offered and the client's response. For example, "HIV test offered. Client accepted/declined."
HTS	Documentation **must** include an operative note containing ▪ Any pelvic pathology noted ▪ Estimated fluid deficit ▪ Management of complications, if any ▪ Lot number of the micro-insert device
Immunizations	Documentation **must** include ▪ Date given ▪ Lot number ▪ Expiration date ▪ Injection site ▪ Name and title of staff administering ▪ Name and edition date of Vaccine Information Statement (VIS) given

Service	Documentation Requirements
Intrauterine Contraception	Documentation **must** include ▪ Insertion date ▪ Type of IUC ▪ Lot number of IUC inserted ▪ Uterine size, position, and sounding depth
IPV/RC	Documentation **must** include ▪ All instances of client disclosed IPV, abuse, or reproductive coercion (Suspected instances should also be documented.) ▪ Copies of (or notations on) reports to authorities (unless otherwise determined by state/local law) ✓ FYI - Resources for State Specific Reporting Laws and Requirements Related to Minors and Domestic Violence Maintenance of a log or file of reports involving minors is strongly recommended. Logs help demonstrate compliance with reporting laws, if ever challenged.
LEEP	Documentation **must** include ▪ Loop size ▪ Anesthesia: type, quantity used ▪ Other medications used ▪ Number of passes to complete procedure ▪ Measures used to obtain hemostasis ▪ Estimated blood loss
PrEP	If PrEP is discontinued, documentation should include ▪ HIV status at the time of discontinuation ▪ Reason for PrEP discontinuation ▪ Recent medication adherence and reported sexual risk behavior
Tubal Sterilization	Documentation **must** include an operative note containing ▪ Operative and occlusive technique used ▪ Pelvic pathology noted ▪ Management of complications, if any Documentation **must** include a discharge summary including BP, assessment of amount of bleeding (if relevant), and general condition of client.

Service	Documentation Requirements
Ultrasound	Documentation **must** include images and final report/interpretation of every ultrasound examination ▪ Images - all images required for the examination type (typically 2 to 5 images) **must** be saved as part of the medical record. Official documentation for the ultrasound image should include, but is not limited to, o Client's name and other identifying information o Date of ultrasound examination ▪ Interpretation/Written Report — should include o Name(s) of person(s) performing and interpreting the ultrasound o Special techniques, equipment, media, or medications used, if any o Whether exam was satisfactory with notation of limitations, if any o Anatomic areas scanned o Normal findings and/or abnormalities o Diagnostic Impression o Specific findings related to the purpose of the exam (e.g., intrauterine gestation/size, number, IUC) o Comparison with previous ultrasounds for the same condition, if applicable Documentation **must** include that client was offered the opportunity to see her ultrasound, her response to the offer, whether she was given a copy of the ultrasound image and that she was informed of the limitations of the ultrasound
Vasectomy	Documentation **must** include an operative note containing ▪ Operative and occlusive technique used ▪ Any pathology noted ▪ Management of complications, if any

5.3 REPORTING REQUIREMENTS

All state and local mandatory reporting requirements **must** be followed.

5.3.1 Sexually Transmitted Infections

I. For all states, reporting of confirmed chlamydia, gonorrhea, and syphilis cases (no matter the stage) is required.

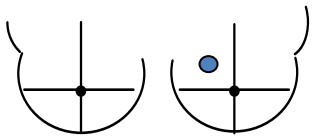
II. State policies concerning mandatory STI, hepatitis, and HIV reporting or permissible partner treatment options, such as client delivered partner therapy (aka expedited partner treatment), **must** be followed.

5.3.2 Vaccination

I. Report promptly, accurately and completely, any adverse events following an immunization.
II. Adverse events requiring medical attention within 30 days after receipt of a vaccine are reported on the "Vaccine Adverse Event Reporting System" (VAERS) form. [24 hour information line: 1-800-822-7967] The form can be submitted online or printed out from http://www.cdc.gov/vaccinesafety/Activities/vaers.html

5.4 ADDITIONAL INFORMATION

5.4.a. Table: For Your Information

Section	Topic	Detail
5.2.a.	Sample Breast Mass Documentation	*Bilateral breasts are symmetrical. No skin changes or lymphadenopathy are noted. A 5mm x 3mm oval mass was found in the left breast at 10:00, 5cm from the areolar edge. The mass is non-tender, well-defined, soft, mobile.* 
5.2.a.	Resources for State Specific Reporting Laws and Requirements Related to Minors and Domestic Violence	Each state's domestic violence coalition should have information on its reporting laws. Information may be accessed from the National Network to End Domestic Violence. (www.nnedv.org) Children protection/child welfare services in each state have information about reporting requirements for minors experiencing violence and any reporting requirements for statutory rape.

5.4.b. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ ARMS Accepted Medical Abbreviations List	After logging in to ArmsConnect: search "medical abbreviations list"
Training	**CAL Courses** Dos and Don'ts of Documentation and Informed Consent	

ADMINISTRATIVE CHAPTER 6: PERSONNEL

Revised June 2014

Admin Chapter 6 Table of Contents

6.1 ROLES AND RESPONSIBILITIES

6.1.1 Collaborative Team Approach

The health care services provided at Planned Parenthood affiliates typically utilize a collaborative team approach with the following categories of clinical staff.

I. Clinician — physician (MD or DO); advanced practice clinician (APC); advanced practice nurse (APN), i.e., nurse practitioner (NP); certified nurse midwife (CNM); certified registered nurse anesthetist (CRNA); and physicians assistant (PA) **must**
   A. Have completed an NP, CNM, CRNA, PA, MD, DO or other state-approved educational program OR be certified as an NP, CNM, CRNA, or PA by a national certification organization AND
   B. Have met state requirements for licensing and certification
   C. Provide clinical services and supervise other clinicians only within the confines of her/his individual education, training, scope of practice, certification and applicable state regulations. Clinicians **must** refer clients to appropriate professional when a medical condition is outside the scope of the clinician's experience.

II. Licensed health professional — includes all clinicians listed above as well as registered nurses (RN), sexual assault nurse examiners (SANE), licensed vocational/practical nurses (LVN, LPN), social workers, psychologists, etc. All licensed health professionals **must**
   A. Have completed an educational program specific to that profession AND
   B. Have met applicable state requirements for licensing and/or certification
   C. Provide clinical services and supervise others only within the confines of her/his individual education, training, and certification and applicable state regulations

III. Non-licensed, certified staff (volunteer and paid) such as Certified Allied Health Providers (CMA, certified sonographer, etc.) **must**
   A. Have completed an accredited program specific to their area of service AND
   B. Be certified by a national certification organization

IV. Other non-licensed staff

6.1.2 Affiliate Responsibilities

I. Affiliates **must**
   A. Designate at least 1 medical director. (See the HR page of the Extranet for a sample job description).
   B. Ensure that only those health professionals who by state law, education, and experience are qualified to perform a particular clinical function are allowed to do so (e.g., prenatal care must only be provided by clinicians trained in this area)
   C. Ensure there is written assurance of current state licensure or certification of all licensed health professionals.

D. Credential all clinicians supervising or performing services as determined by ARMS. (This differs from the credentialing or provider enrollment required by third party payers.)
E. Ensure that clinical leadership (medical directors, associate/assistant medical directors, directors of surgical services, patient services directors, lead clinicians, and risk/quality managers, etc.)
    1. Be placed on the PPFA/ARMS listserv appropriate for their affinity group
    2. Be given access to the Extranet and ARMS Connect.
F. Have written job descriptions for each position that describes education and training requirements, expected experience thresholds, job duties, etc.
G. Ensure that there are adequate time and resources for personnel to meet the demands of the duties listed in their job description.
H. Assess and ensure the training and competency of individuals who deliver interpreting and translating services. Bilingual staff that communicate directly with clients in their preferred language must demonstrate a command of both English and the target language.
I. Ensure that the scope of direct clinical care services provided by non-licensed, non-certified individuals (paid or volunteer) are consistent with state and federal regulations, when applicable.
J. Provide orientation, ongoing education, and monitoring for all health center staff. It is expected that if a responsibility or duty is listed in the job description, health center staff will receive appropriate training.
K. Ensure that all mandatory trainings, according to the type of staff person (i.e. staff, contract physicians, volunteers, students) are completed. For a list of mandatory trainings, go to the Accreditation page of the Extranet or Affiliate 411
L. Ensure that there be a proctoring program (a period of supervised practice) in order to assess the clinical skills of each individual. Written evidence of completed proctoring must be maintained.
    1. The Performance Management Toolbox can be accessed on the Accreditation page of the Extranet.
M. Ensure that all members of the medical staff, including the medical director and contract physicians, are privileged for the services they provide and receive an annual written evaluation that includes an evaluation of clinical skills
N. Encourage medical staff to attend at least 1 major CME/CEU program annually.

✓ FYI – In-person Educational Conferences

6.1.3 Medical Director Responsibilities

I. The medical director **must** be a physician (MD or DO) licensed to practice in at least 1 state included within the affiliate's geographic boundaries.
II. The medical director(s) is responsible for overseeing the

A. Development and implementation of affiliate medical policies and protocols in accordance with the PPFA Medical Standards and Guidelines and state and local regulations
B. Implementation of policies and procedures pertaining to the general handling of pharmaceuticals within the affiliate
C. Medical care provided at the affiliate that is in accordance with state and local regulations

III. The medical director **must**
A. Ensure that supervision and monitoring of affiliate clinicians is in accordance with state and local regulations and RQM program (i.e. annual chart review)
B. Ensure that clinical privileging is completed as required
C. Provide clinical services and supervise other clinicians only within the confines of her/his own training, certification, or credentialing
D. Practice within the confines of the affiliate's protocols
E. Serve as or designate Program Directors for the clinical services listed in Table 6.1.a. Program Directors.
F. meet the program director requirements, listed below, for all services that do not require a program director

IV. The Medical Director may designate appropriate staff to assist in the performance of these responsibilities.

6.1.4 Program Director responsibilities

I. A program director must be designated for the clinical services listed in Table 6.1.a. Program Directors. The Program Director must
A. Have formal education and training in the service(s) provided, either as part of her/his basic program or as post-graduate continuing education
B. Have experience providing the service(s)
C. Be privileged to provide the services they supervise in accordance with state and local regulations
D. Be competent in the supervision of complex cases within the service

II. The Program Director is responsible for the supervision of the service including
A. Developing and updating affiliate protocols in accordance with the PPFA Medical Standards and Guidelines
B. Overseeing the training/education/supervision/proctoring and ongoing monitoring of health center staff
C. Providing ongoing availability of consultation when needed
D. Granting clinical privileges relevant to the service according to Table 6.3.a. Clinical Privileging
1. EXCEPTION - The program director may designate other clinician(s) who may grant clinical privileges for ultrasound.
E. Participating in RQM activities, including, but not limited to
1. Medical record review and other program audits
2. Peer review

3. Review of required documentation (program complications, outcome/quality, etc.)

III. The Program Director may designate staff to assist in the performance of these responsibilities.

6.1.a. Table: Program Directors

Service	Who/Specifics Related to the Service
Abortion — Medication	Physician/APC ▪ **Must** be signatory or designate a physician to be the signatory to the *Prescriber's Agreement* provided by Danco Laboratories, LLC and meet all the requirements outlined in the *Prescriber's Agreement*
Abortion — Surgical	Physician
Breast – Basic	Physician/APC
Breast — Expanded	Physician breast specialist
Colposcopy/ Cryotherapy	Physician/APC
Early Pregnancy Evaluation and Management of Complications	Physician/APC
Gynecology — Expanded (Level II)	Board-certified obstetrician-gynecologist / family physician
Gynecology — Expanded Gynecologic Surgery (Level III)	Board-certified obstetrician-gynecologist
Infertility — Basic	Board-certified obstetrician-gynecologist
Infertility — Expanded	Board-certified reproductive endocrinologist
Leep	Physician/APC
Men's Reproductive Health Care	Physician /APC (ANP, FNP, PA, only)
Prenatal — comprehensive	Physician/Certified Nurse Midwife
Primary Care — Limited	Physician /APC (ANP, FNP, Women's Health NP, OB/GYN NP, or PA)
Primary Care — Expanded	Physician
Primary Care — Comprehensive	Family Practice or Internal Medicine Physician
Sedation	Anesthesia Professional or Nonanesthesiologist Sedation Practitioner ▪ An Anesthesia Professional is an anesthesiologist or certified registered nurse anesthetist (CRNA). ▪ A Nonanesthesiologist Sedation Practitioner is a physician who has not completed postgraduate training in anesthesiology but is specifically trained to personally administer or supervise the administration of sedation.

Service	Who/Specifics Related to the Service
Sterilization - Female (BTL and HTS)	Physician
Sterilization - Male	Physician
Transgender Care –Level II	Physician /APC
Ultrasound Services	Physician/APC In addition to mandatory training requirements **must** complete ARMS web-based proficiency exam.
Urinary Incontinence	Physician /APC

6.2 TRAINING

6.2.1 Training Requirements

I. Staff **must** be trained in the provision of the service as outlined in the relevant section of the MS&Gs. They must read the informed consent and required educational materials provided to clients.

6.2.a. Table: Specific Mandatory Trainings per the PPFA MS&Gs

The following trainings **must** be completed.

Required Training	Required for Which Staff*	When/Frequency
Talking About Abortion (CAL) OR Pass competency test	Anyone who talks to women about pregnancy options (including those who do not provide abortion services)	Within 6 months of hire
Orientation to the Abortion Pill (CAL) – Modules 1 and 2 OR Pass competency test	Anyone who talks to clients about pregnancy options (including those who do not provide abortion services)	Within 6 months of hire
Orientation to the Abortion Pill (CAL) – Module 3 OR Pass competency test	All licensed clinical staff who assess for expected effects, side effects, complications, and completion of the procedure	Within 6 months of hire
Ultrasound in Abortion (CAL) OR	Anyone who provides ultrasound services for abortion	Prior to individual performing ultrasound at the affiliate

Required Training	Required for Which Staff*	When/Frequency
Pass advanced placement test OR Demonstrate completion of equivalent ACCME-accredited training		
*See Affiliate Training and Onboarding Resources Toolkit for more detailed guidance on categories of affiliate personnel and other required trainings.		

6.2.b. Table: Other Training Requirements per the PPFA MS&Gs

Staff **must** be trained in the following areas via affiliate-designed programs, courses available on the CAL, or other available trainings.

Required Training	Required for Which Staff*	When/Frequency
Breast Health	Clinicians	within 6 months of hire
Drills (Medical) ▪ Medical Emergencies ▪ Sedation Emergencies (if provided)	Staff who work in health centers	Annually
Intimate Partner Violence/Reproductive Coercion	Staff who work in health centers	within 6 months of hire
Medical Equipment – proper use and maintenance	Staff who use medical equipment	within 90 days of hire and ongoing as appropriate or as required by state and local laws
Orientation/Job description duties	Staff who work in health centers and call centers	within 90 days of hire and ongoing as appropriate or as required by state and local laws
Ultrasound – hands-on training component** OR Demonstration of previous hands on training	Staff who perform ultrasound	prior to individual performing ultrasound at the affiliate
*See Affiliate Training and Onboarding Resources Toolkit for more detailed guidance on categories of affiliate personnel and other required trainings. **Process of initial training **must** include a combination of direct observation of scanning technique and submission of scans to Program Director for review. A minimum of 20 scans **must** be completed by the trainee. The number of scans performed will vary by individual. Each trainee **must** perform the number of scans that ensures competency. Discretion is allowed, especially in cases of trainees with past experience.		

6.3 CLINICAL PRIVILEGING AND SKILLS ASSESSMENT

6.3.1 Clinical Privileging

I. Each affiliate **must** create a system for granting clinical privileges to licensed staff (APC, RN, LPN, physician) who will perform specialty procedures.
   A. The system **must** include a proctoring program in which there is direct observation of the procedure being performed.
      1. Proctoring may only be performed by clinicians (APC, physician) designated by the Medical Director or Program Director
         a. Exception: hands-on Ultrasound training may be performed by any appropriately trained and skilled personnel.
      2. Proctoring should be done until competence has been reached.
   B. Licensed staff (APC, RN, physician) **must** demonstrate knowledge and skill in the procedure before being granted clinical privileges.
   C. Physicians that can demonstrate current or past privileges to provide a service at a hospital may be waived from the affiliate privileging requirement for that service.
   D. The clinical privileging of licensed staff by a Planned Parenthood affiliate may be accepted by other affiliates if there has not been a gap of Planned Parenthood employment of more than 2 years.
   E. Only the Medical Director or Program Director may grant privileges for specialty procedures.

6.3.2 Skills Assessment for Non-licensed Staff

I. Each affiliate **must** create a system for evaluating skills for services provided by non-licensed staff.

6.3.a. Table: Clinical Privileging

Procedures that require clinical privileging	Services	Notes
Aspiration of simple breast cyst	Breast	
Biopsy (genital, skin)	Men's Reproductive Health GYN/STI	
Colposcopy See Table 6.3.c.	Colposcopy/Cryotherapy	▪ Requires separate privileging for pregnant and non-pregnant women o Physicians only, if >12 weeks gestation ▪ Colposcopy of vulva requires colposcopy privileges
Cross-sex hormone therapy	Transgender Care	

Procedures that require clinical privileging	Services	Notes
Cryotherapy See Table 6.3.c.	Colposcopy/Cryotherapy	▪ Requires separate privileging for pregnant and non-pregnant women o Physicians only, if >12 weeks gestation
ECS	Colposcopy/Cryotherapy	▪ Requires separate privileging for pregnant and non-pregnant women ▪ Does not require colposcopy privileging when performed independent of colposcopy
Endometrial biopsy	Colposcopy/Cryotherapy GYN/Menopause	
Fetocidal digoxin injection	Abortion	
Fulgeration	Level II / Level III GYN	▪ OB/GYN or Family Practice physician or by waiver
Hysteroscopic tubal sterilization	HTS	▪ Physicians only
Hysteroscopy	HTS Level II / Level III GYN	▪ OB/GYN or family practice physician or by waiver
Implant insertion and removal	Contraception	
Incision and drainage of perineal abscesses	GYN	
IUC insertion	Contraception	
LEEP See Table 6.3.c.	LEEP	▪ Chart review of APC's LEEP cases **must** be performed by Program Director or designee for at least 1 year.
Marsupialization	Level II / Level III GYN	▪ OB/GYN or Family Practice physician or by waiver
Medication abortion	Abortion	▪ Physicians/APCs **must** read, understand, and meet the qualifications of the Mifepristone *Prescriber's Information and Agreement*
Recovery area supervision	Recovery Care	▪ Pertains to licensed health professionals only ▪ Privileging includes competence in monitoring post sedation and analgesic drugs, management of a compromised airway, provision of reversal agents, and other surgically related complications*
Sedation administration	Analgesia and Sedation	▪ Pertains to all nonanesthesiologist sedation practitioners and supervised sedation professionals**

Procedures that require clinical privileging	Services	Notes
		▪ Privileging includes competence in the safe administration of sedative and analgesic drugs, management of a compromised airway and provision of reversal agents
Surgical abortion	Abortion	▪ Requires privileging for specific gestational age limits and procedures
Ultrasound See Table 6.3.b.	Ultrasound	▪ Pertains to all licensed professional staff only (See skills documentation for non-licensed staff) ▪ Requires separate privileging for performing and interpreting and for each type of ultrasound performed. ▪ For personnel who will interpret ultrasound, proctoring **must** be done by staff who are privileged to interpret.
Vasectomy	Vasectomy	
Word catheter placement	STI	
*Where sedation is not used, privileging is not required. Licensed staff **must** be available at all times. Staff providing recovery area care **must** be trained in proper recovery care for procedures performed. **A supervised sedation professional is a licensed RN, APN, or PA who is trained to administer medications and monitor clients during moderate sedation under the direct supervision of a nonanesthesiologist sedation practitioner or an anesthesiologist.		

6.3.b. Table: Who Can Perform/Who Can Interpret Ultrasound

Type of Service	Affiliate staff who may perform ultrasound	Affiliate staff who may interpret ultrasound
▪ Gynecologic Conditions ▪ Menopause ▪ Infertility	▪ Certified sonographers ▪ Certified radiologists ▪ Affiliate physicians	▪ Certified radiologists ▪ Affiliate physicians with the following qualifications o Completion of an OB/GYN residency which included at least 300 ultrasounds OR o Completion of at least 16 hours of Cat I CME in basic and advanced ultrasound, and documentation of a minimum of 100
▪ IUC localization	▪ Licensed health professional ▪ Certified sonographer	▪ Radiologist ▪ Affiliate physician

Type of Service	Affiliate staff who may perform ultrasound	Affiliate staff who may interpret ultrasound
	▪ Radiologist	▪ When confirmation of an intrauterine IUC is made by ultrasound, interpretation may be done by APC
▪ Abortion ▪ Early Pregnancy Evaluation	▪ Non-licensed personnel ▪ Licensed nurses ▪ APCs ▪ Certified sonographers ▪ Physicians	▪ APCs ▪ Physicians

6.3.c. Table: Prerequisites for Clinicians Performing Colposcopy, Cryotherapy, and LEEP

Colposcopy and Cryotherapy: Colposcopy includes performance of Cervical Biopsy and ECS		
	Physician	APC
Prerequisites	▪ Training includes a minimum of 2 years experience as a practicing clinician providing GYN care.	
Initial training in colposcopy/ cryotherapy	▪ Residency program or	
	▪ Two to five day training course (or equivalent) with hands-on component by qualified faculty	
Preceptorship — if no prior experience in colposcopy/ cryotherapy	If training was not part of a residency program, physicians **must** meet the same preceptorship requirements as APCs. ▪ Preceptorship may be within or outside of affiliate. ▪ Preceptor(s) **must** be approved by the affiliate colposcopy program director. ▪ Preceptorship **must** entail direct supervision and guidance by experienced preceptor(s) who meet the criteria for clinicians performing colposcopy/biopsy/cryotherapy at the affiliate. ▪ No more than 4 preceptors, with 25 percent of required procedures directly overseen by a supervising physician colposcopist.	
Preceptorship — Experience requirements	▪ A minimum of 50 exams with cervical biopsy on 45 clients is recommended ▪ ECS procedures until competency showing proficiency with both curette and cytobrush (25 recommended) ▪ Direct participation in the evaluation of 10 clients with biopsy-proven HSIL or worse	

<table>
<tr><th colspan="4">Colposcopy and Cryotherapy: Colposcopy includes performance of Cervical Biopsy and ECS</th></tr>
<tr><th></th><th colspan="2">Physician</th><th>APC</th></tr>
<tr><td>or

Prior-experience requirements</td><td colspan="3">▪ Cryotherapy until competency (5-10 minimum)

Colposcopy Director must review prior experience to determine if criteria have been met and must determine need for additional supervision or observation for those being approved on the basis of prior experience.</td></tr>
<tr><td>Preceptorship — for review and approval by the Physician Program Director</td><td colspan="3">If preceptorship takes place during employment at affiliate, documentation must include
▪ A written log of procedures
▪ Written assurance of the clinician’s competency from each preceptor, whether within or outside of affiliate</td></tr>
<tr><th colspan="4">LEEP</th></tr>
<tr><th></th><th colspan="2">Physician</th><th>APC</th></tr>
<tr><td rowspan="2">Prerequisites</td><td colspan="3">▪ OB/GYN residency program or hands-on training course in LEEP by qualified faculty</td></tr>
<tr><td colspan="2">Proctoring of at least 1 LEEP procedure by clinician experienced in LEEP – if an affiliate clinician – must have affiliate privileges in LEEP.
If indicated, proctoring at affiliate by clinician privileged in LEEP until competency has been demonstrated.</td><td>Experience performing at least 100 colposcopies, including those done during the colposcopy preceptorship

Proctoring to include direct supervision and guidance of at least 10 LEEP procedures by clinician experienced in LEEP – if an affiliate clinician – must have affiliate privileges in LEEP.</td></tr>
</table>

6.4 PRECEPTING OF TRAINEES

✓ FYI – What is a trainee?

I. Affiliates may train any type of health care professional that can legally provide Planned Parenthood core services in their state.

6.4.1 All trainees **must**

I. Work under the supervision of a licensed clinician who is fully trained and experienced in the clinical area being precepted
II. Be precepted only during the provision of services that are part of a course of training (e.g., nurses providing care as part of a nurse practitioner training program **must** be precepted when providing services as a nurse practitioner, but not when providing solely nursing services)
III. Be identified by an appropriate nametag
IV. Be given written consent by the client prior to the trainee's performance of any examination or procedure. This consent is in addition to all other informed consent requirements. To obtain written consent, affiliates who provide training **must** include the following language in form their Request for Medical Services form. (See MS&Gs Part III: Required Documents and Additional Resources for translations in other languages.)
"Please note that [affiliate name here] is a teaching institution, and that persons in training, under strict supervision, may be involved in some aspects of your care."
V. Have all documentation countersigned by the supervising licensed personnel
VI. Agree to practice according to the Affiliate MS&Gs and affiliate specific policies and procedures

6.5 ADDITIONAL INFORMATION

6.5.a. Table: For Your Information

Section	Topic	Detail
6.1.2	In-Person Educational Conferences Produced for Planned Parenthood Medical Providers	▪ **MeDC Annual Clinical Meeting —** The Medical Directors Council (MeDC) holds an annual CME conference on reproductive health and medical leadership in the spring for physician medical directors (including associate/assistant) and 1 affiliate clinician in a leadership role. Tuition is free. Attendees are responsible for travel expenses. Scholarships are available. ▪ **PPFA National Medical Meeting —** The PPFA National Medical Conference/NMC Meeting is held each fall. Although all affiliate staff and volunteers are welcome to attend, this meeting is geared

Section	Topic	Detail
		toward a medical audience. Tuition is nominal. CME/CEUs are provided for many of the presentations. It's also a great opportunity to observe the NMC in action and participate in the process.
6.4	What is a trainee?	A trainee is a licensed* professional who is enhancing or learning a new skill(s) within their scope of practice. A trainee may be seeking a "hands-on" or "hands-off experience. ▪ Hands-on — trainee's work is done in collaboration with, and reviewed and co-signed by, a Planned Parenthood preceptor until competency in the particular skill(s) is demonstrated. Competency is assessed by the Planned Parenthood employee(s) providing the training. ▪ Hands-off — trainee observes under direct supervision of a Planned Parenthood employee. Examples of trainees are: Resident Physicians*, Fellows, Advanced Practice Clinicians, SANE Nurses *Depending on state law, resident physicians may not be licensed.

6.5.b. Table: References

Section	Reference
6.3.a.	American Society of Anesthesiologists. Statement on Qualifications of Anesthesia Providers in the Office-Based Setting. October 21, 2009. https://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx. Accessed June 5, 2014
6.3.a.	American Society of Anesthesiologists. Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners who are not Anesthesia Professionals. October 19, 2011. https://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx. Accessed June 5, 2014

6.5.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIICs	Items to Add to Request for Medical Services for Affiliates Who Provide Training	Part 3, Chapter 01_04

6.5.d. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ Affiliate Training and Onboarding Resources Toolkit ✓ Clinician Performance Monitoring Toolkit ✓ APC Orientation Toolkit	
Training	**CAL Courses** Caring for the Caregiver Series: Assisting the Healthcare Provider After an Adverse Event Compliance 101 for Staff Compliance Programs for Management Series The Components of the Planned Parenthood Volunteer Program Federal Employment Law Series Healthcare Ergonomics Health Insurance Portability and Accountability Act (HIPAA): The Security Rule HIPAA 101—Protecting Patient Privacy History of the Federation Hostile Encounters in the Workplace Intimate Partner Violence (IPV) in the Workplace Intimate Partner Violence (IPV) in the Workplace for Managers Managing Productivity Series Managing Suspicious Encounters Melissa's Story: Anatomy of a Sexual Harassment Case Myths, Facts, and Actions: How Planned Parenthood Culture Affects Services Office and Telecommuter Ergonomics	

ADMINISTRATIVE CHAPTER 7: PHARMACEUTICALS

Revised June 2014

Admin Chapter 7 Table of Contents

7.1 PHARMACEUTICAL SERVICES

7.1.1 Policies and Procedures – **must** include

I. Formulary of all drugs stocked in the affiliate that is reviewed annually
   A. Consider the potential for medication errors when developing formulary. Look-alike, sound-alike drugs should be identified as being at "high risk" for potential error. Extra steps should be taken to ensure safety.

✓ FYI - Look-alike, Sound-alike (LASA) Medications

II. List of additional therapeutic/pharmacologic classifications of drugs that may be ordered for clients to obtain at outside pharmacies
III. Provision of pharmaceuticals in accordance with all state/local laws and regulations
IV. A drug control system that covers the interval from the time pharmaceuticals are ordered until they are provided to the client
V. Inspection of all drug storage areas to remove expired drugs
VI. Designation of which staff may have access to bulk storage areas
VII. Management of pharmaceutical product irregularities and drug and device recalls

7.1.2 Procurement

I. There **must** be a written order for all drugs/pharmaceuticals/chemicals brought into the affiliate:
   A. A copy of the purchase order or the prescription **must** be kept in the affiliate's files. A signed receipt **must** be obtained for pharmaceuticals shipped from a central location to outlying centers or clinics. If delivery is made by affiliate staff, a signed receipt is not necessary.
   B. Controlled substance order and receipt records **must** be filed separately from the other pharmaceutical purchase records.
II. If pharmaceuticals are routinely purchased from a community or hospital pharmacy and if the items are not supplied in manufacturer original containers, there should be a written contract specifying, at a minimum, requirements for labeling.
III. If available, pharmaceuticals should be purchased in manufacturer prepared unit-of-use packages.
IV. Only drugs and devices approved by the Federal Food and Drug Administration (FDA), and manufactured for sale in the United States may be used. Affiliates may not import drugs and/or medical devices from other countries for use in their health centers.

7.1.3 Storage

I. Access
   A. The bulk storage area **must** be secure.
   B. Controlled substances **must** be locked and in a secure area at all times.

C. Access to pharmaceuticals dispensed from within client care areas should be limited to health care providers responsible for dispensing these items.

II. How to store
   A. Arrange medications so that the oldest stock is used first.
   B. Do not store look-alike, sound-alike medications alphabetically. Store them out of order or in a separate location.[R1]
   C. Pharmaceuticals meant for internal use **must** be stored separately (i.e., on a separate shelf) from those for external (i.e., topical) use only.
   D. All prescription medications should be stored in containers that protect them from light.
   E. All manufacturer recommendations for storage **must** be followed.

III. Storage for contraceptive vaginal ring (CVR)
   A. An expiration date **must** be on the label of each ring package. If needed, use the adhesive labels provided in the carton.
   B. For rings that will not be refrigerated, the adhesive label **must** be applied directly over the pre-existing expiration date on each cachet pouch (and on the outer carton). This date should not exceed either 4 months from the date of dispensing, or the product expiration date, whichever comes first.
   C. For refrigerated NuvaRing, the product expiration date may be used.
   D. NuvaRing packages that need to be refrigerated **must** be clearly marked.
   E. NuvaRing should never be stored in direct sunlight or at temperatures above 30°C (86°F).

IV. Store Mifepristone and misoprostol at room temperature.

V. Storage of multi-dose vials
   A. Unopened multi-dose vials – **must** follow manufacturers' recommendation for storage
   B. Opened multi-dose vials
      1. When a multi-dose vial is used, appropriate infection prevention procedures to prevent contamination should be employed.[R2]
      2. Vials **must** be discarded if there is evidence of contamination.
      3. If a multi-dose vial has been opened or accessed (e.g., needle-punctured) the vial **must** be dated and discarded in accordance with manufacturer's instructions and state/local regulations.
      4. If no specific guidelines are provided, CDC recommends discarding the vial within 28 days. [R2]
      5. Open vials of misoprostol should be discarded after 30 days.

7.1.4 Repackaging

✓ FYI - Definition of Repackaging

I. Repackaging **must** be done in accordance with state/local laws/regulations.

II. A log **must** be maintained to document the supervisor (by signature), the person doing the repackaging (by signature), and the identification of the bulk drug being repackaged. Logs **must** be archived according to state/local laws/regulations. The log should contain the following information:

A. Complete product description — name, strength, manufacturer

B. The manufacturer's lot number

C. An expiration date, no later than the manufacturer's expiration date of a not previously opened manufacturer's container

D. A control number or some other unique (code) identification that will link that manufacturer and drug lot with the repackaged units

III. All repackaged units **must** have a standard label affixed to each package (bottle, etc.) before they are entered into active stock. The label **must** include at least the following:

A. Name and address of the affiliate

B. Name of the drug and quantity

C. Strength of the drug when appropriate

D. The expiration date, for drugs repackaged in "tight" containers such as plastic vials or glass bottles.

1. This should be the date specified on the original manufacturer's container, or 1 year from the date the product was repackaged, whichever is earlier.
2. The expiration date for drugs that are repackaged from unit dose containers should be no greater than 60 days from the date of repackaging, or the manufacturer's expiration date on the original container, whichever is earlier.
3. State laws may be applicable to expiration date for repackaged pharmaceuticals.

E. The control number linking that unit with the manufacturer's product drug lot — for example, a code showing the month and day of repackaging and number repackaged that day (as below, where 01=month, 21=day of repackaging, and 04=fourth item repackaged that day)

Sample label for drugs repackaged in airtight containers:

Planned Parenthood of Upper Peninsula 888 Main St., City, State, ZIP
Acetaminophen Tablets 325 mg, Qty. 25 Exp. 12/15, Control #012104

IV. Safety precautions should be taken to indicate if the original repackaging unit has been opened prior to this dispensing, e.g., such as putting latex seals over the cap of the original vial after carrying out repackaging. An "x" could also be marked on the bottle cap or label to indicate it has been opened.

7.1.5 Compounding

✓ FYI — Definition of Compounding

I. With the exception of reconstituting a medication for injection using the diluent as supplied and/or provided by the manufacturer, affiliate **must not** compound medications for use.
II. Compounded products **must** only be ordered from compounding pharmacies that are certified through the Pharmacy Compounding Accreditation Board or some other nationally recognized accrediting body.
III. Compounded menopausal hormone therapy and compounded contraceptives **must** not be used.
IV. Approval from PPFA Medical Services is required to prescribe other compounded products.

7.1.6 Labeling Prescription Vials for Clients

I. Prescription labels should be designed to enhance client safety. For recommendations from the Institute for Safe Medication Practices see Principles of Designing a Medication Label for Community and Mail Order Pharmacy Prescription Packages
II. All prescription vials **must** have a permanently adhering label affixed directly to the container with at least the following information:
   A. Name and address of the affiliate
   B. Name, strength, quantity dispensed of the drug
   C. Expiration date
   D. Lot number

III. The label **must** also include the following information, which may be added by hand at the time of dispensing:
   A. Date of the prescription
   B. Name of the client
   C. Directions for use including frequency and route of administration
   D. Name of the prescriber
   E. Number of refills, if applicable

Sample label for prescription vial for client.

Planned Parenthood of Upper Peninsula 888 Main St., City, State, ZIP
{date} {client name} Take ____ tablets every ____ hours [by route] as needed for pain. {Dr. _____}
Acetaminophen Tablets 325 mg, Qty. 25 # refills Exp. 12/15, Control #012104

IV. Auxiliary labels should be used to provide other information to the client, such as "Do not drink alcohol." in the case of metronidazole. The label(s) that should appear on the prescription container can be found in the literature about each drug, including the manufacturer's package insert. There should be a policy standardizing the use of auxiliary labels for consistency.

V. The plastic case or other container for oral contraceptives **must** bear the full label and include the FDA package insert. The refill units given at the same time need not be individually labeled. If the original case or container is not presented for subsequent refills, then the refill units can be put into a bag and the outside of the bag labeled.

7.1.7 Dispensing Containers

I. Coin envelopes **must not** be used to dispense solid dose pharmaceuticals.

II. Prescription medications should be dispensed in containers that protect them from light.

7.1.8 Contraception and Other Hormones

I. Over-The-Counter Contraceptives
   A. At every visit, condoms that do not contain nonoxynol-9 should be proactively offered to all sexually active clients who receive medical services unless they are expressly declined.
   B. Affiliates may make available any FDA-approved, non-prescription contraceptive to clients or to unregistered individuals.
   C. Age-restricted 2-pill generic OTC EC (only) - affiliate **must** check purchaser's ID to verify that purchaser is at least 17 years old prior to OTC sale. Note: 2-pill generic products require a prescription for purchasers younger than 17 years old.
   D. Written educational materials should be available to clients and others regarding the use of non-prescription contraceptive products stocked by the affiliate including the detailed client product information

II. Contraceptives may be mailed to clients. Mailings **must** conform to good medical practice taking care to avoid excessive heat or cold per the product labeling. FDA-approved client package labeling **must** be included.

III. Patient package inserts **must** be available for IUCs, hormonal contraceptives, and other estrogenic and progestational substances.

7.1.9 Controlled Substances

I. All controlled substances dispensed for outpatient use **must** bear the federally mandated auxiliary label: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

II. A daily count at the beginning and at the end of the clinic day **must** be taken on days when controlled substances are administered or prescribed. Discrepancies **must** be immediately reported to the supervisor and recorded in the controlled substances inventory:
   A. Two countersignatures are required at the time of the count
      OR
   B. One person signing the daily count, and two persons taking and signing a full count every thirty days
      OR
   C. as required by state law

III. All inventory and purchase records for controlled substances **must** remain on file for the duration specified in state law if greater than the federal standard of 5 years.

7.1.10 Administering Medications On-site

I. Whenever clients are given a parenteral injection at the affiliate, they ~~must~~ be observed on site for at least 20 minutes before being allowed to leave

II. If a client is beyond the date of expected menses, a pregnancy test **must** be performed and documented before prescribing any antibiotic that is contraindicated in pregnancy.
III. Antibiotics should not be withheld during the luteal phase (before the expected menses), even if the client did not use effective contraception earlier in the cycle.
IV. All clients receiving medications **must** also receive written or verbal instructions including the name, purpose and appropriate administration technique for each drug.

7.1.11 Perioperative or other Procedural Settings

I. ~~**Must** label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings. (Note: Medication containers include syringes, medicine cups, and basins.)~~[R1]

7.2 MANAGEMENT OF PHARMACEUTICAL PRODUCT IRREGULARITIES

7.2.1 Pharmaceutical Product Irregularities

I. May be detected in the form of defects in drug or device packaging, tablet coloration, or dose sequencing. Such problems may be the result of defective manufacturing or packaging processes, failure of the pharmaceutical company's product inspection mechanism, or tampering with the product at any point between the product's packaging and its use by the client. Because these products may be dangerous to the client and because other units may be defective, prompt action is necessary to deal with these events.

7.2.2 Managing Suspected Product Irregularities – the following **must** be done:

I. Package — the package of medication in question **must** be held in a secure place at the affiliate, as later transfer to the manufacturer or the FDA may be necessary. There **must** be no attempt to manipulate or otherwise alter the package, as it may constitute evidence in a criminal suit or other action.
II. Remaining Stock — Remaining stock of medication with the same lot number **must** be identified, put aside, and not dispensed to clients until the problem has been resolved.
III. Notifications — Medical Services **must** be notified immediately by telephone for evaluation of the situation and provision of further instructions. The affiliate **must** not take any additional steps (such as notification of the pharmaceutical company, FDA, other clients who may have been exposed to the product, and the media) until it receives guidance from PPFA.

7.3 DRUG AND DEVICE RECALLS

The FDA initiates drug recalls of drugs or devices that are found to be in violation of federal law. The recalls are classified according to the potential adverse impact of the violative drug or device upon the health of exposed individuals.

7.3.1 Definitions

I. Class I Recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
II. Class II Recall: a situation in which use of or exposure to the violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.
III. Class III Recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

7.3.2 Procedures

I. Class I Recalls
   A. Purchase logs **must** be evaluated for a period of not less than 2 years prior to the date of the recall.
   B. All violative product **must** be quarantined. Product **must** not be provided to any client until it is verified that stock does not contain involved lot number(s).
   C. Any of the violative product found in stock **must** be removed from inventory unless otherwise directed in the recall information.
   D. If it is determined that none of the violative lot(s) have been received by the affiliate, then the only further action required is to verify that none of the involved lots are shipped to the health center during the next 2 months.
   E. If it is determined that product from the violative lot(s) has been provided to clients within the past 2 years, the following actions **must** be taken:
      1. Daily logs and/or medical records **must** be reviewed to determine which clients received product from the violative lot(s).
      2. An attempt **must** be made to contact identified clients by telephone.
         a. If it is determined that the client received product from the violative lot(s), or if the lot cannot be determined, the client **must** be instructed to discontinue the medication and bring it back to the clinic immediately for replacement with a non-involved lot of the same medication, if available. If a non-involved lot cannot be obtained for the client, the client **must** be changed to an alternate medication.
         b. If it is determined that the client received the named medication, but not from the involved lot(s), she or he should be reassured that continuation with their prescribed regimen is safe.

3. If an identified client cannot be contacted by telephone, a letter **must** be sent to her/him, explaining the nature of the recall and requesting that the clinic be contacted.
4. If a client experiences a significant medical problem resulting from the use of violative product, PPFA Medical Services and ARMS **must** be informed.

II. Class II Recalls

A. Purchase logs for the past year **must** be checked to determine if any of the violative lots have been received
B. Any violative product found in stock **must** be removed from inventory and prepared for return to the supplier.
C. If it is determined that product from the violative lot(s) has been provided to clients within the last 6 months, the following actions **must** be taken:
   1. Daily logs and/or medical records **must** be reviewed to determine which clients received product from the violative lot(s).
   2. An attempt **must** be made to contact identified clients by telephone.
      a. If it is determined that the client received product from the violative lot(s), the nature of the recall **must** be explained and the client **must** be requested to return any outstanding supply of the violative product to the clinic.
      b. If it is determined that the client received the named medication, but not from the involved lot(s), she or he should be reassured that continuation with their prescribed regimen is safe.
   3. If an identified client cannot be contacted by telephone, a letter **must** be sent to her/him, explaining the nature of the recall and requesting the return of any outstanding violative product.
   4. If a client experiences a significant medical problem resulting from the use of the violative product, PPFA Medical Services and ARMS **must** be informed.

III. Class III Recalls

A. No product lot listed in a Class III recall may be provided to a client.
B. The violative substance **must** be removed from inventory and returned to the supplier.

7.4 ADDITIONAL INFORMATION

7.4.a. Table: For Your Information

Section	Topic	Detail
7.1.1	Look-alike, Sound-alike (LASA)	Confused drug names are one of the most common causes of medication error. With tens of thousands of drugs currently on the market, the potential for error due to confused drug names is significant and exists worldwide. Contributing to the risk of confusion are illegible handwriting, incomplete knowledge of drug names, newly available

Section	Topic	Detail
	Medications[R3, R4]	products, similar packaging or labeling, similar clinical use, similar strengths, dosage forms, frequency of administration, and the failure of manufacturers and regulatory authorities to recognize the potential for error and to conduct rigorous risk assessments, both for nonproprietary and brand names, prior to approving new product names. Go to the Institute of Safe Medication Practices for a list of LASA medications. The list includes those medications that are known to have been involved in medication errors, as well as the Joint Commission's list of LASAs.
7.1.4	Definition of Repackaging	The preparation of multiple containers of dispensing size from a bulk container (for example, repackaging a bottle of 1000 tetracycline tablets into vials of 20 tablets each). Repackaged vials are stored and dispensed to clients as needed.
7.1.5	Definition of Compounding[R5]	Compounding is the act of preparing, mixing, assembling, packaging, and/or labeling a drug or device as the result of a practitioner's prescription drug order or initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice, or for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders, on the basis of routine, regularly observed prescribing patterns.

7.4.b. Table: References

Section	R#	Reference
FYI	R5	American Pharmacists Association. Guidelines for Compounding Practices. HYPERLINK GOES HERE. (accessed June 2014) http://www.pharmacist.com/sites/default/files/files/Allen_%20Chap_%201_Art,%20Science%20and%20Technology%20of%20Pharmaceutical%20Compounding,%204e.pdf
7.1.3	R2	CDC. *Injection Safety*. February 9, 2011. http://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html (accessed June 6, 2014).
FYI	R4	ISMP (Institute for Safe Medication Practices). 2010. Principles of Designing a Medication Label for Community and Mail Order Pharmacy Prescription Packages.
7.1.3 7.1.11	R1	The Joint Commission. 2010. "National Patient Safety Goals: Effective July 1, 2010" Accreditation Program: Ambulatory Health Care.
FYI	R3	WHO (World Health Organization). "Look-Alike, Sound-Alike Medication Names." Patient Safety Solutions, Volume 1, Solution 1. May 2007.

7.4.c. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ FDA Drug Shortages ✓ ASHP Drug Shortages ✓ MedlinePlus Drug Information	
Training	**CAL Course** How to Administer Intramuscular Injections	

ADMINISTRATIVE CHAPTER 8: SYSTEMS FOR NOTIFICATION AND FOLLOW-UP

Revised June 2014

Admin Chapter 8 Table of Contents

8.1 SYSTEMS FOR NOTIFICATION AND FOLLOW-UP

Every affiliate **must** have a written, standardized, affiliate-wide, and consistently used system for notification of results and follow-up of referrals and abnormal results for all services. A detailed description of the system/procedures must be included in the affiliate medical manual. If an automated system is used, affiliate's procedures must stipulate when a letter/referral will be mailed to a client who has been notified of a result via the automated system. Resources are available at www.armsconnect.org.

8.1.a. Table: Components of System

Receiving, Reviewing, and Tracking Results, Reports, etc.		▪ Mechanisms **must** be in place for o Timely receipt of all lab results, reports, etc. o Review of all lab results, reports, etc. • Any time an hCG is sent to the lab, results **must** be received and reviewed within 48 hours. o Tracking of all lab results, reports, etc. to ensure timely follow-up o Obtaining records when client seen out of affiliate for care (e.g., client seen in ER) ▪ A licensed health professional (e.g., RN, LPN, clinician) **must** review all lab results, reports, etc. o All abnormal results **must** be correlated with clinical findings and followed up appropriately. Management plans **must** be documented in the medical record (not on the result or report). o Normal results **must** be correlated with clinical findings, as indicated. (e.g., normal diagnostic mammogram following abnormal CBE).
Communicating with the Client	Methods of Contact	▪ The affiliate **must** establish a process that allows clients to choose a preferred method(s) of contact. Clients **must** be informed that when a life-threatening condition is suspected or detected, the preferred method may not be used. ▪ Clients **must** provide an emergency contact. ▪ Automated systems and patient portals may be used for client notification. ▪ Clients may receive limited electronic communication. o They **must** give written consent.

		○ An e-mail or text may substitute for a telephone attempt at notification. ○ The mandatory PPFA guidelines for communicating with clients electronically, such as with unsecured e-mail or text messaging are available on the ABACUS page of the PPFA Extranet.
	Electronic Communication	▪ If client gives written consent per affiliate protocol to receive electronic communication and the use of electronic notification of test results is not specifically excluded, the affiliate is obligated to send 1 electronic notification even if 3 attempts (1 telephone call and 2 letters) have already been made. ▪ The affiliate **must** have systems and processes in place to ensure that ○ Only clients who have consented to e-mail or text messaging receive it ○ All clients who have consented to electronic communication receive an e-mail or text as part of their notification, unless specifically excluded as noted above
	Notification of Results or need for follow-up	▪ The affiliate **must** make reasonable attempts to inform the client of abnormal findings and test results. See 8.1.2 Timing and Types of Client Notification below for detailed requirements. ▪ Clients should be notified of normal results. ▪ Once notification has been established (e.g., client is reached by phone or responds to first letter or receives results via automated system or patient portal), additional client contacts for notification purposes are not required. ▪ Whenever notification is made by phone, providing the client with additional written information is recommended. ▪ If using an automated system or patient portal, when system notification attempts are completed and the client has not accessed their test results, notification is not complete and 1 written notification attempt **must** be made.
	Content of notifications	Verbal or written notification of abnormal results **must** include these 5 components ▪ The nature of the abnormal findings ▪ The implications of the findings ▪ The possible consequences of not receiving additional diagnosis and/or treatment

		▪ An explanation of management options and provision of appropriate referral sources, as indicated ▪ Informing client that it is her/his responsibility to obtain follow-up care If a management plan has been determined, notification **must** include the details of that plan, e.g., schedule of visits or tests. ▪ Plans should be given in writing as well as verbally. ▪ Clients should be provided with alternative management options (if any) and with an opportunity to ask questions.
	Documentation of notification – normal results	Documentation of notification of normal results may be accomplished by noting standardized letter sent or message entered (for automated systems or patient portals) on the paper copy or in the EMR.
	Documentation of notification – abnormal results	▪ All contacts and attempts at contact with the client **must** be documented in the medical record (with copies of any written communications or citations as noted below). ▪ If forms, form letters, or other client education materials are given or sent to the client, they **must** either be cited in the medical record via a standardized identification system (including revision date) or a copy **must** be placed in the chart. ▪ The client record **must** include documentation that the 5 components of client notification, listed above, have been communicated to the client. o It is only necessary to document these points once. o If a letter or form with the 5 components has been sent or given to the client, citing the letter or form is sufficient. ▪ When clients are notified of abnormal results via an automated system or patient portal and/or the notification attempts have been completed o A printout of the tracking log **must** be placed in the paper chart. o A system to ensure documentation in the electronic chart **must** be developed.

Referrals out of affiliate - advice to obtain a consult, test, or management of any suspected acute, emergency, life threatening, serious, or potentially life-threatening condition. ✓ FYI – Recommendations vs. Referrals ✓ FYI – Tips for Successful Referrals	Referral Sites	▪ The affiliate **must** maintain a list of agencies, physicians/other health professionals, and hospitals to which clients may be directed or referred. ▪ For clients being referred out-of-affiliate for care, 3 alternatives should be provided when possible. ▪ A key strategy for IPV/Reproductive Coercion is the supported referral. ✓ FYI – Supported Referral ▪ The **r**eferral network for breast services consists of the following outside consultants who will be available to perform the designated services: o Radiologist(s) able to interpret mammography and ultrasound in an FDA-accredited unit. o Breast specialist(s) with the capacity and training to evaluate (image, biopsy, and clinically examine) and take responsibility for the plan of care of the client, which may include surgical intervention or referral to an established surgical resource. In situations where a provider who does not meet these criteria is designated by the state or funder as a breast specialist, that provider is also acceptable. o Genetic counselors specializing in cancer genetics who can identify clients at increased risk of breast cancer and develop screening and prevention recommendations for these clients.
	Referral forms	▪ When an out-of-affiliate referral is made, a referral form should be given to the client at the health center. ▪ If the referral is not made in person, the completed referral form should be mailed to the client. ▪ The name of the provider making the referral and reason for the referral as well as results of any testing/evaluation done so far **must** be included. Provider's signature is not required. ▪ The form should include a request for feedback. ▪ A copy of the form **must** be kept in the medical record. ▪ Client's signature is not required unless the form includes an authorization for release of records. Obtaining a signature should not be a barrier to mailing the referral form to the client. ▪ A referral form is not required for in-affiliate management.

	Urgent and emergent referrals	▪ The referring clinician **must** call the emergency department to explain the reason for the referral and to relay any pertinent findings, speaking directly to the emergency department physician, if possible.
	Releasing information to referral site	▪ Written consent to release information to the referral source **must** be present in the medical record when required by state law/regulation. ▪ Obtain written consent whenever possible when there is no state requirement. ▪ In some circumstances (e.g., when the client is admitted to an emergency room), requiring written consent may result in a delay in the client's care.
	Documentation of Referrals	▪ Affiliates **must** document all referrals in client's medical record. (A copy of the referral form in the medical record is not documentation.) ▪ Results of visits conducted elsewhere, whether by referral or per client's choice, should be obtained and recorded when possible. ▪ All contacts and attempts at contact with the referral source **must** be documented in the medical record.
Receiving a Referral		▪ Clients evaluated or treated elsewhere for a non-malignant condition are eligible for follow-up care at the affiliate. ▪ Copies of pertinent medical records, including pathology reports, **must** be requested. If they become available, they **must** be reviewed and entered into the client's medical record.
Tickler/Alert System		The affiliate **must** establish a system that alerts staff who have access to medical records and/or alerts in patient management systems (including call center staff with such access) to take appropriate action whenever there are any outstanding follow-ups of results and/or referrals. ▪ If there is confirmation that client received notification (documentation of a conversation with client, for example), no action is required until the required follow up is past due. ▪ If there is no confirmation that client received notification despite required attempts, and client calls or visits health center, staff **must** take necessary action to ensure client is notified. ▪ Once it is known that care was received, the alert should be cleared or removed. ▪ Affiliate staff without access to medical records and/or the alerts within the patient management systems (i.e. certain call center staff) are excluded from this requirement.

Appointments		▪ Out-of-Affiliate Appointments — The affiliate **must** document all known out-of-affiliate visits and missed or cancelled appointments. ▪ In-Affiliate Appointments — The affiliate **must** document in the medical record, patient management system, or EMR all missed or cancelled appointments for follow-up of abnormal findings/tests, **and** the information **must** be easily retrievable for as long as the client record is maintained (whether on-site or in storage).
Reminders to Obtain Care		▪ The affiliate **must** remind clients to obtain the care it advises unless there is documentation in their medical records that care was already received. ▪ One reminder is required. o Reminder by letter is preferred. o Telephone contact is acceptable only if a letter cannot be sent (e.g., client prohibits communication by mail, or address on file is out of date). ▪ The reminder **must** include that o Follow-up is due o Follow-up is important and why (e.g., if a breast mass — to rule out cancer) o Affiliate will help client with scheduling and rescheduling appointments ▪ Reminders **must** be sent around the expected appointment time, either before or after it is due. Timing depends on the situation. (Examples — for treatment of an STI, reminder should be sent approximately 7 days after notification is completed; for post medication abortion follow up, reminder should be sent no later than 7 days after the scheduled visit; for a follow-up Pap due in 12 months, reminder should be sent no more than 30 days before the Pap is due and no more than 30 days afterwards.) o Post vasectomy/HTS reminders – If PVSA or HSG results have not been received by 4 months post procedure, **must** make 1 reminder attempt. ▪ EXCEPTION: should remind clients of recommended vaccines and next vaccine in series
Failure to Obtain Care / Continuation of Other Services		▪ When the client fails to receive follow up care (including PVSA post vasectomy and HSG post HTS), the client **must** sign the release “When Test/Service/Consultation Will Not Be Obtained as Recommended” before further clinical services can be provided.

		▪ See 8.1.3 Continuation of Services When Client Fails to Follow-Up for breast and Pap/histology findings ▪ When no specific Standards apply, affiliates should consider developing protocols for circumstances in which the medical director or program director needs to review a client's records (e.g., pelvic mass with no follow-up).

8.1.b. Table: Follow-up Process

Condition/Result	Process
Emergent Acute Condition/Malignancy on Lab Result or Report	▪ Give/call/fax referral form or information to client ▪ For acute condition, immediately transfer to ER or hospital or, with client's consent, arrange immediate care ▪ For malignancy on lab result or report, help client make appointment unless she/he declines ▪ Initiate tracking system ▪ Place tickler on chart
Very Serious Potential Malignancy, HIV	▪ If out-of-affiliate, give referral form at visit or mail referral form ▪ Unless she/he declines, help client make appointment when indicated to facilitate an appointment ▪ Initiate tracking system ▪ Place tickler on chart
Other Other referrals, abnormal test results or findings, unsatisfactory test results, or other follow-up	▪ If out-of-affiliate, give referral form at visit or mail referral form ▪ Help client make appointment when indicated to facilitate an appointment unless she/he declines ▪ Initiate tracking system ▪ Place tickler on chart

8.1.2 Timing and Types of Client Notification

8.1.c. Table: Specific Requirements Related to Timing/Types of Client Notification not Cervical Cancer Screening/Management Results

Condition/Result	Notification Requirements*
EMERGENT	
Acute Condition (e.g., suspected ectopic, acute abdomen, thromboembolic event, hemorrhage)	For acute condition suspected or found at visit or by client report on telephone, **must** notify client of need for immediate medical attention. Note: If hCG is indicated for suspected ectopic, **must** communicate all results to client immediately upon receipt. Any client sent to the emergency room or hospital **must** be followed up. One telephone contact **must** be attempted within 24 hours (72 hours if on a Friday), followed by 1 letter if the client is not reached by phone.
Malignancy (e.g. BI-RADS 5 on mammogram, invasive cancer of vulva or vagina, on endometrial biopsy) **STI/UTI Results** (e.g. positive HSV culture; positive urine culture; GC/CT, trichomonas (if sent to lab), syphilis, Hemophilus ducreyi (chancroid) tests – unless appropriate antibiotic was started presumptively)	Malignancy on Result/Report OR STI/UTI Result ▪ **Must** make 3 attempts to notify, 2 of which **must** be a letter within 14 days of receiving results. If appropriate antibiotic treatment was initiated at visit, only 1 notification attempt required. Letter is preferred. ▪ First attempt **must** be a phone call within 72 hours of receiving result/report. ▪ One reminder required.
VERY SERIOUS **Potential Malignancy, HIV**	Very Serious Condition ▪ For very serious condition, suspected or found at visit, or by client report on telephone, **must** notify client of need for referral at that time.

Condition/Result	Notification Requirements*
(e.g., VIN, VAIN 2-3, BI-RADS 4 on mammogram, breast mass, suspicious adnexal mass)	▪ One reminder required Potential Malignancy/HIV Result ▪ **Must** make 3 attempts at notification, 2 of which **must** be a letter, within 6 weeks of receiving results. ▪ Positive HIV test results should be given in person in all but rare circumstances. If test results cannot be given in person, an explanation to the client, client consent, and client preference of how the test results are agreed to be given **must** be documented in client's record. ▪ One reminder required.
OTHER Other referrals, abnormal test results or findings, unsatisfactory test results, or other follow-up (e.g., VAIN 1, +HSV serology)	Other Findings Requiring Referral ▪ For other conditions found at visit that require a referral, **must** notify client of need for referral at that time. ▪ One reminder required. Abnormal or Unsatisfactory Test Results/Reports ▪ **Must** make 3 attempts at notification, 2 of which **must** be a letter, within 6 weeks of receiving results. ▪ One reminder required.

* When only 1 attempt at notification is required, the attempt may be by phone or a letter. However, if the client is not spoken to directly by phone, a letter **must** be sent. Certified letters are not required, but may be used at the discretion of the affiliate. **Must** notify client per state law/health department requirements when applicable.

8.1.d. Table: Specific Requirements Related to Timing/Types of Client Notification* for Cervical Cancer Screening/Management Results

Result	Notification Requirements
PAP RESULTS	
▪ Pap negative ▪ Pap negative **and** HPV negative ▪ Pap negative / endocervical cells or transformation zone components absent **and** HPV negative or HPV unknown ▪ Pap negative / borderline cellularity or partial air drying **and** HPV negative or HPV unknown	▪ Should notify.

Result	Notification Requirements
▪ Pap negative / endometrial cells present (if endometrial biopsy NOT indicated) **and** HPV negative or HPV unknown	
▪ Pap negative / partially obscuring inflammation or blood **and** HPV negative or HPV unknown	▪ **Must** make 1 written attempt to notify within 6 weeks of receiving result. **Must** create alert or tickler for medical record. ▪ Should remind.
▪ Pap ASC-US **and** HPV negative	▪ **Must** make 1 written attempt to notify within 6 weeks of receiving result. ▪ One reminder required.
▪ Pap negative / specific organism identified **and** HPV negative or HPV unknown ▪ EXCEPTION: There is no need to notify or remind if, at the time of the visit, the client was asymptomatic for BV and/or candida or she was treated for trichomonas, BV, and/or candida. (See below for HPV positive)	▪ **Must** make 1 written attempt to notify within 6 weeks of receiving result unless trichomonas is identified. Three attempts within 14 days are required for trichomonas. ▪ One reminder required.
▪ Unsatisfactory Test ▪ Pap negative **and** HPV positive ▪ Pap negative / partially obscuring inflammation or blood **and** HPV positive ▪ Pap negative / endocervical cells or transformation zone components absent **and** HPV positive ▪ Pap negative / borderline cellularity or partial air drying **and** HPV positive ▪ Pap negative / specific organism identified **and** HPV positive (See above for specific organism requirements.) ▪ Pap negative / endometrial cells present if endometrial biopsy** indicated **and/or** HPV positive ▪ Pap ASC-US **and** HPV positive or HPV unknown ▪ Pap LSIL **and** any HPV result or HPV unknown	▪ **Must** make 3 attempts to notify, 2 of which **must** be a letter, within 6 weeks of receiving result. ▪ One reminder required

Result	Notification Requirements
▪ Pap ASC-H **and** any HPV result or HPV unknown ▪ Pap HSIL **and** any HPV result or HPV unknown ▪ Pap AIS, AGC (all categories), Atypical Endocervical Favor Neoplasia or Favor AIS	
▪ Pap Squamous Cell Carcinoma ▪ Pap Invasive Adenocarcinoma	▪ **Must** make 3 attempts to notify, 2 of which **must** be a letter, within 14 days of receiving results ▪ First attempt **must** be a phone call within 72 hours of receiving result. ▪ One reminder required
POST-COLPOSCOPY	
▪ CIN 1 or LSIL histology ▪ CIN 2,3 or HSIL histology ▪ Adenocarcinoma in Situ	▪ **Must** make 3 attempts to notify client of biopsy results and follow-up plan, 2 of which **must** be a letter, within 6 weeks of receiving results. ▪ One reminder required.
▪ Squamous Cell Carcinoma ▪ Adenocarcinoma	▪ **Must** make 3 attempts to notify of biopsy results and follow-up plan, 2 of which **must** be a letter, within 14 days of receiving results. ▪ First attempt **must** be a phone call within 72 hours of receiving result. ▪ One reminder required.
POST LEEP or CRYOSURGERY	
▪ Squamous Cell Carcinoma ▪ Adenocarcinoma	▪ **Must** make 3 attempts to notify of LEEP results and follow-up plan, 2 of which **must** be a letter, within 14 days of receiving results. ▪ First attempt **must** be a phone call within 72 hours of receiving result. ▪ One reminder required
▪ All other post-LEEP results	▪ **Must** make 3 attempts to notify of LEEP results and follow-up plan, 2 of which **must** be a letter, within 6 weeks of receiving results. ▪ One reminder required.

* When only 1 attempt at notification is required, the attempt may be by phone or a letter. However, if the client is not spoken to directly by phone, a letter **must** be sent. Certified letters are not required, but may be used at the discretion of the affiliate. **Must** notify client per state law/health department requirements when applicable.

** If endometrial biopsy is done within affiliate and biopsy is negative, **must** make 1 attempt to notify of biopsy result.

8.1.3 Continuation of Services When Client Fails to Follow-Up

✓ FYI - Determining the Time-Frame for Client Non-Adherence or Refusal

8.1.e. Table: Continuation of Services for Breast and Pap/Histology Results

Pap/Histology Results	Continuation of Services
PAP RESULTS	
▪ Squamous Cell Carcinoma ▪ Adenocarcinoma in Situ (AIS), Atypical Glandular Cells Favor Neoplasia, Atypical Endocervical Favor Neoplasia, or Favor AIS ▪ Invasive Adenocarcinoma ▪ Atypical Glandular Cells (AGC) with Origin Other than Cervix or Endometrium, for example, Ovarian, Tubal, or Other Origin ▪ Histology Results ▪ Adenocarcinoma ▪ Squamous Cell Carcinoma	If care not received within 30 days of notification, all further affiliate care **must** be discontinued until care is obtained.
All other abnormal Pap/positive HPV Results	During the evaluation process, the client may continue to use all Planned Parenthood services If the client fails to follow up with the required tests and referrals within 90 days other Planned Parenthood services may only be continued at the discretion of the ▪ Medical Director or Program Director for HSIL, ASC-H, AGC, CIN 2,3 ▪ Affiliate clinician for LSIL, ASC-US/HPV+,CIN 1
BREAST RESULTS	
Abnormalities are suspected (not histologically proven malignancy or other strong evidence of malignancy [e.g. BI-RADS 5])	During the evaluation process, the client may continue to use all Planned Parenthood services If the client fails to follow up with the required tests and referrals within 90 days other Planned Parenthood services may only be continued at the discretion of the medical director.

Pap/Histology Results	Continuation of Services
Histologically proven malignancy or other strong evidence of malignancy (e.g. BI-RADS 5)	Client may continue other Planned Parenthood services at the discretion of the medical director or program director. Prior to review, the client may continue services for up to 30 days.

8.2 ADDITIONAL INFORMATION

8.2.a. Table: For Your Information

Section	Topic	Detail
8.1.a.	Recommendations vs. Referrals	When a recommendation is made to obtain a screening test or evaluation outside of the affiliate, there is no need to place this client into the follow-up system. It is the client's choice and responsibility to go for the test. There is no need to attempt to acquire feedback/results. However, if the test result report is returned to the affiliate, the result **must** be reviewed by a licensed healthcare provider, and all abnormal results **must** be followed up appropriately. If the test is normal, it is good practice, but not mandatory, to inform the client. When a referral is made to obtain a diagnostic test or evaluation, the client **must** be placed in the referral follow-up system. Example — Ms. XX, a 45 year old woman with no family history of early heart disease, presents for her well-woman screening visit. She has no complaints, and there are no abnormal findings. She has had a tubal ligation. Based on the periodic table for women ages 40-64, lipid screening is recommended. (Recommendation). On the other hand, Ms. ZZ, another 45 year old woman, presents for her well-woman screening. She has no complaints, and wants to continue her combined hormonal contraception. She is a nonsmoker. Her 50 year-old sister just had a myocardial infarction. Based on her age and family history, she is referred to the lab for lipid screening. (Referral).

Section	Topic	Detail
		Both of these women presented for a routine screening visit. A lipid screen is recommended for one, and the other is referred for lipid testing. Exam finding examples: skin lesions consistent with psoriasis are observed during breast and pelvic exams. The patient does not know what they are. She is advised to consult with her primary care provider or a dermatologist. (Recommendation); A pelvic mass is palpated on pelvic exam of an asymptomatic woman. Ultrasound is ordered. (Referral)
8.1.a.	Supported Referral	Another key strategy for addressing reproductive coercion and IPV as an integral part of reproductive health care is supported referral. The first step in developing supported referral is to connect reproductive health providers with existing support services for IPV in the community. Making this connection is mutually beneficial: ▪ Domestic violence advocates from shelters/advocacy programs are an excellent resource for training and advocacy. ▪ Domestic violence advocates will become more aware of what reproductive health services are available for women experiencing IPV. ▪ Reproductive health care providers will become more familiar with what services for IPV are available locally and have a specific name/person to contact when referring clients. When doing supported referral, the provider may call the shelter or IPV program for a client or have the client call from the clinic. Helping clients link directly with domestic violence advocates from the reproductive health care setting can offer a safer option for clients experiencing abuse. This approach can also increase clients' comfort level when reaching out for assistance and increase the likelihood of following through with referrals. KEY CONSIDERATION: Many staff have never called a local or National Hotline number. It is recommended that all staff call a hotline, explain who they are, and ask what the hotline staff would say if a client of theirs called into clinic. Clinic staff who engaged in this activity reported greater confidence in giving the referral.

Section	Topic	Detail
8.1.a.	Tips for Successful Referrals	▪ Assessment of the client's interest and motivation for using the referral ▪ Familiarity with the referral agencies, their services, and staff ▪ Attempting to contact the agency at the time of the engagement with the client ▪ Providing more than one referral whenever possible ▪ Providing written information on the referral agency including telephone number, address and directions, and the name of a contact person ▪ Providing a way to contact the affiliate for further information or other referrals
8.1.3	Determining the Time-Frame for Client Non-Adherence or Refusal	Interpretation of "90 days from the date the care was to be received" (See above, Client Failure to Adhere to the Advised Follow-up or Referral Plan) may vary somewhat in different settings. If colposcopy appointments, for example, are immediately available to clients in your affiliate or in the community, the 90 days would begin near the time of notification of the abnormal Pap test result. If the availability of services is very limited and client **must** wait 2 to 3 months to get an appointment, the 90-day period for obtaining the care would begin later. Affiliates should make the determination and have protocols for client communication that reflect the realities of their environment.

8.2.b. Table: References

Section	Reference
Throughout	American College of Obstetricians and Gynecologists. Tracking and reminder systems. ACOG Committee Opinion Number 329. Obstet Gynecol 2006;107:745-7.

8.2.c. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ PPFA Guidelines for Electronic Communications with Patients ✓ PPFA EHR Guide Team Guidelines ✓ Sample Phone Scripts for Notification of Test Results	
Training	**CAL Course** How to Simplify Your Follow-Up	

Type	Resource	Location
Sample Forms	Sample Letter Pap Notification Sample Letter Pap Notification Needs Tests Sample Letter Notification STI Sample Letter Reminder Sample Letter Test Results – Findings Notification	Part 3, Chapter 01_08

PART 2: CLINICAL

June 2014

TABLE OF CONTENTS

PART 2: CLINICAL

June 2014

TABLE OF CONTENTS

PART 2: CLINICAL

June 2014

TABLE OF CONTENTS

CHAPTER 1: ABORTION

Revised June 2014

Chapter 1 Table of Contents

1.1 MEDICATION ABORTION

1.1.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

1.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	Should give	**Must** offer
CI Abortion Options			●		
CI How to Take your Abortion Pills buccal			●		
CI How to Take your Abortion Pills oral			●		
CI on all available contraceptive methods				●	
CI Rho(D) Immune Globulin			●		
CIIC Reaspiration after In-Clinic Abortion/Aspiration after Using the Abortion Pill		●	●		
CIIC Second Dose Of Misoprostol		●	●		
CIIC Using the Abortion Pill		●	●		
Danco Laboratories Mifeprex Medication Guide			●		
Danco Laboratories Mifeprex Patient Agreement		●			●
How Much am I bleeding?				●	
Illustration How to Take your Pills				●	
Release When Test/Service/Consultation Will Not Be Obtained As Recommended		Once			
Request for Surgery or Special Procedures		●			●
When to Call Us			●		
Written information about any medication dispensed (package insert may be used)			●		

Important Information – Informed Consent and Abortion

Special care **must** be taken to ensure that women considering abortion are not subjected to duress or to coercion of any kind and that all such decisions are reached on the basis of full information and free discussion. Information that the client needs to make an informed decision **must** be presented in an objective and non-judgmental manner and in language and terminology that she can best understand. She **must** be given the

- opportunity to ask questions and get answers at any time during the process
- option of being accompanied during the counseling session by a person of her own choosing, who also is free to ask questions
- option of deciding not to have the procedure without penalty or denial of other services

1.1.2 Contraindications and Special Conditions – Medication Abortion

I. Table 1.1.b. **must** be followed when making decisions about client selection.

1.1.b. Table: Contraindications and Special Conditions – Medication Abortion

Legend	
A	Contraindications — Medication abortion **must not** be provided
B	Special Conditions Requiring Special Evaluation and Management — Conditions that may complicate medication abortion require management by affiliate protocols or consultation with the program director or medical director before mifepristone can be administered.

Condition	A	B
Adrenal failure – chronic	●	
Allergy to mifepristone, misoprostol or other prostaglandins	●	
Anemia — hct < 30% or hgb < 10 mg/dl		●
Cardiac disease		
▪ AHA Class 3 or worse when not pregnant	●	
▪ Chronic cardiovascular disease		●
Client factors		
▪ Unwilling to have an aspiration abortion	●	
▪ Cannot follow up to confirm the pregnancy was terminated	●	

Condition	A	B
▪ Does not have access to a telephone, emergency medical care (emergency treatment of incomplete abortion, blood transfusion or emergency resuscitation), and transportation	●	
Condition that would preclude aspiration procedure in an outpatient setting*		●
Diabetes mellitus – insulin dependent		●
Ectopic pregnancy – known or suspected**	●	
Gestational age – beyond limits of available regimen	●	
Hemorrhagic disorder	●	
Hypertension – chronic		●
IUC in place that will not be removed	●	
Liver Disease+		
▪ Acute hepatitis	●	
▪ Cirrhosis	●	
Medications		
▪ Anticoagulants	●	
▪ Corticosteroid – long-term systemic use ✓ FYI - Use of Steroids & Mifepristone	●	
Molar pregnancy – suspected	●	
Porphyria – inherited	●	
Renal failure	●	
Respiratory disease – chronic		●

* Medication abortion may be provided if the affiliate has a staff physician or clinician with the capacity to perform an aspiration in a hospital (approved for Level III GYN services) or a referral agreement with a physician with the capacity to perform an aspiration in a hospital.

**based upon signs, symptoms, serial hCG measurements and transvaginal ultrasound or an adnexal mass suspicious for ectopic pregnancy

+Clients with chronic hepatitis or hepatitis carriers are not restricted from having a medication abortion.

1.1.3 Medical Screening and Evaluation

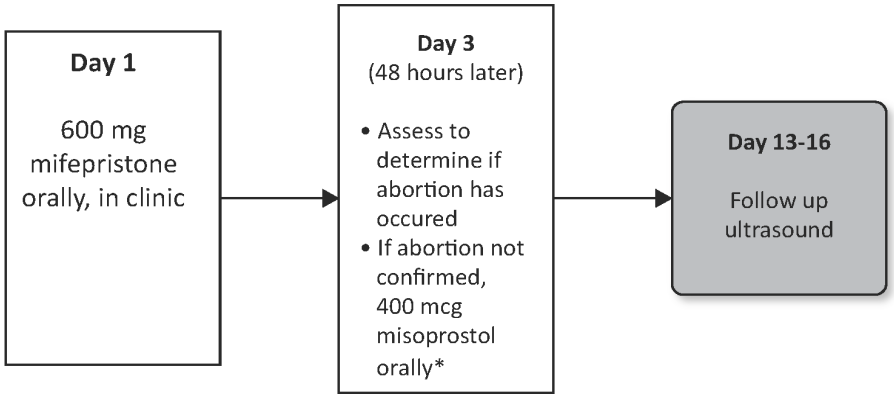
1.1.c. Table: Medical Screening and Evaluation – Medication Abortion

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Must include ▪ LMP ▪ Screening to identify possible contraindications and/or special conditions	**Must** include ▪ BP ▪ Bimanual exam when indicated (e.g., vaginal bleeding or abdominal/pelvic pain) ▪ Additional examination as indicated by history or laboratory findings	**Must** include ▪ Hgb or hct ▪ Rh typing — unless client reports she is Rh-negative or written documentation of Rh status is available. ▪ GC/CT Testing per CDC STD Treatment Guidelines ✓ CDC STD Treatment Guidelines ▪ Ultrasound confirmation of gestational age ▪ Other tests as indicated

1.1.4 Abortion Procedure

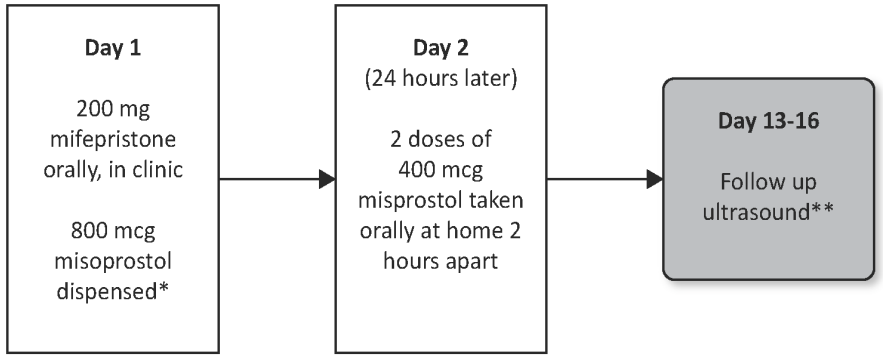
I. Medication Regimens

1.1.d. Algorithm: FDA approved regimen, up to and including 49 days



*If no bleeding after first dose, client may take additional 400 mcg dose within 48 hours

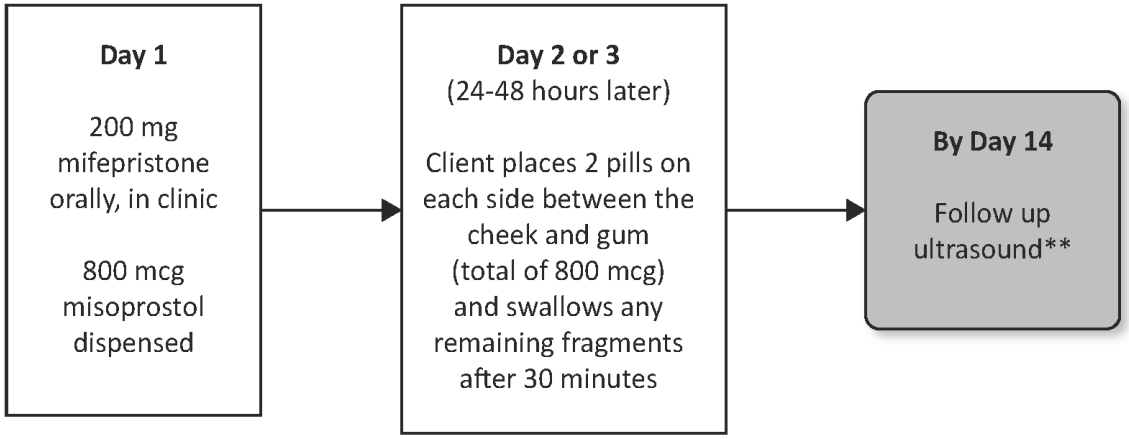
1.1.e. Algorithm: Evidence-based oral regimen, up to and including 49 days



*Antiemetic **must** be offered/prescribed

**Unless following with serial hCG

1.1.f. Algorithm: Evidence-based buccal regimen, up to and including 63 days*



*Affiliates may request a waiver to provide this regimen to 70 days gestation.
**Unless following with serial hCG

II. Antibiotic Prophylaxis
   A. All clients undergoing medication abortion **must** be treated with antibiotics using one of the following regimens consistent with the principles of prophylaxis
      1. Doxycycline 200 mg PO once
      2. Azithromycin 500 mg PO once
      3. Metronidazole 500 mg PO once
   B. Each regimen is a single-dose to be taken at the time of mifepristone, time of misoprostol, or at any time between those two medications.

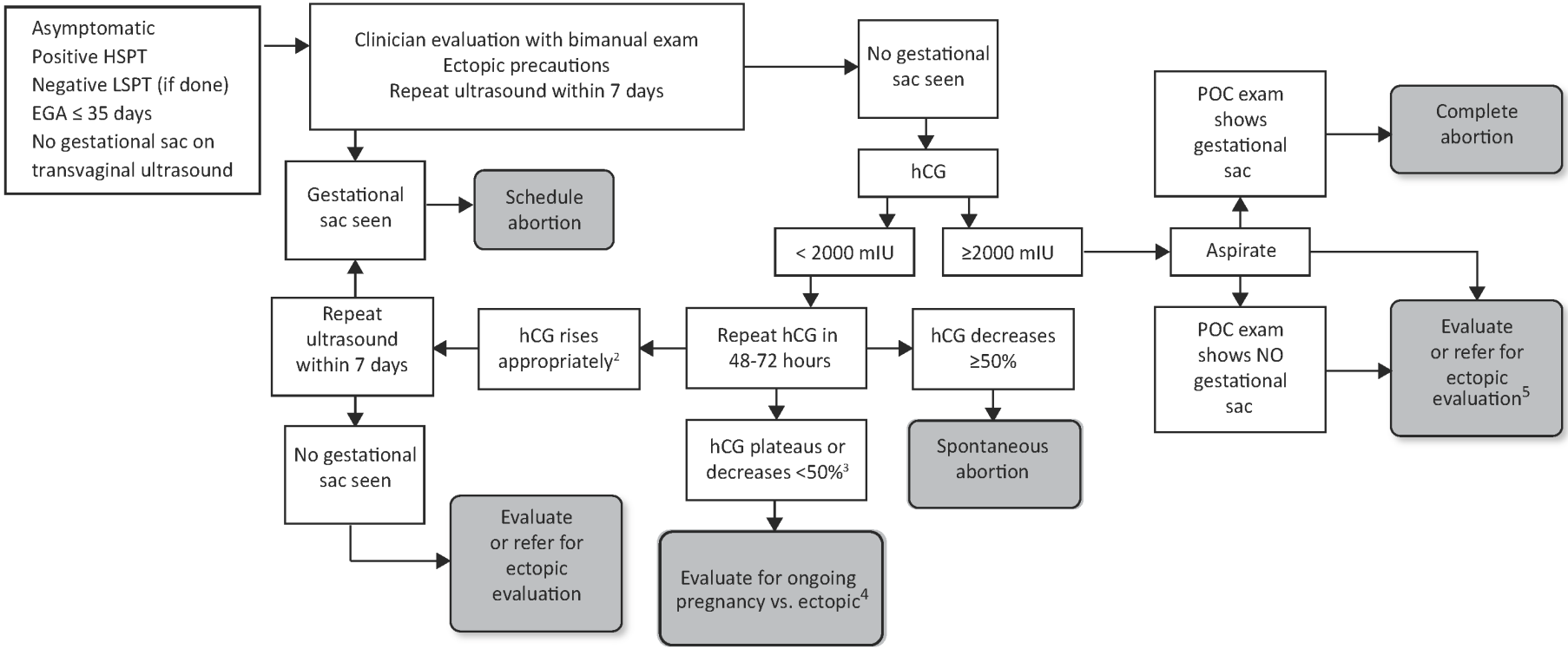
III. Rho(D) Immune Globulin
   A. If Rh-negative, Rho(D) immune globulin (at least 50 mcg) **must** be given the same day as mifepristone or within 72 hours of mifepristone administration.

1.1.5 Management of Pregnancies of Unknown Location or Status

Clients may present requesting medication abortion before intrauterine pregnancy has been confirmed. Medication abortion may still be provided using one of the management options listed below.

I. Management options for clients ≤ 35 days estimated gestational age

1.1.g. Algorithm: Confirming Diagnosis of Intrauterine Pregnancy Before Initiating Medication Abortion



[1]When hCG ≥ 2000 mIU and no gestational sac seen on ultrasound:

- may consider repeat ultrasound by more experienced provider
- if client history suspicious for spontaneous abortion, and client asymptomatic, may follow with repeat hCG (which **must** decrease ≥ 50%)

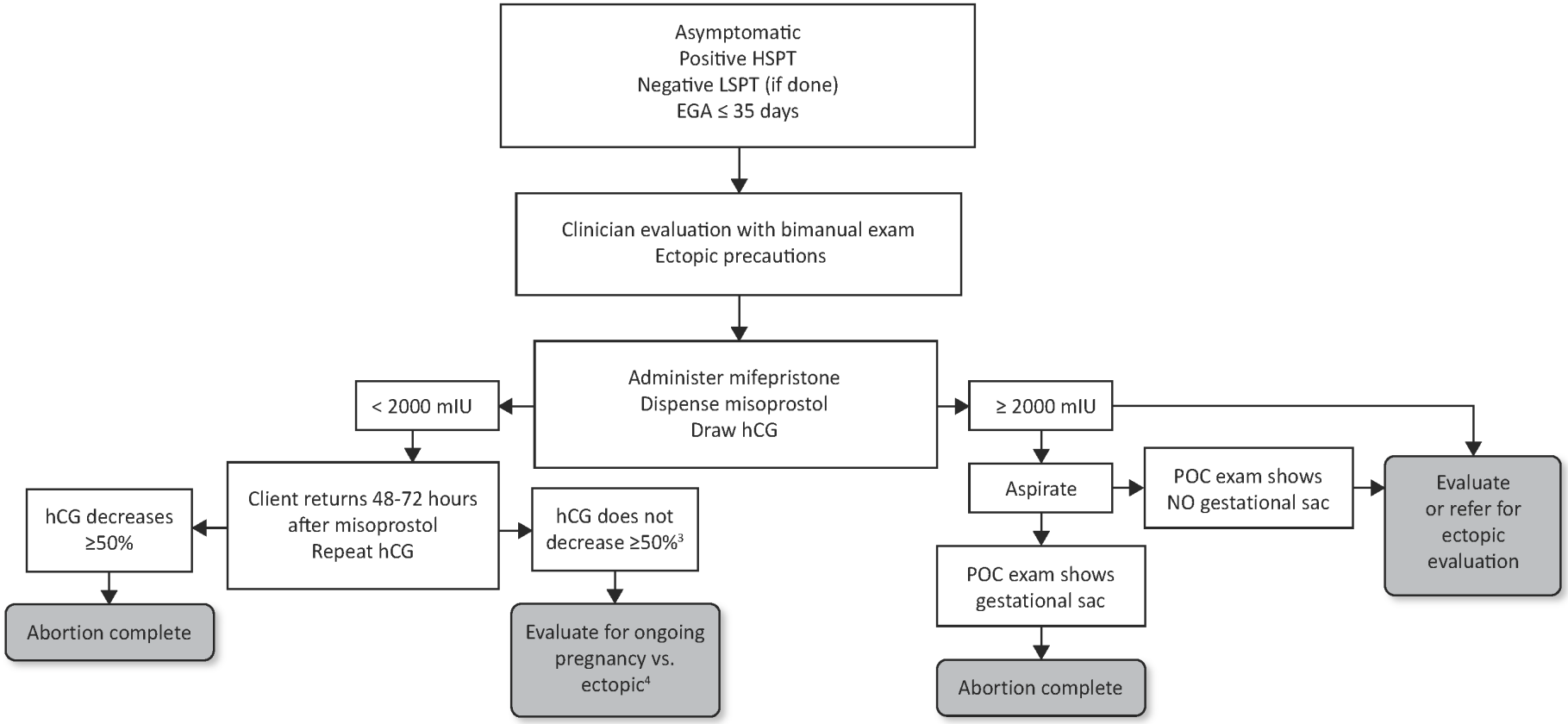
[2]In a normal intrauterine pregnancy, hCG should rise by 50% in 48 hours or 100% in 72 hrs

[3]In select asymptomatic clients, may follow 3rd hCG with physician consult

[4]See Chapter 13.5 FYI — Evaluating for Ongoing Pregnancy vs. Ectopic

[5]Follow hCG +/- send tissue to pathology. Refer out for ectopic if 2nd hCG does not decrease by ≥50%

1.1.h. Algorithm: Initiate Medication Abortion While Simultaneously Determining the Location of Pregnancy



[1]When hCG ≥ 2000 mIU and no gestational sac seen on ultrasound

- May consider repeat ultrasound by a more experienced provider
- If client history suggests completed medication abortion, may follow with a repeat hCG (which **must** decrease by ≥ 50%)

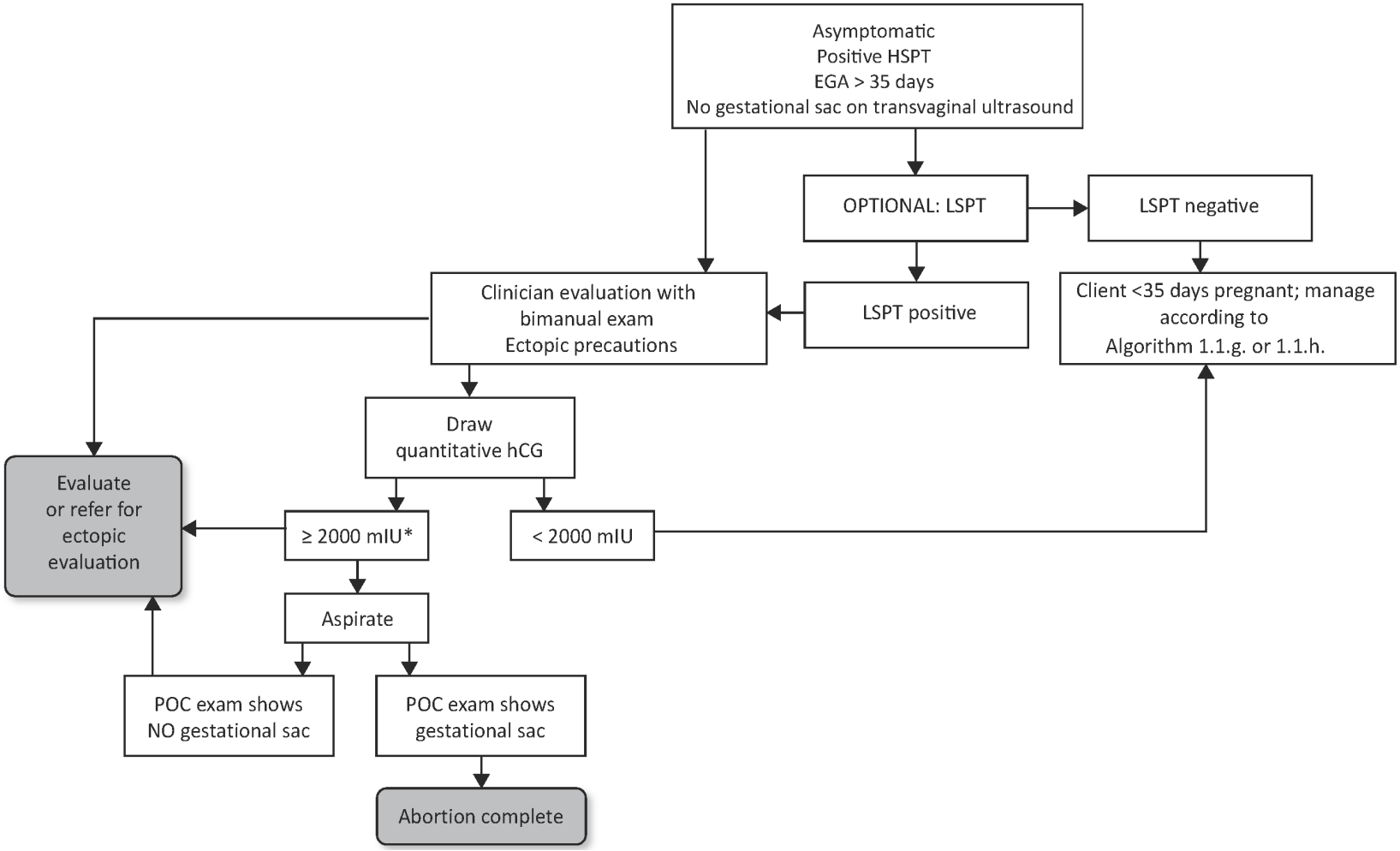
[2]If client has little to no bleeding after misoprostol, repeat ultrasound if hCG expected to be ≥ 2000 mIU

[3]In select asymptomatic clients, may follow 3rd hCG with physician consult

[4]See Chapter 13.5 FYI — Evaluating for Ongoing Pregnancy vs. Ectopic

II. Management for clients > 35 days estimated gestational age

1.1.i. Algorithm: Management of clients with EGA > 35 days when no gestational sac is seen on transvaginal ultrasound



*When hCG ≥ 2000 mIU and no gestational sac seen on ultrasound

- May consider repeat ultrasound by a more experienced provider
- If client history suggests complete abortion, may follow with repeat hCG in 48-72 hours (which **must** decrease by ≥ 50%)

1.1.6 Management of Pain, Nausea, and Bleeding

I. Analgesia
   A. It is suggested that all clients be given or prescribed analgesia (without anticoagulant properties) when the abortion agent is given, e.g., an NSAID and a prescription for a narcotic analgesic.
II. Antiemetics — use as needed.
   A. If the client vomits 15 minutes or more after taking mifepristone, she has probably absorbed enough to be effective.
   B. Many affiliates routinely provide an antiemetic with instructions to take 30 minutes before misoprostol ingestion.
III. Uterotonics
   A. Ergotamine compounds may be given any time after misoprostol has been administered. The standard dose of methylergonovine is 0.2 mg PO 3-4 times a day for 1 to 2 days. Methylergonovine may be useful for problematic bleeding. The client should be informed that this may cause uncomfortable uterine contractions. Ibuprofen may be taken with methylergonovine.
   B. Misoprostol — a second dose of 800 mcg can be given. Cramping and bleeding is expected to be less than following the initial dose.

1.1.7 Follow-up

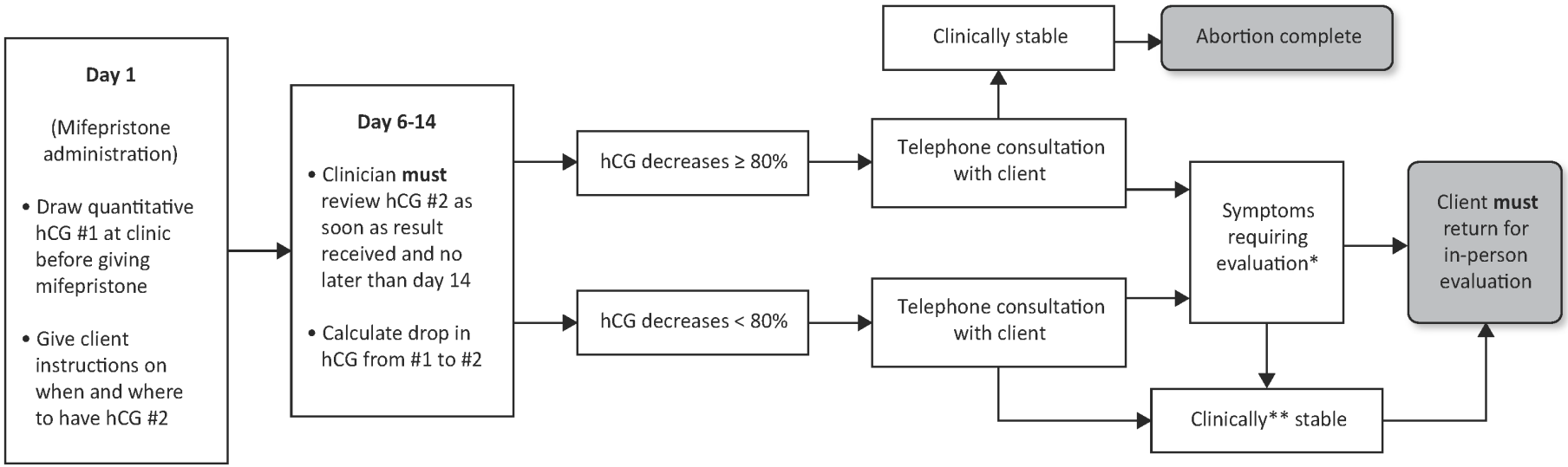
I. **Must** confirm abortion completion in one of two ways
   A. In-person follow-up visit with ultrasound evaluation
      1. If there is an ongoing, viable pregnancy — 2 options:
         a. Suction procedure

            OR

         b. Second dose of misoprostol — EGA **must** be ≤ 63 days
      2. If there is a persistent gestational sac that is not growing in size or an embryo without cardiac activity, the client may
         a. Wait until up to 4 weeks post mifepristone for completion of procedure.
         b. Repeat misoprostol and wait up to 4 weeks as noted above.
         c. Undergo suction procedure.
   B. hCG follow up
      1. Client **must**
         a. Have a documented intrauterine pregnancy
         b. Be aware that this option may carry additional expenses
         c. Have her blood drawn for a repeat quantitative hCG on or around 1 week from her initial visit

d. Be available for a phone call within 2 weeks of the date mifepristone given
e. Follow–up in the health center if requested by a clinician for any reason or doubt regarding complications, complaints or non-compliance

1.1.j. Algorithm: hCG Follow-up After Medication Abortion



*Symptoms requiring evaluation include problematic bleeding or signs of hemodynamic instability or infection.
**If hCG #2 is very close to, but not quite 80% less, a physician may determine if client can be followed with additional hCG.

2. Management of an abnormal hCG follow-up test or a symptomatic client - if client has either of the following she **must** return for evaluation
   a. hCG results indicate ongoing pregnancy or do not drop as expected
   b. Persistent or abnormal bleeding pattern

1.1.8 Contraception After Medication Abortion

I. Information regarding all methods of contraception should be offered, and, if requested, a method **must** be provided or referrals given for that method.
II. Providers are encouraged to dispense contraception on Day 1 or to encourage a return visit for initiation of DMPA or a LARC method as soon as possible.
III. EC, a prescription for EC, and/or information describing how EC can be obtained should be given to each client.
IV. Initiate contraception according to the following
    A. CHC
    B. DMPA
    C. Implant
    D. IUC
    E. POPs
    F. Prescription barriers
    G. Non-prescription Methods

✓ See Chapter 6 Contraception — Reversible

1.1.9 Referral

I. Abortion Referrals — Referrals **must** be provided if the client is not eligible for care at the affiliate. The list of referral providers **must** include providers of abortion services at different gestational ages as well as information about anesthesia options. (See www.plannedparenthood.org or call National Abortion Hotline at 1-800-772-9100.)

1.2 SURGICAL ABORTION

1.2.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

1.2.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	Should give	**Must** offer
CI Abortion Options			●		
CI on all available contraceptive methods				●	
CI Rho(D) Immune Globulin			●		
CI Taking Care Of Yourself After An In-Clinic Abortion			●		
CI When A Small Amount Of Pregnancy Tissue Was Seen			●		
CIIC Cervical Prep with Dilators or Miso		●	●		
CIIC Digoxin		●	●		
CIIC In-Clinic Abortion		●	●		
CIIC Reaspiration after In-Clinic Abortion/Aspiration after Using the Abortion Pill		●	●		
CIIC When you Decide to Stop Your In-Clinic Abortion		●	●		
Release When Test/Service/Consultation Will Not Be Obtained As Recommended		Once			
Request for Surgery or Special Procedures		●			●
Written information about any medication dispensed (package insert may be used)			●		

Important Information – Informed Consent and Abortion

Special care **must** be taken to ensure that women considering abortion are not subjected to duress or to coercion of any kind and that all such decisions are reached on the basis of full information and free discussion. Information that the client needs to make an informed decision **must** be presented in an objective and non-judgmental manner and in language and terminology that she can best understand. She **must** be given the

- opportunity to ask questions and get answers at any time during the process
- option of being accompanied during the education session by a person of her own choosing, who also is free to ask questions
- option of deciding not to have the procedure without penalty or denial of other services

1.2.2 Contraindications and Special Conditions – Surgical Abortion

I. Table 1.2.b. **must** be followed when making decisions about client selection.

1.2.b. Table: Contraindications and Special Conditions – Surgical Abortion

Legend	
A	**Musts**/Shoulds
B	Contraindications — Surgical abortion **must not** be provided
C	Special Conditions Requiring Special Evaluation and Management — Conditions that may complicate surgery require management by affiliate protocols or consultation with the clinician performing the procedure.

Condition	A	B	C
Anemia — hct < 30% or hgb < 10 gm/dl	**Must** evaluate and determine the appropriate management or referral		●
Asthma	All women who report a history of asthma should be instructed to ▪ Take regularly scheduled doses of asthma medication before the procedure. ▪ Bring their asthma medication with them for the procedure.		●
Cervicitis – mucopurulent	▪ Assume gonorrhea/chlamydia. ✓ Initiate treatment per CDC guidelines before procedure. ▪ Complete treatment post-procedure as necessary.		●

Condition	A	B	C
Diabetes ✓ See sample protocol in Part 3: Required Documents and Additional Resources	All women who report a history of diabetes should be ▪ Encouraged to see their regular diabetes care provider prior to the appointment. ▪ Scheduled as the first client of the day.		●
Fetal demise – second trimester ✓ FYI - Interpretation of Laboratory Results for Evaluation of Second Trimester Fetal Demise	▪ If indicated, a DIC panel (should consist of CBC with platelet count, PT/PTT, fibrinogen and D-dimers).[R5, R6, R7]		●
Gestational age – exceeds limits of affiliate program		●	
Hemorrhagic disorder			●
HIV/AIDS			●
Hydatidiform mole			
▪ ≥ 14 week size	Client **must** be referred out of the affiliate for management unless affiliate provides Level III GYN services.	●	
▪ < 14 week size	If procedure is performed at the affiliate, a quantitative hCG **must** be sent to lab and the results **must** be provided to the provider/health center doing the follow-up. ✓ See Chapter 13.3 Hydatidiform Mole		●
Illness/Condition – any condition judged to be so severe that the procedure would pose significant or life threatening risks (i.e., uncontrolled diabetes, with suspicion of diabetic ketoacidosis or insulin shock; hypertension suggestive of imminent stroke, etc.)		●	
Infective endocarditis – at risk for	**Must** follow the current recommendations of the American Heart Association (AHA). ✓ AHA: Prevention of Infective Endocarditis		●

Condition	A	B	C
Intolerance of			
▪ Available sedation and analgesia options		●	
▪ Insertion of osmotic cervical dilators, if required	**Must** evaluate and determine the appropriate management or referral.		●
Medications			
▪ Anticoagulants			●
Obesity – morbid	**Must** evaluate and determine appropriate management or referral.		●
Placenta previa in unscarred uterus	May have an outpatient D&E by a surgeon experienced in these types of procedures as determined by the medical director or program director.		●
Seizure disorder — poorly controlled	**Must** coordinate with physician and consider appropriate setting for procedure.		●
Uterine conditions			
▪ Scarred	▪ All women ≥ 14 weeks gestation with a scarred uterus **must** have the location of the placenta documented. ▪ All women ≥ 14 weeks gestation with a scarred uterus and a placenta previa and/or a placenta overlying the incision site **must** be evaluated for placenta accreta/increta/percreta. ▪ Doppler (ultrasound) studies and/or MRI are sufficient for diagnosing an invasive placenta in a woman ≥ 14 weeks gestation. Doppler (ultrasound) and/or MRI can be performed at the affiliate with the appropriate equipment, training and skill to do so. ▪ Women with a reassuring evaluation may have an outpatient D&E by surgeon experienced in these types of procedures. Experience is determined by the medical director or program director.		●
▪ Infection	▪ Procedure **must** be provided with appropriate antibiotic coverage.		●

1.2.3 Medical Screening and Evaluation

1.2.c. Table: Medical Screening and Evaluation – Surgical Abortion

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Must include ▪ LMP ▪ Screening to identify possible contraindications and/or special conditions ▪ Allergies to medications, antiseptic solutions, and latex For digoxin use ▪ Assessment of family history for sudden cardiac death in young healthy family member or strong family history of cardiac arrhythmias	**Must** include ▪ Temperature, if symptomatic of infection ▪ BP ▪ Visual exam of the vulva, vagina, and cervix ▪ Bimanual exam, including estimation of uterine size and position and palpation of the adnexa ▪ Abdominal palpation (not required when ultrasound and bimanual exam are consistent with gestational age) ▪ Additional examination as indicated by history or laboratory findings For digoxin use ▪ Cardiac auscultation	**Must** include ▪ Urine or blood pregnancy test performed at affiliate within 7 days, unless ultrasound documented an intrauterine pregnancy ▪ Hgb or Hct ▪ Rh typing — unless client reports she is Rh-negative or written documentation of Rh status is available. ▪ GC/CT testing per CDC STD Treatment Guidelines ✓ CDC STD Treatment Guidelines ▪ Ultrasound, if indicated ▪ Other tests as indicated ✓ FYI - Bacterial Vaginosis and Abortion

1.2.4 Pre-abortion Procedures

I. Cervical Preparation

✓ FYI — Guidelines on Cervical Dilation/Preparation Prior to Surgical Abortion

A. Prior to first trimester abortion

1. For early abortion, the use of osmotic cervical dilator(s) and/or misoprostol is optional.
2. Misoprostol should be considered for all adolescents.
3. Misoprostol is recommended for all women at 12 to 14 weeks gestation.
4. Misoprostol is strongly recommended for adolescents at 12 to 14 weeks gestation.
5. Optimal regimens include 400 mcg vaginally, buccally, or sublingually 2 to 4 hours prior to procedure.

B. Prior to mid-trimester abortion
   1. Osmotic cervical dilator(s) and/or misoprostol **must** be used unless the cervix permits insertion of an appropriately sized cannula with minimal dilation.
   2. Osmotic dilators alone
      a. The number of dilators inserted and the number of dilators removed **must** be noted on the chart.
      b. When dilator placement and D&E are to be performed on the same day, cervical preparation with Dilapan-S™or Lamicel® is preferred over laminaria tents
   3. Misoprostol alone
      a. Buccal misoprostol 400-800 mcg alone may be used for procedures <16 weeks gestation; no time interval from administration of misoprostol to D& E is specified because there is variability in practice and no guidance from data to suggest an appropriate interval range.
      b. Misoprostol alone may be used for abortion > 16 weeks gestation only after obtaining a waiver from Medical Services.
   4. Misoprostol as an adjunct to osmotic dilators
      a. Not recommended before 16 weeks gestation but may be considered at later gestational ages.
   5. Misoprostol may be given prior to D&E to women with a prior cesarean delivery since uterine rupture or scar dehiscence occurs rarely in this setting.

C. Clients who have been given misoprostol for cervical preparation **must** not leave the health center so they may be observed by staff in the event they experience any complications.

D. If a client decides to stop an abortion procedure after receiving misoprostol or after the insertion of dilators, the client **must** be instructed to start prenatal vitamins and seek prenatal care as soon as possible

II. Feticide

A. Digoxin may be used for pregnancy terminations at ≥ 18 weeks gestation.

B. Table 1.2.d. **must** be followed when making decisions about client selection.

✓ FYI – Digoxin

1.2.d. Table: Contraindications and Special Conditions for Digoxin

Legend	
A	**Musts**/Shoulds
B	Contraindications — Digoxin **must not** be provided
C	Special Conditions Requiring Special Evaluation and Management — Conditions that may complicate digoxin use require management by affiliate protocols or consultation with the clinician performing the procedure

Condition	A	B	C
Allergies			
▪ Digoxin		●	
Bleeding disorder - known		●	
Cardiac abnormalities			
▪ Heart rate or rhythm irregularities found on physical exam	Should consider EKG and cardiology consult to rule out contraindications		●
▪ Ventricular tachycardia or fibrillation; idiopathic hypertrophic subaortic stenosis; constrictive pericarditis; amyloid disease; second- or third-degree heart block (except in patients with a functioning artificial pacemaker); Wolff-Parkinson-White syndrome		●	
▪ Arrhythmias – positive personal history	Should refer for evaluation. May delay until after procedure.		●
▪ Murmur that radiates to the carotids (especially if the murmur is louder standing than supine)	**Must** refer for cardiac evaluation before the abortion procedure.		●
Digoxin toxicity – history of		●	
Gestational age < 18 weeks gestation	**Must** obtain written approval from PPFA Medical Services	●	
Hypersensitivities			
▪ Digoxin or any component of the formulation		●	
▪ Cardiac glycosides		●	

Condition	A	B	C
Medications – concurrent use of digoxin or medications that may reduce the clearance of digoxin (such as quinine/quinidine, plaquenil, verapamil, flecainide, amiloride, amiodarone, propafenone, cyclosporine, nifedipine, diltiazem or aldomet)		●	
Obesity – which would make the procedure technically difficult			●
Renal failure – chronic		●	

C. Digoxin Administration

1. Laminaria are usually placed before digoxin is administered eliminating the possibility of giving digoxin and subsequently not being able to insert laminaria.
2. Both clinician preference and route of administration (intraamniotic or intrafetal) will determine the timing of digoxin administration. In clinical practice, this varies from about 24 hours to 30 minutes prior to the procedure. As a general guideline
   a. Intracardiac administration works immediately, up to 30 minutes post injection;
   b. Intrafetal administration from 1 to 2 hours and
   c. Intraamniotic administration from 3 to 24 hours
3. Ibuprofen or other pain medication may be offered pre or post procedure.
4. Draw 1 milligram (mg) digoxin through a filtered syringe. Change to a 22-gauge spinal needle or needle of sufficient gauge and length to be used for the injection.
5. In the case of multiple gestations, administer 1 mg digoxin into each amniotic sac or fetus, not to exceed a total of 2 mg.
6. Prepare the site of needle placement using antiseptic solution. Use aseptic technique during the injection.
7. Needle placement under ultrasound guidance is required.
8. It is acceptable to traverse an anterior placenta.
9. For intraamniotic placement — Confirm correct needle placement by aspiration of a few milliliters of clear amniotic fluid. If bloody fluid is aspirated, reposition needle until amniotic fluid is obtained.
10. If fetal demise is not induced after the first injection, a second injection of 1 mg digoxin or a maximum of 2 mg may be given at the provider's discretion.

III. IV Access — IV access should be maintained for clients 14 to 15 6/7 weeks gestation (heparin lock, butterfly, etc.). IV access **must** be maintained for clients ≥ 16 0/7 weeks gestation until the client's condition is deemed stable in recovery area.

IV. Infection Prevention

✓ FYI – Cleansing the Vagina

A. Antibiotic Prophylaxis
   1. All clients undergoing surgical abortion **must** be treated with antibiotics using one of the following, single-dose regimens consistent with the principles of prophylaxis
      a. Doxycycline 200 mg PO once
      b. Azithromycin 500 mg PO once
      c. Metronidazole 500 mg PO once
   2. First trimester
      a. Prophylactic antibiotics should be given preoperatively for maximal effect at the lowest risk of adverse reactions.
      b. Initiation of antibiotics after induced abortion is unlikely to be beneficial.
   3. Second trimester
      a. Antibiotics for infection prophylaxis for second trimester abortion should be given at the time of the D&E.
      b. Administration is permissible within the 24 hours prior to the start of surgery.
      c. When giving a single dose at the time of osmotic dilator placement, for instance, consideration should be given to using an antibiotic with a longer half-life, such as azithromycin.
      d. When antibiotics for infection prophylaxis are given > 24 hours before the procedure, as in the case of multiple day osmotic dilator placements, or a client who fails to return as scheduled for the procedure, affiliates should consider repeat antibiotic dosing at the time of procedure.

V. Rho(D) Immune Globulin

A. If Rh-negative, give Rho(D) immune globulin. If digoxin is used, give Rho(D) immune globulin the same day or within 72 hours of the digoxin injection.
   1. Up to 12 6/7 weeks gestation: 50 micrograms IM
   2. ≥ 13.0 weeks gestation: 300 micrograms IM

VI. Uterotonic Medications

A. Uterotonic drugs, such as methylergonovine, may be given immediately after abortion to prevent hemorrhage. Vasopressin added to the paracervical block may also decrease the amount of intraoperative and postoperative bleeding, especially with midtrimester abortion procedures.

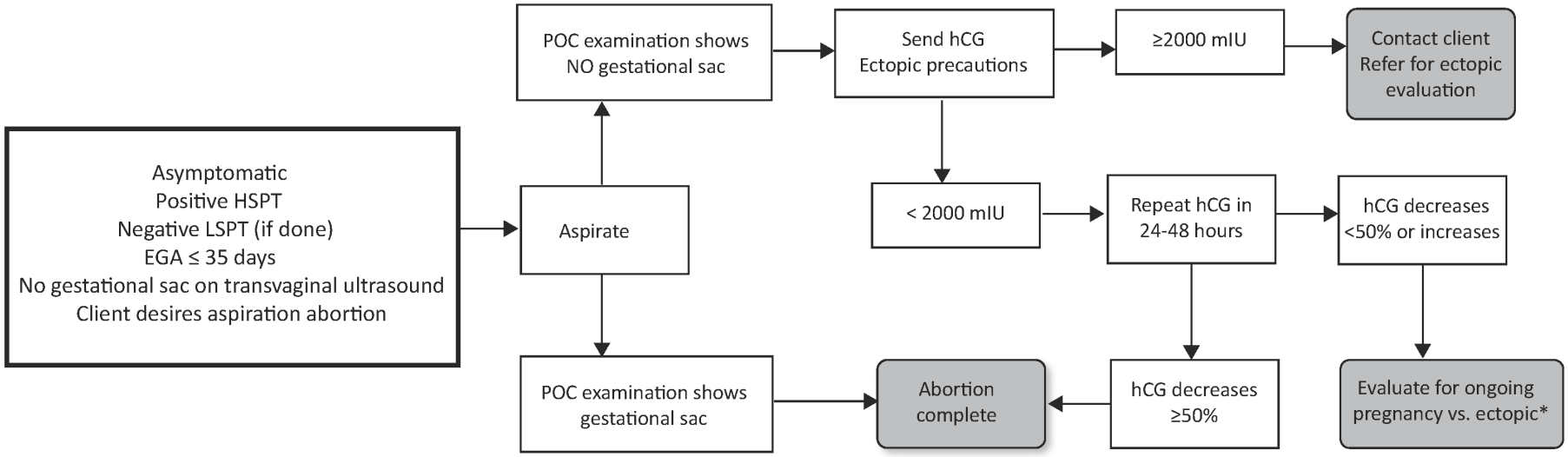
1.2.5 Abortion Procedure

I. Types of Procedures

A. Very Early Abortion (VEA) (positive pregnancy test up to 6 weeks LMP)

1. **Must** manage according to Algorithm 1.2.e – Very Early Abortion.

1.2.e. Algorithm: Very Early Abortion



*See Chapter 13.5 FYI — Evaluating for Ongoing Pregnancy vs. Ectopic

B. First-Trimester Abortion (through 13 6/7 weeks from Day 1 of LMP) performed using either manual vacuum aspiration or electromechanical suction.

C. Mid-trimester abortion **must** be performed in a manner that complies with the federal Partial Birth Abortion Ban Act of 2003 (the "federal abortion ban").

1.2.6 Post-Procedure Management

I. Tissue Evaluation

A. Gross examination of all tissue specimens **must** be performed by the clinician who performed the procedure or by clinic personnel with special training and clinician supervision in the performance of this task. Tissue evaluation is considered to be complete if all of the following occur:

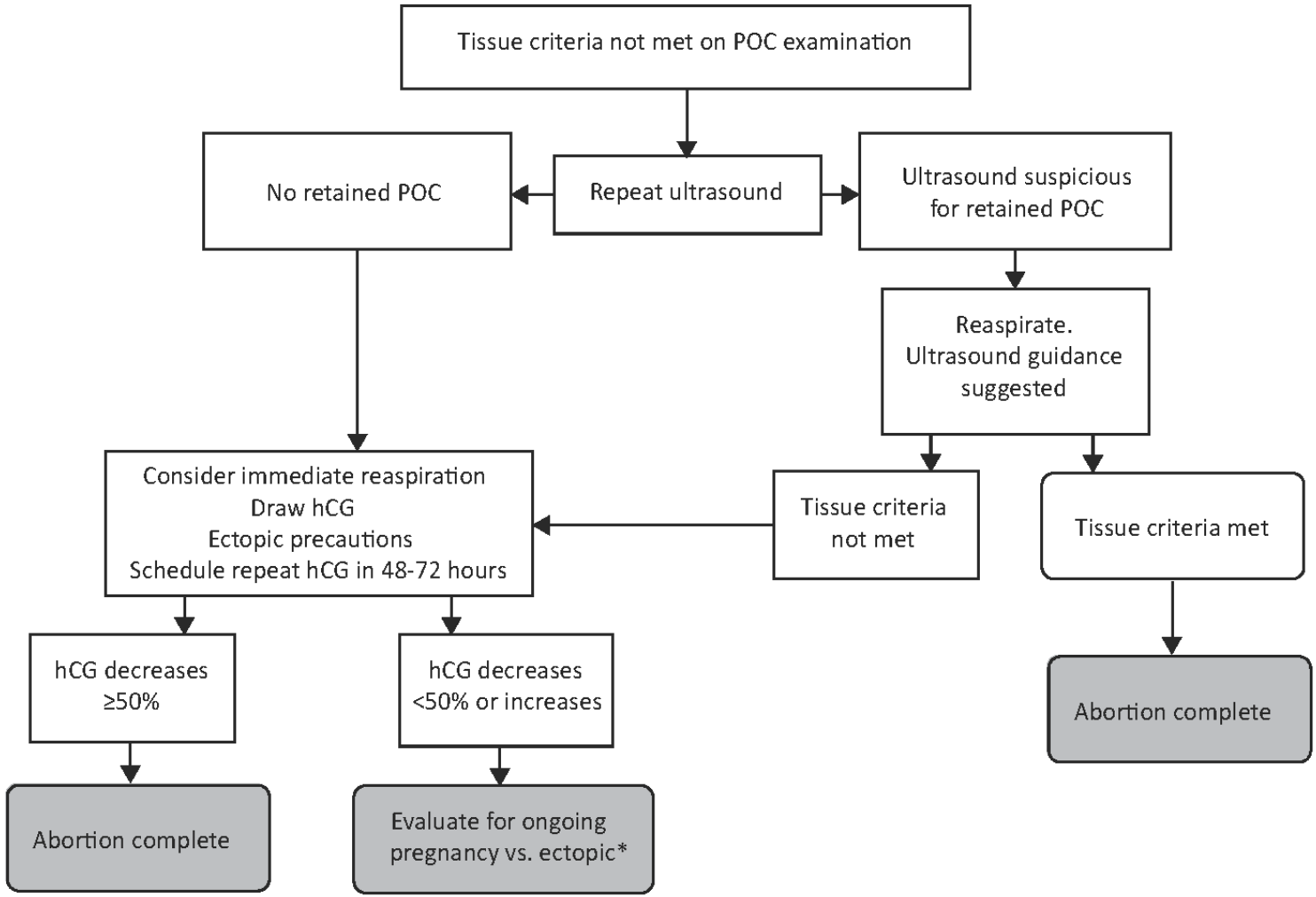
1. Villi and membranes are positively identified.
2. In pregnancies of 10 to 13 weeks gestation, fetal parts are positively identified.
3. In pregnancies ≥ 13 weeks gestation, all fetal parts **must** be accounted for, i.e., calvarium, spine, and four extremities.

B. If adequate placental or fetal tissue is not readily identifiable, the tissue **must** be examined by flotation in water or vinegar and inspected, with back lighting preferred. Tissue examination should be done while the client is still in the procedure room, and **must** be done before the client leaves the facility. If adequate tissue is not identified, the clinician performing the abortion **must** be notified immediately.

C. **Must** follow Algorithm 1.2.f. Tissue Criteria Not Met After Aspiration, a high alert management plan designed to exclude the diagnoses of ectopic pregnancy or continuing intrauterine pregnancy when tissue criteria are not met.

✓ FYI - Examination of Products of Conception After Surgical Abortion

1.2.f. Algorithm: Tissue Criteria Not Met After Aspiration



*See Chapter 13.5 FYI — Evaluating for Ongoing Pregnancy vs. Ectopic

D. Confirming Complete Abortion in Special Circumstances - in cases of known multiple gestation or known uterine anomalies ≤ 10 weeks gestation, **must** confirm complete abortion by
   1. Identification of 2 or more separate embryos or fetal parts
      OR
   2. Use of intra or post-operative ultrasound
      OR
   3. Follow-up visit involving ultrasound or hCG to confirm complete abortion

II. Client Discharge Criteria
   A. For recovery area care and discharge criteria, see Chapter 17 Recovery Area Care**.**
   B. Before leaving, the client **must** receive and understand **postoperative instructions.**

1.2.7 Follow-up

I. Mandatory follow-up visits - not recommended unless there is a specific indication. Indications for such a visit include, but are not limited to
   A. Suspected ongoing pregnancy
   B. Suspected incomplete abortion
   C. Suspected ectopic gestation

II. If the client returns for follow-up
   A. The visit does not require either bimanual or speculum exam if a continuing pregnancy is not suspected and there is no other clinical indication.
   B. A low-sensitivity urine pregnancy test may be used at the time of the follow-up visit for the purpose of identifying a continuing pregnancy.

✓ See 1.3 for Management of Complications

1.2.8 Referral

I. Abortion Referrals — Referrals **must** be provided if the client is not eligible for care at the affiliate. The list of referral providers **must** include providers of abortion services at different gestational ages as well as information about anesthesia options. (See www.plannedparenthood.org or call National Abortion Hotline at 1-800-772-9100.)

1.2.9 Contraception After Surgical Abortion

I. Information regarding all methods of contraception should be offered, and, if requested, a method **must** be provided or referrals given for that method.
II. Providers are encouraged to initiate contraception on day of procedure.
III. EC, a prescription for EC, and/or information describing how EC can be obtained should be given to each client.
IV. Initiate contraception according to the following
    A. CHC
    B. DMPA
    C. Implant
    D. IUC
    E. POPs
    F. Prescription barriers
    G. Non-prescription Methods

✓ See Chapter 6 Contraception — Reversible

1.3 MANAGEMENT OF ABORTION COMPLICATIONS

✓ Refer to ARMS Emergency Manual for management of acute emergencies.

1.3.1 Early Complications and Problems

I. Usually present prior to discharge, on day of abortion visit
II. **Must** manage per Table 1.3.a.

1.3.a. Table: Early Complications and Problems

Condition	Timing	Finding	Management
Atony, uterine	Intraoperative Postoperative	▪ Excessive vaginal bleeding ▪ Enlarged boggy uterus	▪ Perform aggressive bimanual uterine massage. ▪ Empty bladder. ▪ Uterotonics: ○ Methylergonovine maleate 0.2 mg IM ○ Misoprostol 1000 mcg rectally ○ Oxytocin 20-40 units IV or 10 units IM ○ Vasopressin 4-6 units, intracervically ▪ Perform ultrasound to rule out retained tissue; reaspirate as indicated. ▪ Initiate hospital transfer if bleeding fails to respond to above measures or client unstable. ▪ If bleeding continues despite well-contracted uterus, source may be from placental site or vascular trauma. If bleeding significant, while awaiting arrival of EMS, insert 30 cc foley catheter or Bakri balloon into uterus and inflate with saline.
Bleeding during medication abortion	Within 24 hours of misoprostol administration	▪ Persistent heavy bleeding (≥2 saturated pads/hour or large clots) ▪ Prolonged bleeding ▪ Symptoms/signs of hypovolemia	▪ If duration of heavy bleeding ≤2 hours and client stable, advise continued monitoring of bleeding and re-evaluate in another 1 to 2 hours. ▪ Remove tissue from vagina or cervix, if present ▪ Consider repeat dose of misoprostol or methergine 0.2 mg orally every 4-6 hours x 24-72 hours as indicated. ▪ If heavy bleeding persists >4 hours or symptoms/signs of hypovolemia,

Condition	Timing	Finding	Management
		▪ Blood clot/tissue at cervical os or in vagina ▪ Ultrasound reveals retained POCs	refer for prompt clinical evaluation. ▪ Treat with antibiotics if pelvic infection suspected.
Calvarium, trapped	Intraoperative	▪ Calvarium in uterine fundus, may be unable to reach with instruments. ▪ Calvarium absent on tissue examination. ▪ Ultrasound reveals trapped calvarium	▪ Remove calvarium with suction and/or forceps using ultrasound guidance, if possible to do so safely. ▪ Infuse oxytocin 20-40 units per liter of IV fluid x 1-2 hours or administer misoprostol prep and reattempt extraction. ▪ Transfer to hospital.
Cervical stenosis/ inability to dilate	Preoperative Intraoperative	Endocervical canal cannot be identified or entered	▪ Attempt dilation with os finders or lacrimal duct probe. ▪ Apply cervical traction using two tenacula (anterior and posterior lips). ▪ Use ultrasound guidance. ▪ Prepare cervix with misoprostol per Section 1.2.4 Pre-abortion Procedures ▪ Provide medication abortion if EGA ≤ 63 days. ▪ Reschedule procedure in 1 to 2 weeks if early pregnancy and gestational age limit of affiliate allows. ▪ Refer for hospital-based procedure.
Digoxin toxicity, suspected	Shortly after injection	▪ Nausea ▪ Vomiting ▪ Arrhythmias ▪ Bradycardia ▪ Dysrhythmias ▪ Headache ▪ Visual disturbances and colored halo vision	▪ Oxygen ▪ Trendelenburg position ▪ Atropine for bradycardia ▪ Transfer to hospital

Condition	Timing	Finding	Management
False passage	Intraoperative	▪ Increased resistance to passage of dilators ▪ Dilator "dead ends" after advancing only 2-3 cm ▪ Passage feels "tough" or "dry" rather than smooth and moist. ▪ No tissue obtained during suctioning. ▪ Excessive bleeding suggests perforation	▪ Repeat pelvic examination to assess anatomical relationship of cervix to uterine corpus. ▪ Use ultrasound guidance and firm traction and cautiously attempt to locate endocervical canal with small dilator. ▪ Proceed with abortion if endocervical canal located. ▪ If canal cannot be located or is obstructed (e.g., by stenosis or fibroid), discontinue procedure and reschedule or refer.
Fibroids	Intraoperative	▪ Enlarged and/or irregular uterus on exam and ultrasound ▪ Inability to reach pregnancy with cannula	▪ Prepare cervix with misoprostol per Section 1.2.4 Pre-abortion Procedures ▪ Mechanically overdilate cervix ▪ Use ultrasound guidance ▪ Use long flexible cannula ▪ Provide medication abortion if EGA ≤ 63 days ▪ Refer for hospital-based procedure
Laceration / bleeding, exocervix	Intraoperative	Tear visible (usually at tenaculum site)	▪ Observe ▪ Apply pressure ▪ Apply Monsel's solution ▪ Compress with ring forceps ▪ Consider 4-6 u vasopressin intracervical ▪ Suture
Obesity	Preoperative Intraoperative		If difficulty visualizing cervix: ▪ Use specialized speculum (elongated bivalve, Klopfer) ▪ Have assistants aid with exposure of vagina/cervix ▪ Apply condom to speculum with tip cut off to retain vaginal sidewalls ▪ Have assistant apply fundal pressure

Condition	Timing	Finding	Management
			If standard instruments cannot reach pregnancy: ▪ Use flexible cannulae (which are longer than rigid) ▪ Use extension tube ▪ Use longer forceps Other: ▪ Trendelenberg positioning ▪ McRobert's positioning
Osmotic dilators, broken or missing	Preoperative Intraoperative	Dilators removed do not equal dilators inserted Dilator removed is visibly broken or incomplete	▪ Confirm with client that nothing was passed prior to procedure ▪ Consider ultrasound to locate dilator/fragment ▪ Inspect POC at completion of procedure for dilator/fragment ▪ Transfer to hospital
Osmotic dilators, trapped	Preoperative	Unable to remove dilator(s) from cervix	▪ Prepare cervix with misoprostol per 1.2.4 Pre-abortion Procedures ▪ After paracervical block, apply tenaculum to cervix with one blade as far into cervical canal as possible and attempt to pass small dilator alongside osmotic dilator ▪ Postpone the procedure until next day, with or without the addition of misoprostol for cervical ripening

1.3.2 Delayed Complications and Problems

I. Usually seen after the abortion visit
II. **Must** manage per Table 1.3.b.

1.3.b. Table: Delayed Complications and Problems

Condition	Timing	Finding	Management
Amenorrhea	Weeks to months post abortion		See Chapter 8 Gynecological Conditions
Asherman Syndrome	Weeks to months post abortion	▪ Persistent amenorrhea post abortion, may be associated with cyclic cramping in ovulating women ▪ Most often cervical agglutination after abortion, rarely uterine synechiae	▪ Rule out hormonal contraceptive effect (e.g., DMPA). ▪ Dilate cervix to diameter of 7-8 mm using local anesthesia. ▪ If amenorrhea persists for 2 to 3 months post dilation, refer for further evaluation.
Bleeding in medication abortion See Table ~~1.1.c.~~	Delayed (3 to 5 weeks after administration of misoprostol)		
Failed abortion (continuing pregnancy)	Postoperative (immediately or delayed)	▪ No gestational sac or fetal tissue identified on POC exam ▪ Persistent positive LSPT 2 weeks post abortion ▪ Rapidly rising quantitative serum hCG ▪ Continued symptoms of pregnancy (e.g., nausea, breast enlargement/tenderness) ▪ Uterus enlarged, soft ▪ Ultrasound reveals ongoing pregnancy	▪ Recounsel client on pregnancy options. ▪ If client chooses to continue pregnancy, refer for prenatal care. ▪ If client chooses to terminate pregnancy, provide aspiration (with ultrasound guidance if needed) or medication abortion, depending on client eligibility and preference. ▪ If client chooses adoption, refer out as appropriate.

Condition	Timing	Finding	Management
Incomplete abortion	Any time in first month post procedure Persistent nonviable pregnancy after medication abortion	▪ Intermittent or persistent pelvic pain ▪ Prolonged or heavy bleeding ▪ Continued pregnancy symptoms. ▪ Uterus soft, boggy, not always enlarged; ▪ Tissue may be visible at os. ▪ Persistent elevated quantitative hCG levels. ▪ Intrauterine heterogeneous echoes usually seen on ultrasound, although small amounts of tissue may not be detected by ultrasound.	▪ Offer aspiration or uterotonics (See 1.2.4 Pre-abortion Procedures VI. Uterotonic Medications) ▪ Provide antibiotic therapy if symptoms or signs of infection.
Infection ✓ FYI – Typical vs. Atypical Infection	Usually within first week postabortion	Typical infection ▪ Lower abdominal pain ▪ Fever ▪ Heavy or prolonged bleeding ▪ Uterine or adnexal tenderness ▪ Foul discharge ▪ Uterus may feel boggy ▪ Ultrasound may reveal retained tissue. Atypical infection ▪ Abdominal pain ▪ Nausea ▪ Vomiting ▪ Diarrhea ▪ Weakness ▪ Flu-like symptoms ▪ With or without fever more than 24 hours after misoprostol use	▪ Obtain results of STI screening results, if performed. ▪ Initiate PID treatment per CDC STD Treatment Guidelines. ✓ CDC STD Treatment Guidelines ▪ Aspirate retained tissue, if present. ▪ Refer for immediate inpatient treatment if signs or symptoms of atypical infection.

1.4 ADDITIONAL INFORMATION

1.4.a. Table: For Your Information

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>1.1.b.</td><td>The Use of Steroids with Mifepristone</td><td>Mifepristone is an antiglucocorticoid. Medication abortion is contraindicated in clients on concurrent or long-term systemic steroids. Clients taking a short course of systemic steroids to treat acute, non-chronic problems (e.g., poison oak rash or sinusitis) need to complete steroid therapy before initiating mifepristone.

Non-systemic steroids (inhaled, topically applied) are absorbed locally and are not contraindicated nor are they a special consideration. Commonly used inhaled steroids are weak corticosteroids. There is no evidence that a single 200-mg dose of mifepristone will have an impact on the pulmonary effect of inhaled corticosteroids.</td></tr>
<tr><td>1.2</td><td>Interpretation of Laboratory Results for Evaluation of Second Trimester Fetal Demise[R1, R2, R3]</td><td>PT (prothrombin time) of <60%, PTT (partial thromboplastin time) of more than 30 seconds, fibrinogen of <200 mg/mL,* thrombocyte count <100000/mL3, FSP (Fibrinogen Split Products) of >40 mg/mL, and antithrombin III activity of <80% are all indicative of DIC.

Positive predictive value of elevated levels of FSP and D-dimer is 100%.

<table><tr><th colspan="2">WNL values for D-Dimers in adults:</th></tr><tr><td>Non-pregnant: 0.22- 0.74 (ug/ML)</td><td>220 – 740 ng/ML</td></tr><tr><td>First trimester: 0.05 – 0.95</td><td>50 – 950 ng/ML</td></tr><tr><td>Second trimester: 0.32 – 1.29</td><td>320-1290 ng/ML</td></tr><tr><td>Third trimester: 0.13- 1.7</td><td>130 – 1700 ng/ML</td></tr></table>
* Fibrinogen > 100 mg/dl is WNL per ACOG</td></tr>
<tr><td>1.2</td><td>Bacterial Vaginosis and Abortion</td><td>Clients presenting for abortion do not require screening for bacterial vaginosis (BV). However, if it is determined that a woman has BV, she should be treated. Treatment may occur either before or immediately after the procedure.</td></tr>
</table>

Section	Topic	Detail
1.2	Guidelines on cervical dilation/preparation prior to surgical abortion	Society of Family Planning has published a series of clinical guidelines on cervical preparation prior to abortion. A summary of those guidelines and the quality of the evidence is included below. In addition, the full guidelines may be accessed here. *Level A: recommendations are based primarily on good and consistent scientific evidence* *Level B: recommendations are based primarily on limited or inconsistent scientific evidence* *Level C: recommendations are based primarily on consensus and expert opinion* *Cervical preparation for abortion <14 weeks gestation* ▪ Effective methods of cervical priming include osmotic dilators and misoprostol. (A) ▪ The shortest time for efficacy is 3 to 4 h and occurs with the use of Dilapan-S™, Lamicel® and misoprostol. (A) ▪ When misoprostol is used the optimal dose and timing are o 400 mcg vaginally 3–4 h before the procedure (A) o 400 mcg sublingually 2–4 h before the procedure (A) o 400 mcg orally 8-12 hours before the procedure (A) ▪ Cervical priming should be considered for all adolescents and is strongly recommended for adolescents at 12 to 14 weeks' gestation. (C) ▪ Cervical priming is recommended for all women at 12 to 14 weeks' gestation and for any woman in whom an initial attempt at rigid dilation is difficult. (C) *Cervical preparation for abortion >14 and <20 weeks gestation* ▪ When osmotic dilator placement and D&E are to be performed on the same day, Dilapan-S™ is preferred over laminaria tents to achieve adequate priming more quickly(A) ▪ Dilapan-S™ placed 3–4 h prior to D&E is a safe alternative to overnight dilator placement up to 18 weeks' gestation. (B) ▪ Use of misoprostol or mifepristone as an alternative to osmotic tents increases risk of inadequate cervical dilation; however, this has not been shown to increase the rate of rare, severe complications, such as uterine perforation and cervical lacerations. (B) ▪ Routine use of adjunctive buccal misoprostol in addition to osmotic dilators is not recommended before

Section	Topic	Detail
		16 weeks but may be considered at later gestational ages. (B) ▪ Misoprostol may be given prior to D&E to women with a prior cesarean delivery, since uterine rupture or scar dehiscence occurs rarely in this setting. (B) ▪ Only experienced providers capable of managing difficult cervical dilation should use protocols omitting osmotic tent placement prior to D&E. (C) ▪ Overnight placement of osmotic dilators is recommended after 18 weeks gestation. Highly experienced D&E providers may consider same-day procedures at later gestations utilizing a combination of osmotic and pharmacologic agents or serial doses of misoprostol, if needed, to accommodate the time constraints of patients and staff. (C) *Cervical preparation for abortion from 20-24 weeks gestation* ▪ Buccal misoprostol 400 mcg is an adequate dose for cervical ripening when used as an adjunct to osmotic dilation. It may decrease the need for additional dilation in these procedures. Higher doses of buccal misoprostol do not appear to decrease the need for additional dilation. (B) ▪ Using adjuvant misoprostol with osmotic dilators before D&E at 20–24 weeks' gestation is not associated with significant procedure-associated risks and may aid in cervical dilation. (B) In 2009, the NMC reviewed the available literature and developed the following guidance on acceptable misoprostol regimens for use prior to surgical abortion: ▪ First trimester o Use of osmotic cervical dilator(s) and/or misoprostol optional o Misoprostol 400 mcg orally 8-12 hours prior to the procedure o Misoprostol 400 mcg vaginally 2-4 hours prior to procedure o 400 mcg buccal or sublingual misoprostol 2-4 hours prior to the procedure (buccal use no longer requires a waiver) ▪ Second trimester ≤ 16 weeks o Buccal misoprostol 400-800 mcg alone may be used o Option to use osmotic dilators is still available (no change) ▪ Second trimester > 16 weeks

Section	Topic	Detail
		○ 400-800 mcg buccal misoprostol may be used in addition to osmotic dilators (no change) ○ Misoprostol alone may be used for abortion > 16 weeks with waiver ○ Language to be added: "We are not specifying a time interval from administration to D& E because there is variability in practice and no guidance from data to suggest an appropriate interval range."
1.2	Risks and Side Effects of Digoxin	▪ Failure to cause fetal demise ○ 1 mg intra-amniotic digoxin failed to cause fetal demise in 5 out of 62 (8%) cases. ○ 1-2 mg of intra-fetal digoxin is successful in 85-100% of cases. ▪ Onset of labor - can result in delivery outside the PP health facility. It is estimated that this will occur <1% of the time. ▪ Gastrointestinal side effects ○ nausea and vomiting. In a randomized trial, vomiting occurred significantly more frequently in the group that received digoxin vs. those who received placebo. ○ diarrhea ○ abdominal pain ▪ Complications from injection — leaking of amniotic fluid, amnionitis, injury to abdominal organs, skin bruising, skin infection, vaginal bleeding, and acute abdominal pain after injection (pain typically resolves spontaneously with supportive treatment). There have not been any reports of serious adverse events when digoxin is administered intraamniotically or intrafetally before D&E abortion. ▪ Adverse reactions listed as part of the digoxin drug profile information, for treatment of heart conditions. Refer to the package insert or other drug profile for a complete list of conditions: ○ cardiovascular heart block (1st, 2nd or 3rd degree), asystole; atrial tachycardia with block; AV dissociation; accelerated junctional rhythm; ventricular tachycardia or ventricular fibrillation; PR prolongation; ST segment depression. ○ central nervous system — visual disturbance, headache, dizziness, apathy, confusion, mental disturbances, anxiety, depression, delirium, hallucinations, and fever. ○ neuromuscular — weakness. ○ dermatological reactions — rash, maculopapular rash being the most common

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>1.2</td><td>Cleansing the Vagina</td><td>Cleansing the vagina with an antiseptic solution prior to surgical abortion has not been shown to affect the risk of post-procedure infection. Chlorhexidine may be more effective than povidone iodine at reducing bacteria within the vagina.</td></tr>
<tr><td>1.2</td><td>Examination of Products of Conception After Surgical Abortion[R4]</td><td>Careful examination of the products of conception reduces the likelihood of complications. Below are the expected findings to help identify tissue.
<table>
<tr><th>Tissue Type</th><th>Expected Findings</th></tr>
<tr><td>Fetal parts</td><td>▪ < 9-10 weeks — villi and gestational sac
▪ 10-12 weeks — villi, gestational sac, and fetal parts.
▪ ≥ 12 weeks — villi, placenta, gestational sac, and all fetal parts, i.e., calvarium, spine and four extremities.</td></tr>
<tr><td>Decidual tissue</td><td>Opaque, reddish brown or gray, usually drops to bottom of glass dish</td></tr>
<tr><td>Decidua capsularis</td><td>Opaque sheet with hemorrhagic areas</td></tr>
<tr><td>Gestational sac</td><td>Thin and transparent; may be intact or appear as separate pieces of transparent membranes — should be identified in all pregnancies less than 12 weeks.

Size guidelines:
▪ 6 wk – dime size
▪ 7 wk – nickel size
▪ 8 wk – quarter size</td></tr>
<tr><td>Chorionic villi</td><td>Transparent with frond-like projections; usually floats — will turn bone white when clear vinegar is added to the specimen.</td></tr>
<tr><td colspan="2">▪ Rinsing the tissue in water and floating it in a clear dish can aid in identification. Backlight can also aid gross examination.
▪ Weight and volume of aspirated tissue can vary considerably among clients of the same gestational age; they are not reliable predictors of gestational age or termination of the pregnancy.
▪ To remember to account for all fetal parts, use the mnemonic device C+S+4, which stands for: calvarium, spinal column, and four extremities.</td></tr>
</table></td></tr>
<tr><td>1.3</td><td>Typical vs. Atypical Infection</td><td>When medication abortion was introduced in the US, some assumed that there was little likelihood of infection, since there was no instrumentation of the cervix or uterus. In fact, the rate of infection with</td></tr>
</table>

Section	Topic	Detail
		medication abortion is very low. However, despite the fact that infection is rare, we now know that serious infection, although uncommon, can occur and rarely can even be fatal. Infection following medication abortion can be typical or atypical. **Typical Endometritis** ▪ Presentation — abdominal/pelvic pain and fever ▪ Treatment — If treatment will occur in the outpatient setting, follow full CDC PID regimen. ▪ Follow-up visit **must** be done in 48-72 hours to assess for improvement. **Atypical Endometritis/Sepsis** ▪ Presentation o May present without fever and/or without pain o May complain of painful bloating or abdominal/pelvic pain o May present with severe nausea and vomiting ▪ Evaluation — The following **must** be performed: o CBC with differential • Results must be available the next day, preferably in a.m. • Will see marked leukocytosis with left shift. o Hgb or Hct — may see marked hemoconcentration. o Temperature o BP (assess for hypotension) o Pulse rate (assess for tachycardia) ▪ Management — **must** be referred to the hospital immediately. o Contact **must** be made with ER physician. o Contact on-call OB-GYN and infectious disease physicians, if possible. o Alert physicians to expanded FDA label advising rare presentations of atypical sepsis. o Aerobic and anaerobic cultures are recommended. o All communications with hospital **must** be documented in the medical record.

1.4.b. Table: References

Section	R#	Reference
1.2	R1	Abbassi-Ghanavati M, Greer LG, Cunningham FG. Pregnancy and laboratory studies: a reference table for clinicians. Obstet Gynecol. 2009 Dec;114(6):1326-31.
1.2	R2	American College of Obstetricians and Gynecologists. Diagnosis and management of fetal death. ACOG Technical Bulletin Number 176-January 1993. Int J Gynaecol Obstet. Sep 1993;42(3):291-9
1.2	R3	Bick R. Syndromes of disseminated intravascular coagulation in obstetrics, pregnancy, and gynecology: Objective criteria for diagnosis and management. Hematology/Oncology Clinics of North America 2000;14:99-1004.
1.2.b.	R5	Carey MJ and Rodgers GM. Disseminated Intravascular Coagulation: Clinical and Laboratory Aspects. American Journal of Hematology 1998;59:65–73
1.2.b.	R6	Carr et al. Diagnosis of Disseminated Intravascular Coagulation: Role of D-Dimer. Am J Clinical Pathol 1989;91:280-287
1.2	R4	Goodman S, Wolfe M, and the TEACH Trainers Collaborative Working Group. Early Abortion Training Workbook, Fourth Edition. UCSF Bixby Center for Reproductive Health Research & Policy: San Francisco, CA (2012). Available at http://teachtraining.org/trainingworkbook/EarlyAbortionTrainingWorkbook2012.pdf. Accessed June 1, 2014
1.2.b.	R7	Lurie S. Feinstein M. Mamet Y. Disseminated intravascular coagulopathy in pregnancy: thorough comprehension of etiology and management reduces obstetricians' stress. Arch Gynecol Obstet 2000;263:126–130
1.2 1.3		Paul, M. et. al. (2009). Management of Unintended and Abnormal Pregnancy Comprehensive Abortion Care. West Sussex, UK: Blackwell Publishing Ltd.
1.2		Placenta accreta. Committee Opinion No. 529. American College of Obstetricians and Gynecologists. Obstet Gynecol 2012;120:207–11. Available at http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Obstetric_Practice/Placenta_Accreta. Accessed June 1, 2014.
1.2		Society of Family Planning. Cervical preparation for surgical abortion from 20 – 24 weeks' gestation. Contraception 2014; 89:75-84. http://download.journals.elsevierhealth.com/pdfs/journals/0010-7824/PIIS0010782413006860.pdf Accessed June 1, 2014
1.2		Society of Family Planning. Prevention of infection after induced abortion. Contraception 2011;83:295-309. http://download.journals.elsevierhealth.com/pdfs/journals/0010-7824/PIIS001078241000644X.pdf Accessed June 1, 2014

1.4.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIICs	CI Abortion Options CI How To Take Your Pills – Buccal CI How To Take Your Pills – Oral CI Rho(D) Immune Globulin CI Taking Care of Yourself After An In-Clinic Abortion CI When A Small Amount of Pregnancy Tissue Was Seen CIIC Cervical Prep with Dilators or Miso CIIC Digoxin CIIC In-Clinic Abortion CIIC Reaspiration after In-Clinic Abortion/Aspiration after Using the Abortion Pill CIIC Second Dose of Misoprostol CIIC Using the Abortion Pill CIIC When You Decide To Stop Your In-Clinic Abortion	Part 3, Chapter 02_01
	CI Ectopic Pregnancy	Part 3, Chapter 02_13
Client Education	How Much Am I Bleeding Illustration How to Take Your Pills Buccal Illustration When to Call Us	Part 3, Chapter 02_01

1.4.d. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	Programs for Donation of Blood and/or Aborted Pregnancy Tissue and associated CIIC Sample Protocol for In-Clinic Abortion Care for Diabetic Clients ✓ SFP Clinical Guidelines	Part 3, Chapter 02_01

Type	Resource	Location
Training	**CAL Courses** Averting Vasovagal Fainting: Tips for Managing Neurocardiogenic Syncope Evaluating Products of Conception After First Trimester Surgical Abortion Healthcare Assistant Training for Abortion Services Series Rh Testing with Eldon Card Series Talking About Abortion for Managers Talking About Abortion Series Ultrasound in Abortion Care Staff Training Series Ultrasound Program Director Proficiency Exam (Part 1-3)	
	2014 MeDC Presentation Updates in abortion care: New clinical guidelines from the Society of Family Planning and frequently asked questions	To be posted on the Extranet
Sample Forms	Sample Offsite Information and Treatment Form Sample Routine hCG Telephone Contact Form Sample Telephone Contact Form for Abortion Related Issues	Part 3, Chapter 02_01

CHAPTER 2: ANALGESIA AND SEDATION

Revised June 2014

Chapter 2 Table of Contents

CHAPTER 2: ANALGESIA AND SEDATION

Revised June 2014

2.1 CLIENT EDUCATION AND INFORMED CONSENT

2.1.1 Requirements

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

2.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give
CI Taking Care of Yourself after Sedation			●
CIIC Sedation		●	●
Written information about any medication dispensed (package insert may be used)			●

2.2 DEFINITIONS

2.2.a. Table: Definitions

Term	Definition
Analgesia	The diminution or elimination of pain. This can be accomplished using oral or intramuscular drugs. May be used with minimal or moderate sedation.
Local Anesthesia	The elimination of sensation, especially pain, in one part of the body by the topical application or regional injection of a drug.
Analgesia/ Sedation	A state that allows a client to tolerate an unpleasant procedure while maintaining adequate cardio-respiratory function and the ability to respond purposefully to verbal command and tactile stimulation. Sedation is a continuum, and increasing depth of sedation increases the likelihood that the client's airway, ventilation and cardiovascular function will be affected. In addition, medications administered with the intent to induce one level of sedation may, depending upon the agent(s) used and the physical status and drug sensitivities of the individual client, result in a lighter or deeper level of sedation. There are 4 levels defined by the Joint Commission. ✓ FYI - Continuum of Depth of Sedation

Term	Definition
Minimal Sedation (Anxiolysis)	Generally employs oral routes of a benzodiazepine with or without an oral narcotic. (See 2.6 Analgesics and Sedation Drugs) Administration ▪ Incremental dosing — administration of multiple doses of a drug until a desired effect is reached, but not to exceed the maximum recommended dose (MRD). ▪ Combining both sedatives and narcotics increases the risk of adverse outcomes, and doses should be reduced when given together.
Moderate Sedation/Analgesia	Generally implies using IV narcotics and/or benzodiazepines to achieve a desired level of sedation during procedures. (See 2.6 Analgesics and Sedation Drugs) Administration ▪ **Titration** – administration of incremental doses of a drug until a desired effect is reached. ▪ Drugs may be titrated to achieve the desired level of sedation. ▪ Although the concept of titration of a drug to effect is critical for client safety, when the intent is moderate sedation, one **must** know whether the previous dose has taken full effect before administering an additional drug increment. ▪ Knowledge of each drug's time of onset, peak response and duration of action is essential to avoid oversedation.
Monitored Anesthesia Care (MAC)	Refers to the anesthesia personnel present during a procedure. Administered by an anesthesia professional (anesthesiologist or CRNA). May include the varying levels of sedation, analgesia and anxiolysis as necessary. Achieved with higher doses of narcotics and benzodiazapines, and also propofol, ketamine, brevital, pentothal, etomidate, and inhalation anesthetics. (See 2.6 Analgesics and Sedation Drugs) Administration ▪ **Titration** – administration of incremental doses of a drug until a desired effect is reached. ▪ Drugs may be titrated to achieve the desired level of sedation.

2.3 CONTRAINDICATIONS AND SPECIAL CONDITIONS

2.3.a. Table: Contraindications and Special Conditions for Analgesia and Sedation

When choosing analgesia/sedation, Table 2.3.a. **must** be followed.

Legend	
A	Contraindications — **must** not be provided for a client, whether in the affiliate or in a hospital under the care of an affiliate clinician
B	Special conditions requiring further evaluation before performing procedure

Conditions/signs/symptoms	A	B
Acute Respiratory Infection - clinician providing sedation **must** evaluate client with symptoms of URI to assess for potential ventilation difficulties		Moderate Sedation or MAC
Allergy to medications being used	Minimal Sedation, Moderate Sedation or MAC	
ASA PS Classification of III – see Table 2.3.b.		Moderate Sedation or MAC
ASA PS Classification of IV or greater – see Table 2.3.b.	Moderate Sedation or MAC	
Drug or alcohol abuse - current		Moderate Sedation or MAC
Mallampati score of 3 or 4 or any other abnormal mouth opening, short neck or chin that would make intubation or ventilation difficult. ✓ FYI - Evaluation of the Airway	Moderate Sedation or MAC	
Sleep Apnea		Moderate Sedation or MAC

2.3.b. Table: ASA Physical Status (PS) Classification System

	Classification			
	I	**II**	**III**	**IV**
Definition	Healthy	Mild systemic disease	Severe systemic disease but not incapacitating	Incapacitating Disease
Functional Capacity walk up 1 flight of stairs	▪ Complete without distress	▪ Rest at completion because of distress	▪ Stop en route because of distress	▪ Unable to do
Medical Status	▪ No organic, physiologic, or psychiatric disturbance	▪ Single/multiple systemic disease(s) with good control ▪ No functional limitations or vital organ involvement	▪ Poorly controlled systemic disease(s) ▪ Some functional limitations. ▪ No immediate life threatening condition.	▪ Poorly controlled systemic disease(s) ▪ Significant functional limitation ▪ Constant potential threat to life
Physiologic Status	▪ Normal healthy client	▪ Healthy pregnant woman. ▪ Active allergies	▪ Pre-existing disease in pregnancy, GDM, PIH, Mild pre-eclampsia	▪ Severe pre-eclampsia, eclampsia, HELLP syndrome
CVS		▪ HTN with BP ≤ 140/90 mmHg	▪ BP ≥180/110 mmHG ▪ Stable angina ▪ MI > 6 months/ Cardiac arrhythmia without hemodynamic instability ▪ Compensated heart failure ▪ EF 25% to 50%	▪ Unstable angina ▪ Acute MI ▪ MI ≤ 6 months ▪ Uncontrolled cardiac arrhythmias with hemodynamic instability ▪ Severe heart failure ▪ EF < 25%
RS		▪ Well controlled asthma (attack < 1/wk) ▪ Heavy smoker (> 20 pack year) without COPD	▪ Stress-/exercise-induced or hospitalized asthma ▪ COPD on medications	▪ Asthma or COPD with exacerbation

	Classification			
	I	II	III	IV
Definition	Healthy	Mild systemic disease	Severe systemic disease but not incapacitating	Incapacitating Disease
CNS		▪ Well controlled epilepsy ▪ Parkinsonism	▪ Stroke > 6 months with or without neurologic sequelae	▪ Uncontrolled epilepsy ▪ Stroke < 6 months or bed-ridden status
Endocrine		▪ Well controlled diabetes of any type ▪ Controlled hyper- or hypothyroidism (without symptoms)	▪ Poor controlled diabetes ▪ Symptomatic hyper- or hypothyroidism	▪ Hyperosmolar nonketotic acidosis ▪ Thyroid crisis
GI		▪ Cirrhosis Child-Pugh A ▪ Significant liver enzyme abnormality	▪ Cirrhosis Child-Pugh B	▪ Cirrhosis Child-Pugh C
Hematology		▪ Anemia (Hct < 30%) ▪ Thalassemia minor e.g. Thalassemia trait, Hemoglobin E, CS, H ▪ Platelets 50,000 to 100,000 ▪ INR 1.2 to 1.5	▪ Symptomatic anemia (Hct < 25%) ▪ Thalassemia major ▪ Platelets < 50,000 ▪ INR ≥ 1.5	▪ Platelet < 50,000 ▪ INR ≥ 1.5 with bleeding
Obesity		▪ BMI 35 to 39.99	▪ BMI 40 – 44.99 ▪ (Morbid obesity)	▪ BMI ≥ 45
Renal		▪ Renal impairment ▪ Chronic kidney disease stage 1-2 ▪ Asymptomatic electrolyte imbalance	▪ Chronic kidney disease stage 3-5 ▪ End-stage renal disease ▪ Symptomatic electrolyte imbalance	▪ End-stage renal disease with volume overload or uremia ▪ Hepatorenal syndrome

	Classification			
	I	II	III	IV
Definition	Healthy	Mild systemic disease	Severe systemic disease but not incapacitating	Incapacitating Disease
Others		▪ SIRS ▪ Malnutrition ▪ (BMI < 16.5) ▪ Hypoalbuminemia (albumin < 2.5)	▪ Septicemia	▪ Septic shock

2.4 MEDICAL SCREENING AND EVALUATION

2.4.a. Table: Medical Screening and Evaluation

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Must include ▪ Abnormalities of any major organ systems (pulmonary, cardiac, hepatic function) ▪ Previous experience with analgesia and sedation including regional and general anesthesia ▪ Drug allergies ▪ Current medications ▪ Time and nature of last oral intake ▪ History of sleep apnea ▪ History of tobacco, alcohol, or substance use or abuse - clinician **must** be made aware of any history or current use, and **must** evaluate and determine appropriate management. ▪ Based on history, all clients **must** be classified using the ASA Physical Status Classification System as shown in Table 2.3.b.	**Must** include ▪ Vital signs ▪ Oxygen saturation >95% prior to procedure (for moderate or MAC sedation) ▪ Auscultation of heart and lungs (for moderate sedation or MAC) ▪ Evaluation of the airway and Mallampati classification (for moderate sedation or MAC) ✓ FYI – Evaluation of the Airway ▪ Additional examination as indicated by history	Should be performed as indicated by history

2.5 PROVISION OF SEDATION

2.5.1 Pre-Procedure (before medication is administered)

I. Should consider administration of prophylactic medications to decrease risk of acid aspiration

✓ FYI – Strategies for Decreasing Risk of Acid Aspiration

II. **Must** follow fasting guidelines per Table 2.5.a.

2.5.a. Table: Fasting Guidelines[R1]

Ingested Material	Minimum Fasting Period*
Clear liquids (tea, soda, non-pulp juices, Jell-O, popsicles)	2 hours
Milk Light meal (typically toast and clear liquids) Solids (includes juices with pulp, milk products)	6 hours
NOTE: Several large studies have been published reporting the safety of relaxing food or fluid restrictions prior to the administration of moderate sedation. As a result, the following guidelines may be followed: ▪ For nonpregnant, healthy clients, there is no requirement to restrict any food or fluid before the procedure if IV sedation does not exceed 100 mcg fentanyl **and/or** 2 mg midazolam; medications can be given either IV push or through indwelling IV ▪ For pregnant clients ○ In healthy women up to 16 weeks gestation -- no requirement to restrict food or fluid if medication administered does not exceed 100 mcg fentanyl **and/or** 2 mg midazolam given either IV push or through indwelling IV In healthy women with pregnancies from 16 to 18 weeks gestation, a waiver may be requested to allow administration of sedation not exceeding 100 mcg fentanyl **and/or** 2 mg midazolam either IV push or through indwelling IV, without restriction to food or fluids	
* These NPO requirements may be made more restrictive at the clinician's discretion (e.g., presence of co-morbidities such as hiatal hernia).	

2.5.2 After Administration of Medications

I. Clients who have been given medications for any level of sedation prior to their procedure **must** not leave the health center so they may be observed by staff in case they experience deeper sedation and require additional monitoring.

II. Supplemental oxygen should be available for clients receiving moderate sedation and **must** be administered during MAC.

III. Moderate Sedation and MAC **must** be monitored according to Table 2.5.b.

2.5.b. Table: Monitoring for Moderate Sedation and MAC

✓ FYI – Continuum of Depth of Sedation

Assess the following at regular intervals (every 5 minutes once a stable level of sedation is established).

<table>
<tr><th></th><th>Oxygenation</th><th>Ventilation</th><th>Circulation</th><th>Level of Consciousness</th></tr>
<tr><td>Moderate Sedation</td><td>Continuous pulse oximeter with audible beep
✓ FYI - Prevention and Management of Hypoxemia During Moderate Sedation</td><td>Respiratory rate</td><td>BP
Heart rate</td><td>Response to verbal commands using a level of consciousness scale<table><tr><td>5</td><td>Awake, alert oriented x 3</td></tr><tr><td>4</td><td>Drowsy, but easily aroused (responds by opening eyes when name is called)</td></tr><tr><td>3</td><td>Drowsy, but will open eyes when name is called several times</td></tr><tr><td>2</td><td>Drowsy, but hard to arouse — needs tactile stimuli</td></tr><tr><td>1</td><td>Responds to pain only</td></tr><tr><td>0</td><td>No response</td></tr></table></td></tr>
<tr><td>MAC</td><td>Continuous pulse oximeter with audible beep</td><td>Respiratory rate
End Tidal CO_2</td><td>BP
Heart rate
EKG</td><td>Response to verbal commands using a level of consciousness scale</td></tr>
<tr><td colspan="5">▪ As part of monitoring above, assessment will confirm that client is at intended level of sedation; if not, sedation should be titrated accordingly.
▪ In addition to the clinician performing the procedure, a second trained staff member must be present to monitor the client according to the requirements in this table.</td></tr>
</table>

2.5.3 Transfer to Recovery Area

I. **Must** not stop pulse oximeter nor release client to recovery area unless client is spontaneously maintaining adequate oxygenation >95% without verbal or physical stimulation.

2.6 APPENDIX: ANALGESICS AND SEDATION DRUGS

2.6.a. Table: Analgesics

Analgesics Generic name (Trade name) –Action	Mode of Administration*	Maximum Recommended Dose (MRD) – single dose	Onset of Action	Half-Life	Duration	Comments
Acetaminophen (Tylenol®) – Analgesic	PO	1000 mg	10-60 min	1.25-3 hours	6-8 hours	
Ibuprofen (Motrin®, Advil®) – NSAID	PO	800 mg	30 min	2-4 hours	4-6 hours	
Naproxen (Naprosyn®, Aleve®, Anaprox®) – NSAID	PO	500 mg	1 hour	13 hours	4-7 hours	
Ketorolac (Toradol®) – NSAID Analgesic	IV/IM	30 mg IV 60 mg IM	10 min	2.4-9.2 hours	6-8 hours	
Aceteminophen with codeine – Combination opioid analgesic	PO	Acetaminophen – see above Codeine – 60 mg	Acetaminophen – see above Codeine – 10-30 min	Acetaminophen – see above Codeine – 2.5-4 hours	Acetaminophen – see above Codeine – 4-6 hours	
Acetaminophen / Hydrocodone (Vicodin®, Lorcet®, Norco®, Lortab®) – Opioid analgesic	PO	Acetaminophen – see above Hydrocodone – 10 mg	Acetaminophen – see above Hydrocodone – 10-20 minutes	Acetaminophen – see above Hydrocodone – 3.3-4.4 hours	Acetaminophen – see above Hydrocodone – 4-8 hours	
Fentanyl Citrate (Sublimaze®) – Opioid analgesic	IV	0.5-1 mcg/kg	1-3 min	7.1 hours	Up to 72 hours	▪ Peak effect in 4-6 min. ▪ May be repeated once. ▪ Can cause dizziness, pruritis, nausea and respiratory depression.

Analgesics Generic name (Trade name) –Action	Mode of Administration*	Maximum Recommended Dose (MRD) – single dose	Onset of Action	Half-Life	Duration	Comments
Fentanyl Citrate (Sublimaze®) – Opioid analgesic *(continued)*						▪ Respiratory depression is potentiated when fentanyl is combined with sedatives such as midazolam.
Nalbuphine (Nubain®) – Opioid analgesic	IV/IM	10-20 mg IV/IM	2-3 min IV < 15 min IM	5 hours	3-6 hours	▪ May be repeated once. ▪ Allow adequate time interval (3-4 min) between doses to assess for effect of the previously administered dose. ▪ Respiratory depression when nalbuphine is combined with sedatives such a midazolam ▪ Do not use following other narcotic analgesics -- will reverse effect of the analgesic (this includes maintenance therapies like

Analgesics Generic name (Trade name) –Action	Mode of Administration*	Maximum Recommended Dose (MRD) – single dose	Onset of Action	Half-Life	Duration	Comments
Nalbuphine (Nubain®) – Opioid analgesic *(continued)*						methadone or in a client with suspected narcotic use, can induce symptoms of withdrawal)
Meperedine (Demerol®) – Opioid analgesic	IV/IM	50-150 mg	Rapid	3-5 hours	2-4 hours	
* Doses are chosen to have a margin of safety wide enough to minimize the risk of unintended deep sedation. (Epocrates)						

2.6.b. Table: Sedatives

Sedatives Generic name (Trade name) –Action	Mode of Administration*	Maximum Recommended Dose (MRD) – single dose	Onset of Action	Half-Life	Duration	Comments
Diazepam (Valium®) – Benzodiazepine	PO	10 mg	15-45 min	20-50 hours	7-8 hours	▪ 5-10 mg tablets ▪ Should wait 30 min
Lorazepam (Ativan®) – Benzodiazepine	PO	2 mg	2 hours to peak	12.9 hours	6-8 hours	▪ 0.5 and 1 mg tablets ▪ Should wait 30 min
Alprazolam (Xanax®) – Benzodiazepine	PO	2 mg	1 hour	11.2 hours	5.1±1.7 hours (immediate release) 11.3±4.2 hours (extended release)	▪ Cigarette smoking may decrease alprazolam concentrations up to 50%

Sedatives Generic name (Trade name) –Action	Mode of Administration*	Maximum Recommended Dose (MRD) – single dose	Onset of Action	Half-Life	Duration	Comments
Midazolam Hydrochloride (Versed®) – Benzodiazepine	IV	5 mg	1-5 minutes	1-4 hours	Up to 6 hours	▪ Central nervous system depressant ▪ Produces sedation, anxiolysis, amnesia ▪ Has no analgesic properties ▪ Can be antagonized (reversed) with flumazenil (Romazicon®) ▪ Initial dose 1-2 mg ▪ Administer slowly with adequate time interval (2-3 min) between doses to assess for the effect of the previously administered dose. ▪ Peak effect in 5-10 minutes. ▪ Additional midazolam may be given in 1mg doses (not to exceed a total of 5 mg) to maintain desired level of sedation ▪ Water soluble and minimally painful

Sedatives Generic name (Trade name) –Action	Mode of Administration*	Maximum Recommended Dose (MRD) – single dose	Onset of Action	Half-Life	Duration	Comments
Midazolam Hydrochloride (Versed®) – Benzodiazepine *(continued)*						when injected ▪ Shortest half-life of benzodiazepines ▪ Respiratory depression is potentiated when midazolam is combined with a narcotic.
* Doses are chosen to have a margin of safety wide enough to minimize the risk of unintended deep sedation. (Epocrates)						

2.6.c. Table: Reversal Agents/Antagonists

Reversal Agents / Antagonists Generic name (Trade name) –Action	Mode of Administration*	Maximum Recommended Dose (MRD) – single dose	Onset of Action	Half-Life	Duration	Comments
Naloxone (Narcan®) – Narcotic antagonist	IV	N/A	Approx 2 minutes	0.5-1.5 hours	30-120 minutes	▪ 1 cc ampule (containing 0.4 mg) ▪ Administer from 0.2 to 0.4 mg IV as initial dose (IM or Sub-Q if no IV access) ▪ Can be repeated at 2-3 minute intervals ▪ Used for reversal of narcotic induced respiratory

Reversal Agents / Antagonists Generic name (Trade name) –Action	Mode of Administration*	Maximum Recommended Dose (MRD) – single dose	Onset of Action	Half-Life	Duration	Comments
Naloxone (Narcan®) – Narcotic antagonist (continued)						depression ▪ **Warning:** Duration of action of naloxone may be less than that of the narcotic with re-appearance of narcosis ▪ **Warning:** In narcotic-dependent clients, naloxone can cause acute narcotic withdrawal.
Flumazenil (Romazicon®) – Benzodiazepine antagonist	IV	N/A. See dosing information in comments column.	1-3 minutes	41-79 minutes	Approx 1 hour	▪ Administer slowly ▪ Initial dose is 0.2 mg IV over 15 seconds ▪ A second dose of 0.2 mg can be given after 45 seconds. ▪ If necessary the dose of 0.2 mg may be repeated at 60 second intervals to a maximum total dose of 1 mg, *i.e.*, 5 doses. ▪ May cause seizures in clients physically dependent on

Reversal Agents / Antagonists Generic name (Trade name) –Action	Mode of Administration*	Maximum Recommended Dose (MRD) – single dose	Onset of Action	Half-Life	Duration	Comments
Flumazenil (Romazicon®) – Benzodiazepine antagonist *(continued)*						benzodiazepines. ▪ **Warning:** Duration of action of the antagonist may be shorter than the agonists.
* Doses are chosen to have a margin of safety wide enough to minimize the risk of unintended deep sedation. (Epocrates)						

2.6.d. Table: Local Anesthetic

Local Anesthetic Generic name (Trade name) –Action	Mode of Administration	Maximum Recommended Dose (MRD)*	Onset of Action	Half-Life	Duration	Comments
Lidocaine (such as Xylocaine®)	Injection	4.5 mg/kg	Varies	Varies	Varies	Clinicians should be aware of both toxic, non-allergic reactions resulting from direct intravascular injection and allergic reactions including anaphylaxis. ✓ FYI - Local Anesthesia Toxicity
* Doses are chosen to have a margin of safety wide enough to minimize the risk of unintended deep sedation. (Epocrates)						

2.6.e. Table: Medications Employed During Mac

Medications Employed During MAC Generic name (Trade name) –Action	Mode of Administration	Dose	Onset of Action	Half-Life	Duration	Comments
Propofol (Diprivan®)	IV	Initiation: 100-150mcg/kg/min IV or 0.5mg/kg IV slowly over 3-5 min Maintenance: 25-75mcg/kg/min IV for 10-15 min, then decreased to 25-50 mcg/kg/min IV adjusted to clinical response or may be given in increments of 10 or 20mg IV intermittent bolus PRN	Less than 1 minute	2-24 hours	4-8 minutes	Peak effect in 1-2 minutes Dosage **must** be individualized based on total body weight and titrated to the desired clinical effect. Wait at least 3-5 minutes between dosage adjustments to clinically assess drug effects. Effects potentiated by use of other CNS medications like opioids and barbituates. Smaller doses required when used with narcotics.
Ketamine (Ketalar®)	IV	Initiation: 0.5/mg/kg Maintenance: Titrate to effect	Less than 1 minute		10-15 minutes	Peak effect in 1 minute Administer slowly (over a period of 60 seconds)

Medications Employed During MAC Generic name (Trade name) –Action	Mode of Administration	Dose	Onset of Action	Half-Life	Duration	Comments
Methohexital Sodium (Brevital®)	IV	Initiation: 1-1.5 mg/kg (use 1% solution administered at a rate of 1 ml/5 sec) Maintenance: Intermittent doses of 20-40 mg (2-4 mL 1% solution) every 4-7 minutes	Within 30 seconds	3-8 minutes	5-7 minutes	Gradually reduce rate of administration for longer cases

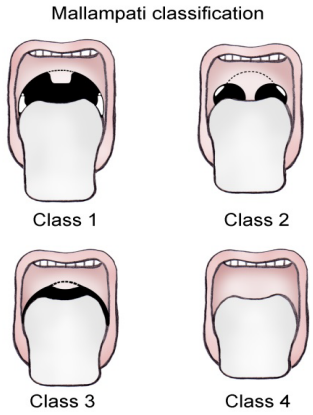
2.7 ADDITIONAL INFORMATION

2.7.a. Table: For Your Information

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>2.2.a.
2.5.b.</td><td>Continuum of Depth of Sedation</td><td>
<table>
<tr><th></th><th>Minimal sedation (anxiolysis)</th><th>Moderate sedation/analgesia</th><th>Deep sedation/analgesia</th><th>General anesthesia</th></tr>
<tr><td>Responsiveness</td><td>Normal response to verbal stimulation</td><td>Purposeful response to verbal or tactile stimulation</td><td>Purposeful response after repeated or painful stimulation</td><td>Unarousable, even with painful stimulus</td></tr>
<tr><td>Airway</td><td>Unaffected</td><td>No intervention required</td><td>Intervention may be required</td><td>Intervention often required</td></tr>
<tr><td>Spontaneous Ventilation</td><td>Unaffected</td><td>Adequate</td><td>May be inadequate</td><td>Frequently inadequate</td></tr>
<tr><td>Cardiovascular Function</td><td>Unaffected</td><td>Usually maintained</td><td>Usually maintained</td><td>May be impaired</td></tr>
</table>
</td></tr>
<tr><td>2.3.a.
2.4.a.</td><td>Evaluation of the Airway</td><td>Bag-valve mask (BVM) ventilation may be necessary if respiratory compromise develops during moderate sedation or if level of sedation exceeds that which is intended or desired. This may be more difficult in some clients.

The following factors have been shown to hinder BVM ventilation:
▪ BMI > 30 kg/m2
▪ Presence of a beard
▪ Mallampati score of 3 or 4
▪ Age of 57 or older
▪ Severely limited jaw protrusion (unable to thrust lower jaw forward so that lower teeth are in front of upper teeth)
▪ Snoring

The Mallampati score, also referred to as the Mallampati classification, is used to determine the potential level of difficulty, and subsequent risk, in intubating a patient undergoing surgery. The score determines a rating for the patient, ranging from Class 1 to Class 4. A Class 1 rating indicates a patient who should prove</td></tr>
</table>

Section	Topic	Detail
		relatively easy to intubate. The highest rating, Class 4, is assigned to patients with a higher risk of complications. Mallampati classification is determined by visual observation of the oral cavity. The test to establish the Mallampati score is performed with the patient in an upright sitting posture, with the head held in a neutral position. As the patient holds his or her mouth open wide and extends the tongue, the clinician checks for clear visibility of pharyngeal structures The 4 levels of classification are shown below:  Class 1 – soft palate, fauces, uvula, anterior and posterior pillars visible Class 2 – soft palate, fauces, uvula visible Class 3 – soft palate, base of uvula visible Class 4 – soft palate not visible (Kheterpal 2006)
2.5.1	Strategies for Decreasing Risk of Acid Aspiration	Pulmonary aspiration of gastric contents is one of the most serious complications possible during the provision of sedation. Aspiration can occur in any client in whom an underlying medical condition or administered drug(s) results in loss of consciousness/protective airway (gag/cough) reflexes. Altered physiologic states such as pregnancy, GI disorders, and diabetes mellitus are associated with delays in the rate of gastric emptying, which increase the gastric volume and increase the risk of aspiration. Prophylactic agents do not reduce the propensity to regurgitation and pulmonary aspiration, but they may limit the damage. They may be given either intravenously or orally.

Section	Topic	Detail
		Affiliates should consider developing protocols for use of a prophylactic medication in clients at risk for aspiration. Citric Acid and Sodium Citrate (Bicitra) – 30 mL PO 15 minutes prior to procedure is a well-tolerated and inexpensive regimen.
2.5.b.	Prevention and Management of Hypoxemia During Moderate Sedation	Supplemental oxygen should be considered for moderate sedation to reduce the frequency of hypoxemia and should be used if hypoxemia develops. If oxygen saturation drops below 93% a clinician **must** be informed. If oxygen saturation drops below 90% **must** initiate affiliate protocol for management of respiratory depression. (Refer to the ARMS Emergency Care Manual for sample protocol.)
2.6.d.	Local Anesthesia Toxicity[R2]	Symptoms of local anesthesia toxicity typically appear 1-5 minutes after injection but onset can range from as soon as 30 seconds to as long as 60 minutes. Initial manifestations affect CNS and include: ▪ Numbness around mouth and/or tongue ▪ Metallic taste in mount ▪ Dizziness/lightheadedness ▪ Difficulty focusing vision ▪ Tinnitus ▪ Disorientation ▪ Drowsiness This is often followed by symptoms of CNS depression including ▪ Muscle twitching ▪ Convulsions ▪ Loss of consciousness ▪ Coma ▪ Respiratory depression and arrest ▪ Cardiovascular depression and collapse Cardiovascular symptoms include: ▪ Chest pain ▪ Shortness of breath ▪ Palpitations ▪ Lightheadedness ▪ Diaphoresis ▪ Hypotension ▪ Syncope

2.7.b. Table: References

Section	R#	Reference
Throughout		American Society of Anesthesiologists. Distinguishing Monitored Anesthesia Care ("MAC") from Moderate Sedation/Analgesia (Conscious Sedation). October 16, 2013. https://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx. (accessed June 5, 2014).
Throughout		American Society of Anesthesiologists. Guidelines for Ambulatory Anesthesia and Surgery. October 16, 2013. https://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx (accessed June 5, 2014).
Throughout		American Society of Anesthesiologists. Guidelines for Office-Based Anesthesia. October 21, 2009. https://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx (accessed June 5, 2014).
Throughout		American Society of Anesthesiologists. Standards for Basic Anesthetic Monitoring. July 1, 2011. https://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx. (accessed June 5, 2014).
Throughout		American Society of Anesthesiologists. "Practice guidelines for sedation and analgesia by non-anesthesiologists." Anesthesiology, no. 96 (2002): 1004-1017.
Throughout		American Society of Anesthesiologists. Basic Standards for Preanesthesia Care. October 20, 2010. https://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx (accessed June 5, 2014).
Throughout		American Society of Anesthesiologists. Standards for Postanesthesia care. October 21, 2009. https://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx (accessed June 5, 2014).
Throughout		American Society of Anesthesiologists. Statement on Nonoperating Room Anesthetizing Locations. October 16, 2013. https://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx (accessed June 5, 2014).
FYI	R2	Kapitanyan, R. "Local anesthetic Toxicity." Medscape. n.d. http://emedicine.medscape.com/article/1844551-overview (accessed June 5, 2014).
2.5.a.	R1	Wiebe E. et al. "Can we safely avoid fasting before abortions with low-dose procedural sedation? A retrospective cohort chart review of anesthesia-related complications in 47,748 abortion." Contraception, no. 87 (2013): 51-54.
Throughout		Wilson, L. et al. "Low-dose fentanyl and midazolam in outpatient surgical abortion up to 18 weeks of gestation." Contraception, no. 79 (2009): 122-128.

2.7.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIIC	CI Taking Care of Yourself After Sedation CIIC Sedation	Part 3, Chapter 02_02

2.7.d. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	American Society of Anesthesiologists (ASA) Resources ✓ Ambulatory Anesthesia and Surgery, Guidelines for ✓ Office-Based Anesthesia, Guidelines for ✓ Qualifications of the Anesthesia Provider in the Office-Based Setting ✓ Basic Anesthetic Monitoring, Standards for ✓ Post-Anesthesia Care, Standards for ✓ Granting Privileges for Administration of Moderate Sedation to Practitioners Who Are Not Anesthesia Professionals, Statement on ✓ Non-Operating Room Anesthetizing Locations, Statement on	

CHAPTER 3: BREAST SERVICES

Revised June 2014

Chapter 3 Table of Contents

CHAPTER 3: BREAST SERVICES

Revised June 2014

3.1 CLIENT EDUCATION AND INFORMED CONSENT

3.1.1 Requirements

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in the record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

3.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	May give	**Must** offer
Breast Referral Information Sheet				●	
CI Breast Engorgement and Mastitis			●		
CI Breast Health – What You Can Do			when routine screening is performed		
CIIC Breast Cyst Aspiration		●	●		
Release when test/service/consultation will not be obtained as recommended		Once			
Request for Surgery or Other Special Services		●			●
Written information about any medication dispensed (package insert may be used)			●		

3.2 BREAST CANCER SCREENING SERVICES

3.2.1 History

I. As part of the well woman visit, inquiry **must** include the following components
   A. History of lobular carcinoma in situ (LCIS) and/or atypical hyperplasia of breast
   B. History of therapeutic thoracic radiation (e.g. for treatment of Hodgkin's lymphoma)
   C. Risk assessment for breast cancer using the Breast Cancer Risk Screening Questionnaire (BRSQ) — when BRSQ is positive, genetic counseling **must** be recommended

✓ FYI – Risk Assessment

✓ FYI – Positive on BRSQ

3.2.2 Breast Exam

I. Required components of CBE include
   A. Inspection
   B. Palpation

✓ See Administrative Chapter 5 Medical Records, Documentation, and Reporting Requirements

3.2.3 Breast Screening Recommendations for Average Risk Women

I. For women age 21 to 39 **must**
   A. Recommend CBE every 1 to 3 years as part of well woman visit
   B. Encourage BSA

II. For women age ≥ 40 **must**
   A. Recommend annual mammogram
   B. Recommend CBE annually as part of well woman visit
   C. Encourage BSA

✓ FYI – When to Discontinue Screening Mammography

III. Breast MRI is not recommended for screening in average risk populations.

3.2.4 Breast Screening Recommendations for Increased Risk Women

✓ FYI – Types of Mammography

I. For women assessed to be at increased risk by genetic counselor, **must** recommend screening and/or refer per genetic counselor or breast expert/consultant recommendations.

II. For women with known BRCA mutation, **must** refer to gynecologist for ongoing management of ovarian and tubal cancer risk.

III. For women with a personal history of LCIS or atypical lobular or ductal hyperplasia of breast **must**
   A. Recommend annual mammogram
   B. Perform CBE every 6-12 months
   C. Encourage self-breast awareness
   D. Consider referral for risk reduction methods (e.g. tamoxifen x 5 years in women age ≥ 35)
   E. Refer to a breast specialist, unless already done. If already done, follow those screening recommendations

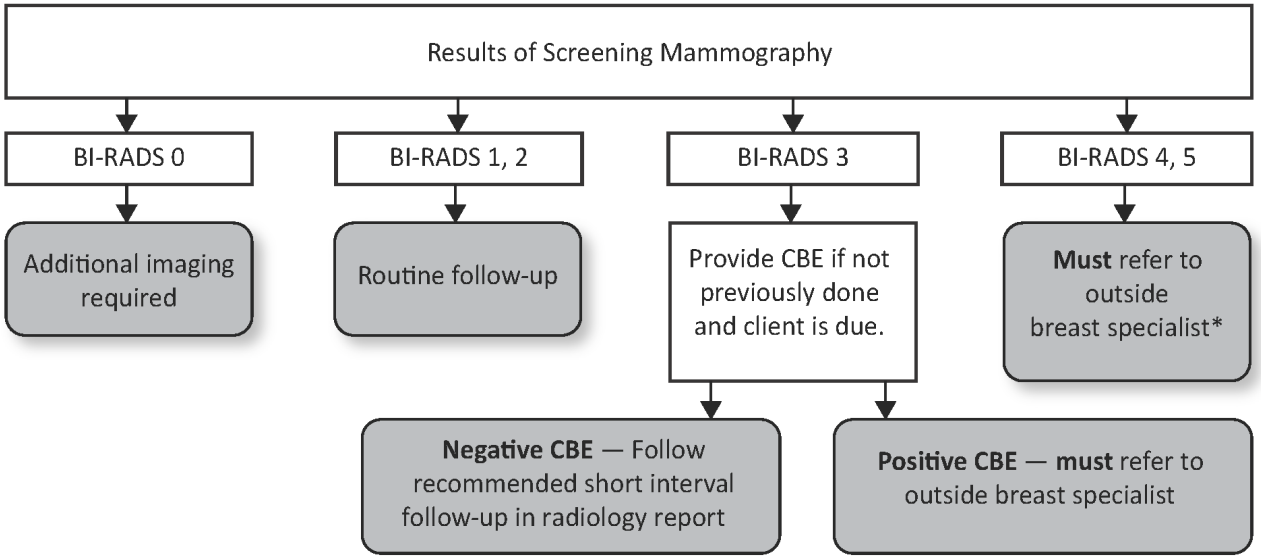
IV. For women with history of therapeutic thoracic radiation (e.g., for treatment of Hodgkin's lymphoma) **must**
   A. Recommend initiation of annual mammography 8-10 years after radiation or at age 25 whichever occurs LATER
   B. Perform CBE every 6-12 months
   C. Encourage BSA
   D. recommend breast MRI as adjunct to mammography starting same year as mammography

3.2.5 Management of Mammography Screening Results

✓ FYI — Breast Tissue Density and Screening for Breast Cancer

3.2.a. Algorithm: Results of Screening Mammography

✓ FYI — American College of Radiology Breast Imaging and Data Systems (BI-RADS)



*Diagnostic imaging and/or breast biopsy may be ordered at the time the referral is made in order to facilitate the evaluation

3.2.6 Management of Abnormal Breast Findings

Abnormal breast findings **must** be managed according to algorithms below.

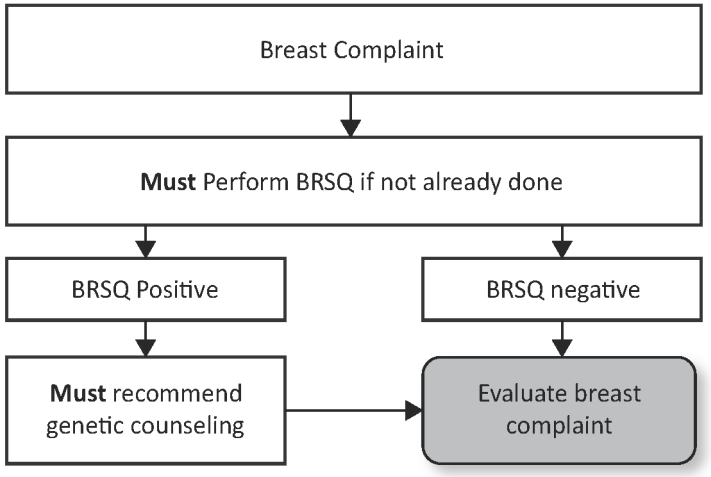
Important Information – Conditions Requiring Immediate Referral Out of the Affiliate

- unexplained inflammatory appearance of the breast skin
- any mass in a postmenopausal woman
- skin dimpling

✓ FYI – Risk Assessment

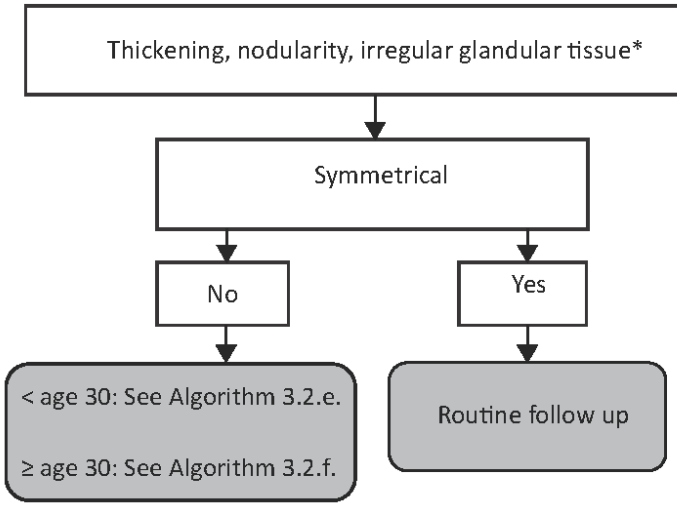
3.2.b. Algorithm: BRSQ Screening for Women with Breast Complaints

✓ FYI — Screen Positive on BRSQ



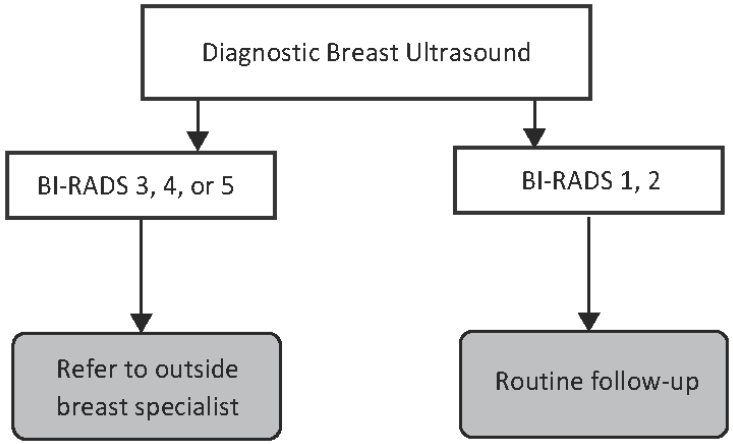
3.2.c. Algorithm: Area of Thickening, Nodularity or Irregular Glandular Tissue

✓ FYI — Area of Thickening, Nodularity, or Irregular Glandular Tissue

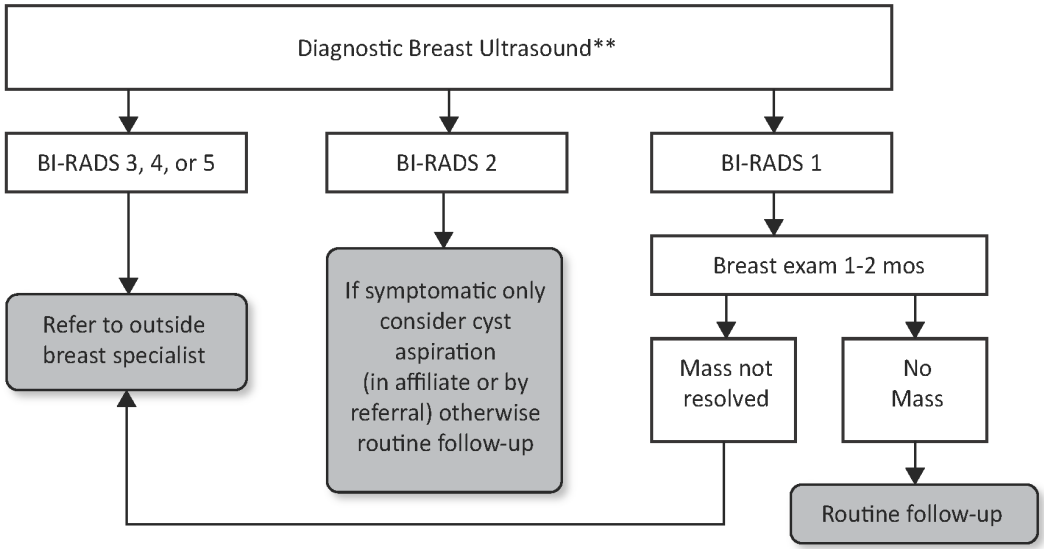


*May schedule CBE with another affiliate provider prior to referring for diagnostic imaging.

3.2.d. Algorithm: New-Onset Nipple Inversion in Woman <age 30



3.2.e. Algorithm: Single Palpable Mass* in Women < age 30

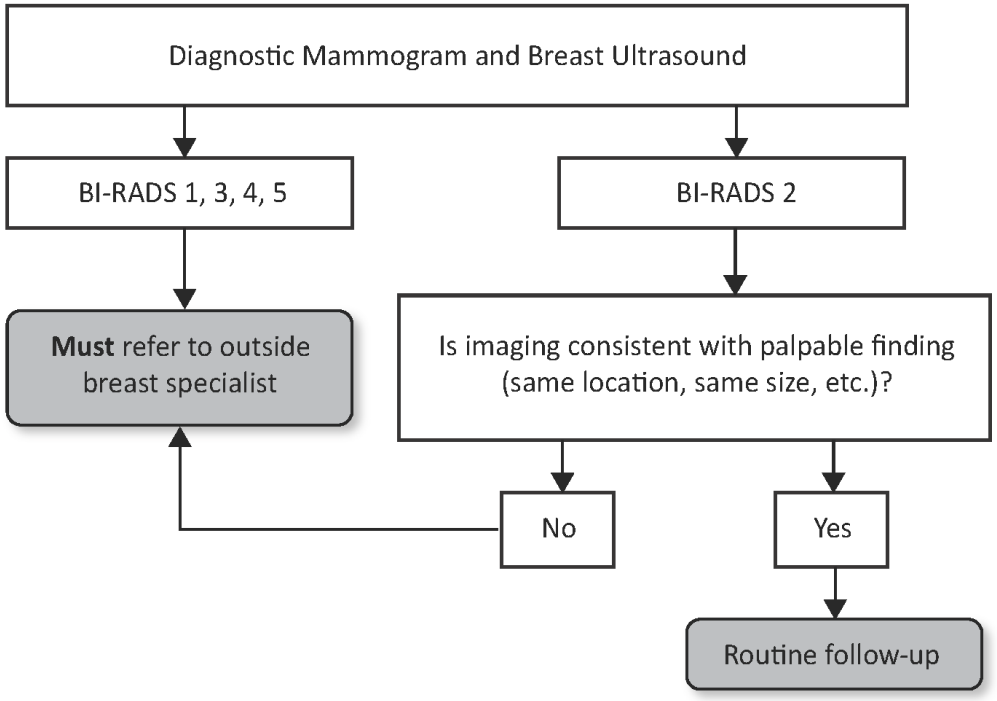


*If client reports mass was evaluated by another provider and found to be benign, **must** request pathology report and/or mammogram report. If benign per pathology or this specific mass is BI-RADS 2, evaluation may be considered complete and no further action required. If documentation unobtainable or results not consistent with a benign finding, follow this algorithm

**May schedule CBE with another affiliate provider prior to referring for diagnostic imaging.

3.2.f. Algorithm: Single Palpable Mass or New-Onset Nipple Inversion in Woman ≥ age 30*, **

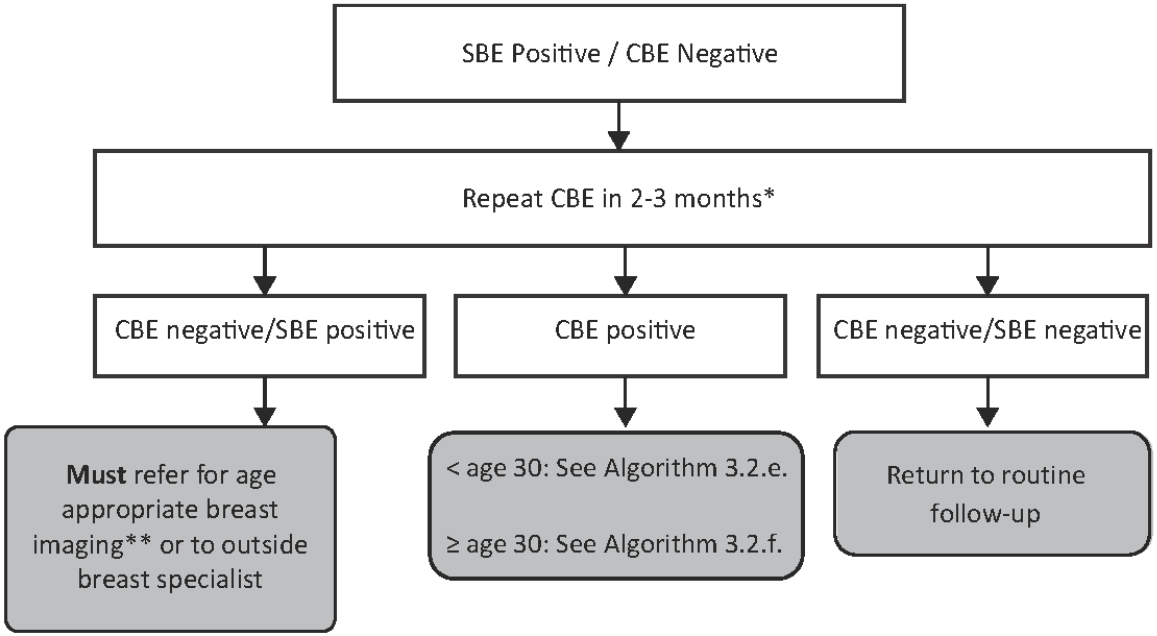
✓ FYI — Non-simple Cyst



* Any mass in a post-menopausal woman **must** be referred to an outside breast specialist.

If client reports mass was evaluated by another provider and found to be benign, **must request pathology report and/or mammogram report. If benign per pathology or this specific mass is BI-RADS 2, evaluation may be considered complete and no further action required. If documentation unobtainable or results not consistent with a benign finding, follow this algorithm

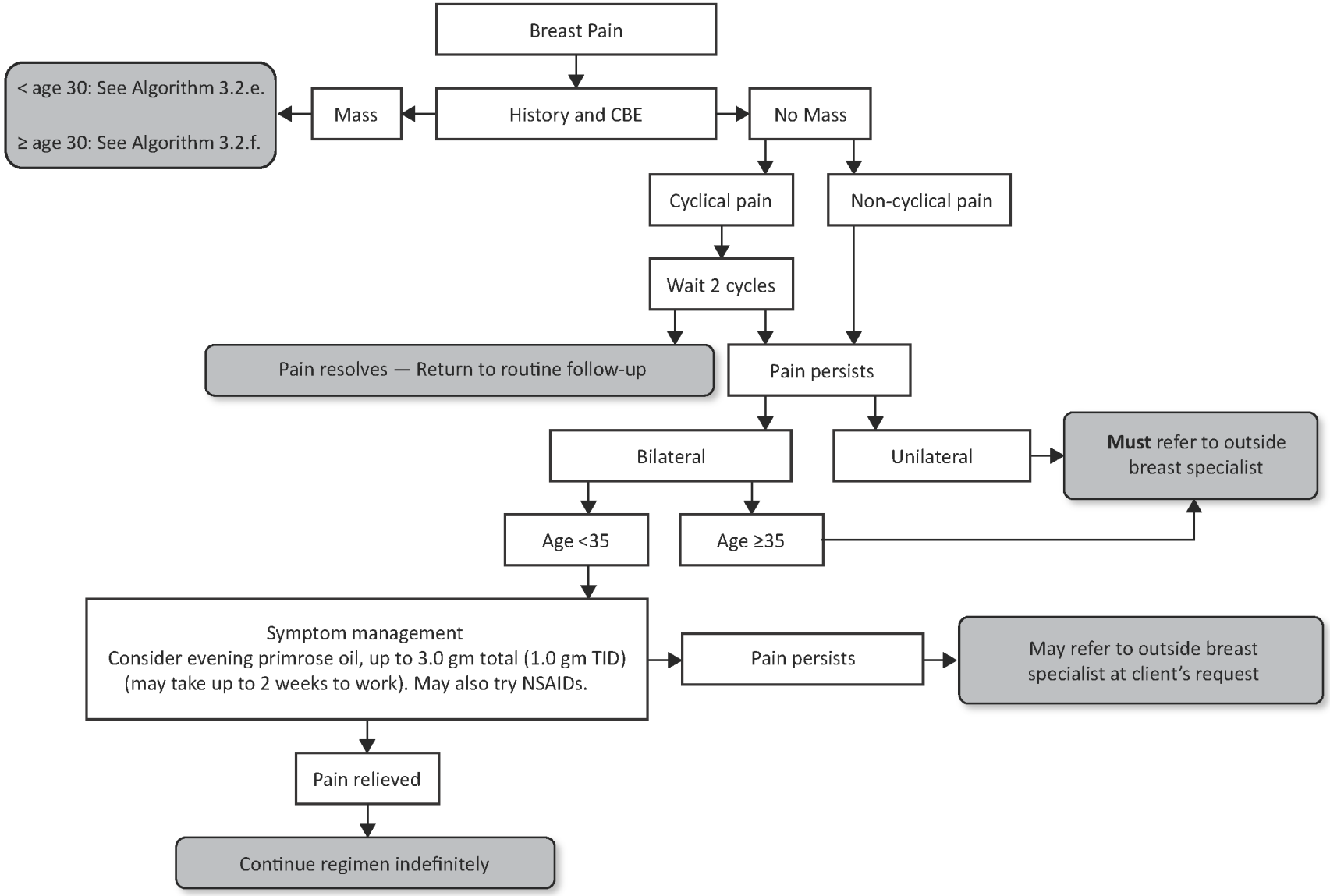
3.2.g. Algorithm: Palpable Mass by Self Breast Exam (SBE)/Negative Clinical Breast Exam (CBE)



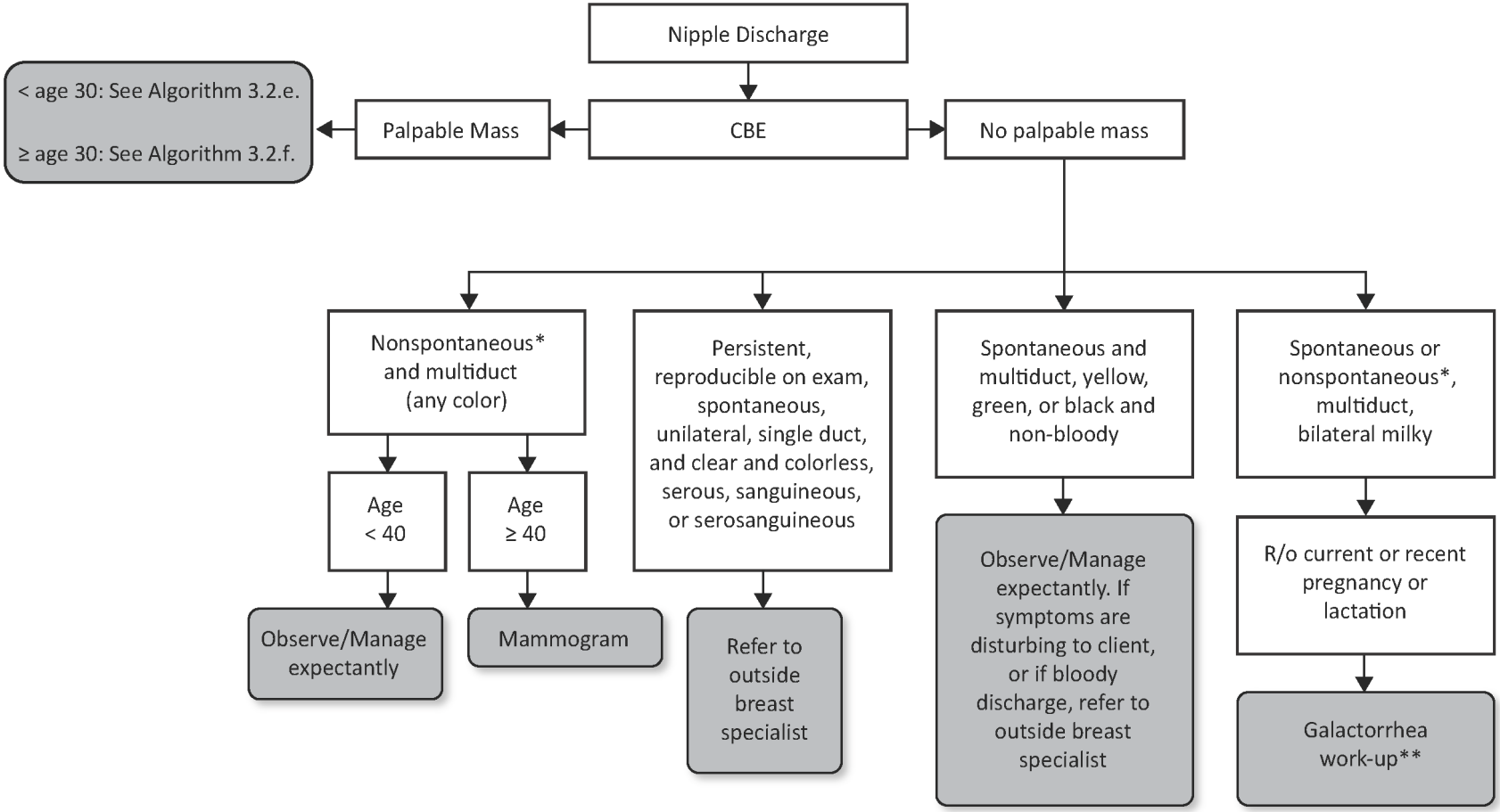
*Or if client desires, may order age appropriate breast imaging and follow 3.2.e. and 3.2.f.

**Breast ultrasound if < 30 years; Ultrasound + diagnostic mammography if ≥ 30 years

3.2.h. Algorithm: Breast Pain



3.2.i. Algorithm: Nipple Discharge

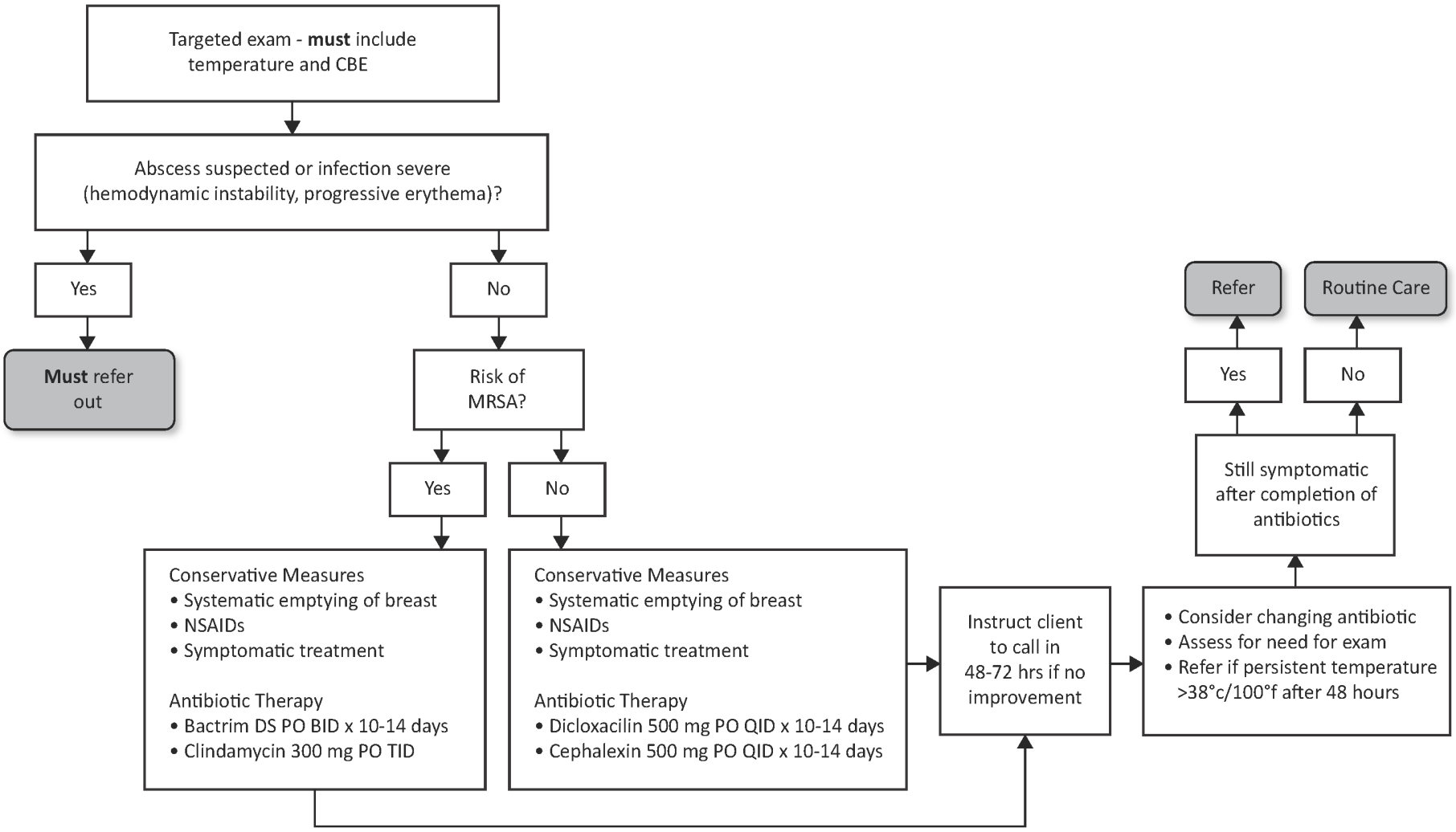


*If nonspontaneous discharge, educate client to stop compression of breast and report any spontaneous discharge.

**See Chapter 8.4 Galactorrhea and Hirsutism

3.2.j. Flow Diagram: Mastitis

✓ FYI — Postpartum Breast Conditions



3.3 ADDITIONAL INFORMATION

3.3.a. Table: For Your Information

Section	Topic	Detail
3.2.1 3.2.b.	Positive on BRSQ	For women who screen positive on the BRSQ, follow age-appropriate, average risk screening recommendations pending availability of genetic counseling consultation.
3.2.3	When to Discontinue Screening Mammography[R1]	Current evidence is insufficient to assess the value of screening mammography in women ≥ 75 years old. Therefore, the decision to discontinue screening mammography in women ≥ 75 years old should be made in conjunction with each individual client, with consideration given to medical comorbidity and life expectancy.
3.2.1 3.2.6	Risk Assessment	Estimation of breast cancer risk for an individual woman typically begins with an initial assessment of personal and familial/genetic factors associated with increased breast cancer risk for the purpose of determining whether more extensive genetic risk assessment and counseling should be undertaken. **Breast Cancer Risk Screening Questionnaire (BRSQ)** Using a series of yes/no questions, the BRSQ stratifies risk into two categories: those at average risk and those needing genetic counseling for a more comprehensive risk assessment. For those clients needing genetic counseling, risk category and screening recommendations are determined by the genetic counselor. The BRSQ begins by asking the client the following two questions (BRSQ-1): a. Have you had breast or ovarian cancer? b. Has a blood relative had breast or ovarian cancer? If the client answers “no” to both questions, she is determined to be at average risk. If the client answers “yes” to either of the questions in BRSQ-1, the clinician administers a series of follow up questions (BRSQ-2a and/or BRSQ-2b) pertaining to the client’s personal and family histories of cancer. If the client answers “yes” to any question on BRSQ-2a or BRSQ-2b, genetic counseling is recommended. If the client doesn’t know the answer to any question on the BRSQ and genetic counseling is not otherwise recommended, efforts should be made to clarify the response (i.e. obtain previous medical records, encourage the client to query appropriate family members about their medical history). She should follow average risk

Section	Topic	Detail
		screening recommendations in the interim. **Other Risk Factors** Women with a personal history of the following factors are at increased risk for breast cancer, independent of the results of the BRSQ ▪ LCIS ▪ Atypical hyperplasia of the breast ▪ Therapeutic thoracic radiation (e.g. for treatment of Hodgkin's lymphoma)
3.2.4	Types of Mammography	▪ Digital Mammogram – digital mammography has increased sensitivity in women under the age of 50 compared to film screen mammography. ▪ 3-D Mammogram (tomosynthesis) — provides three-dimensional images of the breast by using a technology similar to CT scans, or computed tomography. It is an alternative method but is not a requirement. ▪ Thermography — a form of infrared imaging. **Not** an FDA approved independent screening method for breast cancer.
3.2.5	Breast Tissue Density and Screening for Breast Cancer[R2, R3]	While dense breasts are associated with a small increased risk of breast cancer and do limit the sensitivity of mammography, the NCCN and ACOG concludes that there is insufficient evidence to support routine supplemental screening with MRI or ultrasound in women with dense breasts and no other risk factors. Decisions to refer for supplemental screening should be made on a case-by-case basis, after careful consideration of a client's level of risk. In addition, some states have specific statutes regarding disclosure, education and management of women with dense breasts.
3.2.a.	*American College of Radiology* Breast Imaging and Data Systems (BI-RADS)	**0** Assessment incomplete — additional imaging necessary **1** Negative **2** Benign findings **3** Probably benign findings — short interval follow-up suggested (every 6 to 12 months x 2-3 years) **4** Suspicious abnormality — biopsy should be considered **5** Highly suspicious of malignancy—appropriate action should be taken **6** Known biopsy – proven malignancy—appropriate action should be taken
3.2.c.	Area of Thickening, Nodularity, or Irregular Glandular Tissue	An area of thickening, nodularity, or irregular glandular tissue is increased density of breast tissue, most often due to hormonal changes, which causes the breast to feel lumpy in texture.

Section	Topic	Detail
3.2.f.	Non-Simple Cyst[R3]	▪ Complicated — round, circumscribed mass containing low level echoes, without vascular flow fulfilling most but not all criteria for simple cyst. ▪ Complex — contains both cystic and solid components.
3.2.j.	Postpartum Breast Conditions[R4]	Breast engorgement — Postpartum engorgement usually occurs 2 to 3 days after delivery; presents with bilaterally full, hard, tender breasts; is not associated with symptoms or signs of infection such as localized tenderness or redness, and rarely is associated with a temperature >38°C (100.4°F). Postpartum mastitis is an infection of the breast, usually unilateral, occurring in about two to three percent of nursing mothers. Signs and symptoms usually develop from one to four weeks postpartum and often include localized or generalized breast tenderness, redness, and warmth. Systemic symptoms such as chills, malaise, and fatigue are common and fevers commonly exceed 38°C (100.4°F). Mastitis usually is caused by *Staphylococcus aureus*, which is normally carried in the nasopharynx of nursing infants. Newborns and nursing mothers may acquire a penicillin/methicillin-resistant strain of the bacteria, which is an important consideration when prescribing an antibiotic.

3.3.b. Table: References

Section	Reference
R2	ACOG. Committee Opinion No. 593: Management of women with dense breasts diagnosed by mammography. Obstetrics & Gynecology;123:910-911.
R4	Dixon JM. Lactational mastitis. UpToDate. September 16, 2013. http://www.uptodate.com/contents/lactational-mastitis?source=search_result&search=mastitis&selectedTitle=1%7E55 Accessed on April 11, 2014
R1	National Comprehensive Cancer Network. Genetic/Familial High-Risk Assessment: Breast and Ovarian. Version 1.2014. http://www.nccn.org/professionals/physician_gls/pdf/genetics_screening.pdf Accessed on April 11, 2014
R3	National Comprehensive Cancer Network. Breast Cancer Screening and Diagnosis. Version 2.2013. http://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf Accessed on April 11, 2014

3.3.c. Table: Additional Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIIC	CI Breast Engorgement and Mastitis CI Breast Health – What You Can Do CIIC Breast Cyst Aspiration	Part 3, Chapter 02_03
Client Education	Breast Referral Info Sheet	Part 3, Chapter 02_03

3.3.d. Table: Additional Resources for Staff

Type	Resource	Location
Job Tools	✓ National Association of Genetic Counselors' Directory of Genetic Counselors ✓ BRSQ-FAQ about the BRSQ 2013	
Training	✓ Clinical Breast Examination Toolkit ✓ Clinical Breast Examination Workbook	
	CAL Courses Breast Cancer Screening Series Kelly's Story: Anatomy of a Breast Cancer Case	
Sample Forms	Breast Cancer Risk Assessment Questionnaire (BRSQ)	Part 3, Chapter 02_03

CHAPTER 4: CERVICAL CANCER SCREENING AND MANAGEMENT OF CERVICAL ABNORMALITIES

Revised January 2015

CHAPTER 4 Table Of Contents

4.1 CLIENT EDUCATION AND INFORMED CONSENT

4.1.a. Requirements

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

4.1.b. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer	May give
CI Pap and HPV Test					●
CIIC Colposcopy and Biopsy		●	●		
CIIC Cryotherapy		●	●		
CIIC Endometrial Biopsy		●	●		
CIIC LEEP		●	●		
Release When Test/Service/Consultation Will Not Be Obtained As Recommended		Once			
Request for Surgery or Other Special Services		●		●	

4.2 CERVICAL CANCER SCREENING

4.2.a. Table: Cervical Cancer Screening Intervals for Women without Risk Factors[R5]

Age/Population*	Screening Method/Timing	Comments
< 21 Years	None	No screening indicated ✓ FYI — Managing Women Who Had Paps Before 21
21-24 Years	Pap every 3 years	
25-29 Years	Pap every 3 years **OR**	
	HPV testing every 3 years (no Pap)	HPV test **must** be FDA approved for primary screening

Age/Population*	Screening Method/Timing	Comments
30-64 Years ✓ FYI — First Time Screening in Women Older Than 30	Pap every 3 years **OR**	
	HPV testing every 3 years (no Pap) **OR**	HPV test **must** be FDA approved for primary screening
	Co-testing (Pap plus HPV) every 5 years	
65+ Years		
▪ History of adequate negative prior screening**	None	No screening indicated
▪ History CIN 2,3	After initial management is completed, continue screening for at least 20 years	See screening women with risk factors, below.
Post-hysterectomy, cervix present	Routine screening per age-specific recommendations	
Post-hysterectomy, cervix absent		
▪ Hysterectomy for benign reasons	None	
▪ Hysterectomy for CIN 2,3	After initial management is completed, continue screening for at least 20 years	See screening women with risk factors, below
History of cervical cancer†	▪ If disease free for 5 years, continue screening with Pap every year or co-testing every 2 to 3 years (expert opinion) ▪ Should perform rectovaginal exam at each cervical cancer screening visit	

*Follow age-specific screening guidelines for women who have received the HPV vaccine.

**Adequate negative prior screening is defined as 3 consecutive negative Pap results or 2 consecutive negative co-tests (Pap plus HPV) within the last 10 years before ceasing screening, with the most recent test being performed within the past five years[R1]. Cannot exit screening at age 65 if Pap at that time is ASC-US and HPV-negative[R2]. See below for management.

†Clients with cervical cancer **must** be referred out for follow up for at least 2 years by an oncologist or a physician experienced in gynecologic cancer. If there is not evidence of recurrence after 2 years, a gynecologist, within or out of affiliate, **must** follow for 3 additional years.

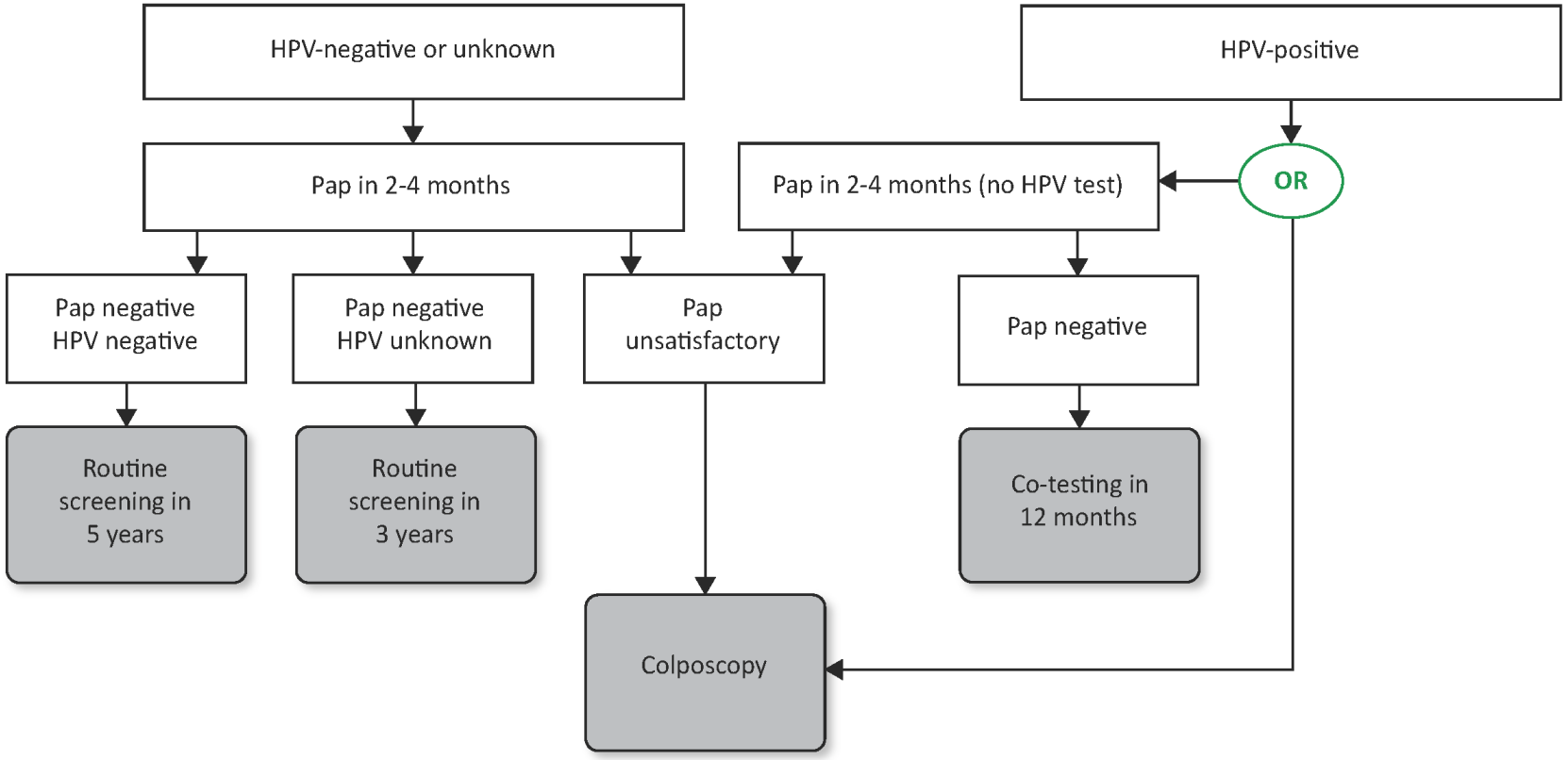
4.2.b. Table: Cervical Cancer Screening Intervals for Women with Risk Factors

Risk Factors	Intervals		Comments
History of CIN 2, 3, AIS	After initial management is completed, **must** continue screening for at least 20 years		
HIV Positive or Immunosuppressed	**< age 30** Pap every year	**≥ age 30** If co-testing normal, intervals may be extended to 2 to 3 years (expert opinion)	
DES Exposure	• Pap of cervix every year • Inspection and palpation of vaginal walls every year		**Initial Screening – must include** • Education about potential reproductive risks • Palpation of vaginal walls • Pap test of cervix and all 4 vaginal walls Consult with medical director or director of colposcopy services if any abnormality is noted

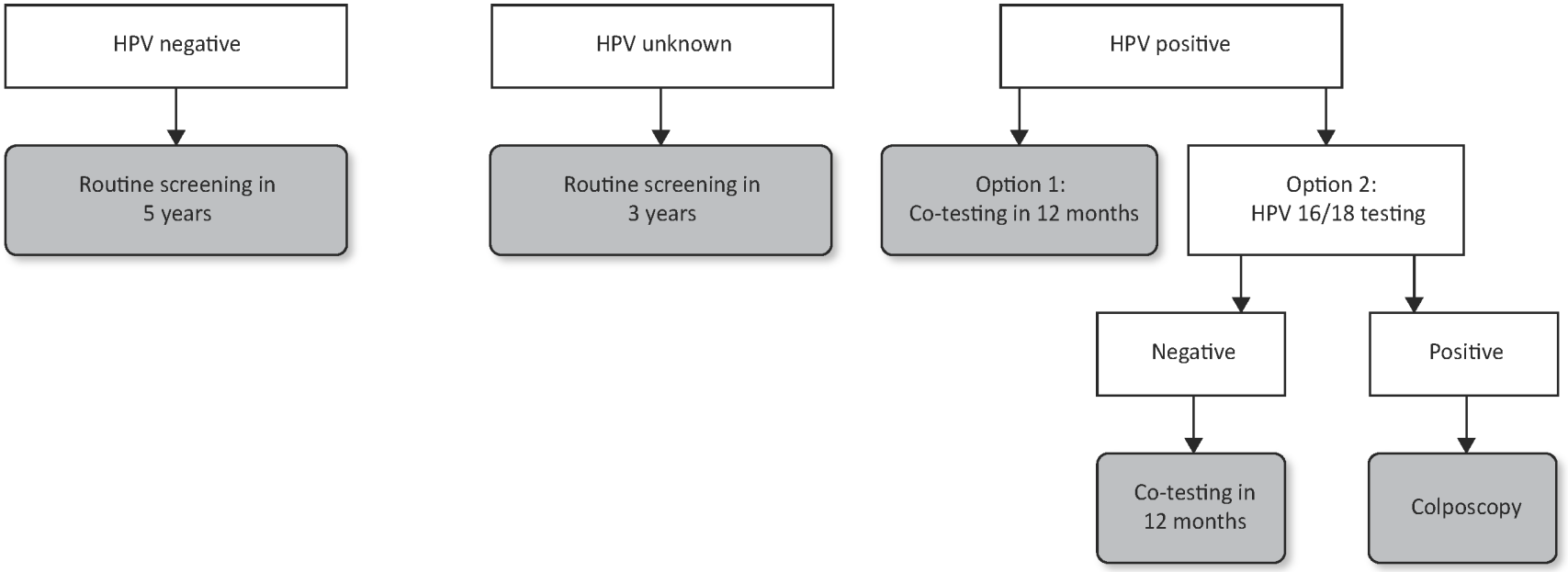
✓ FYI — General Information and Definitions

4.3 MANAGEMENT OF UNSATISFACTORY PAP, NEGATIVE PAP WITH LIMITING FACTORS / ENDOMETRIAL CELLS, AND HPV POSITIVE RESULTS

4.3.a. Algorithm: Pap Unsatisfactory for Evaluation (no cytologic diagnosis provided)

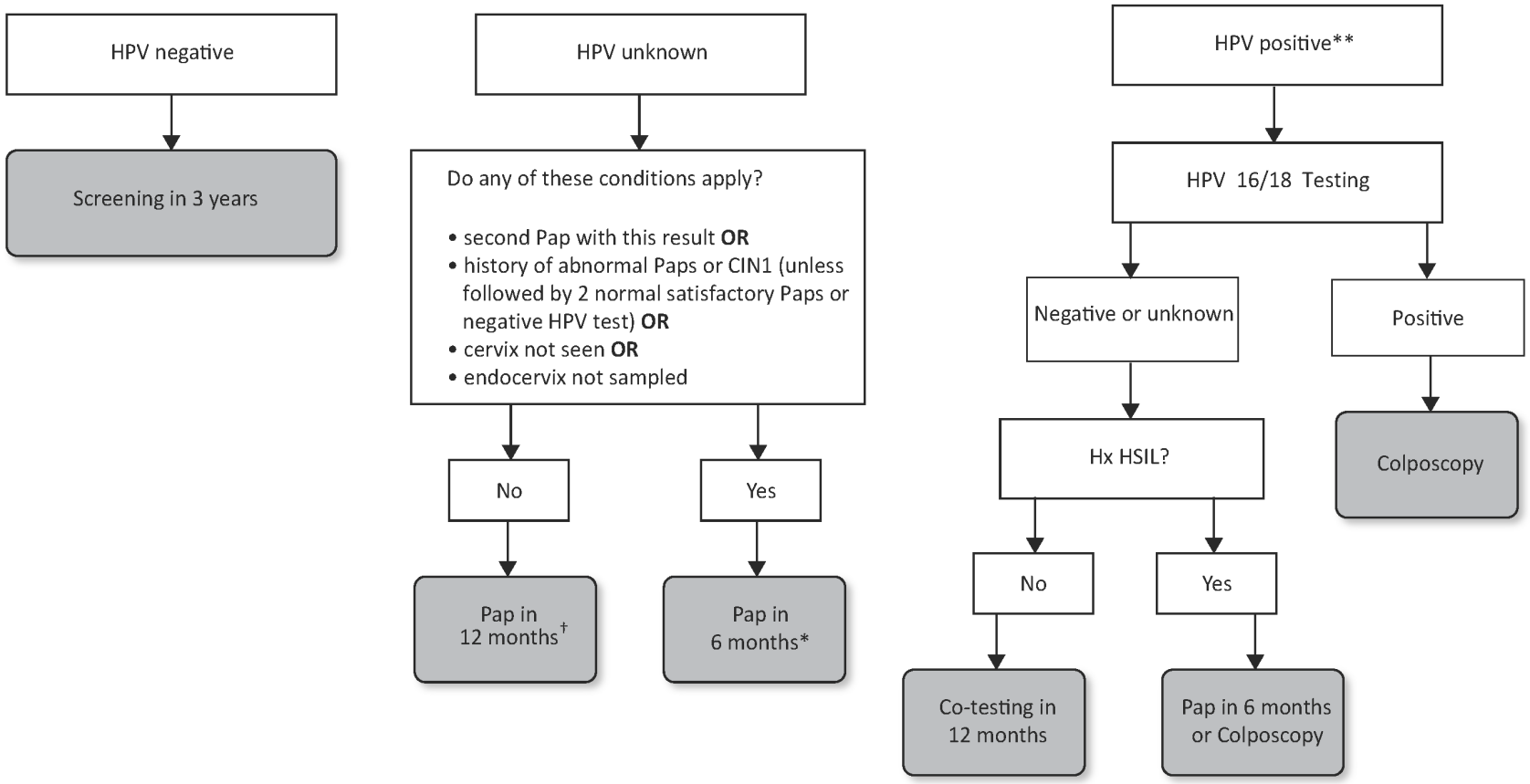


4.3.b. Algorithm: Negative Pap with Endocervical cells or Transformation Zone Components Absent



Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.3.c. Algorithm: Negative Pap with Partially Obscuring Inflammation or Blood



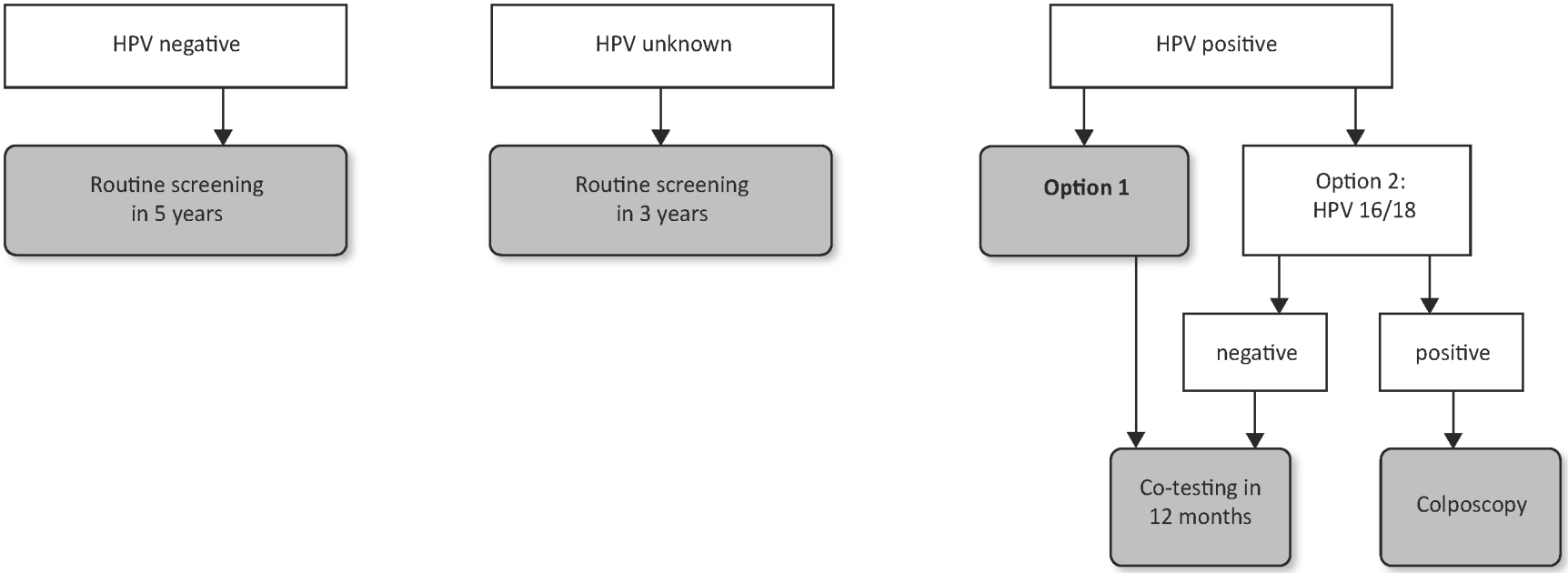
*If repeat Pap same, management options include repeat in 6 months, repeat with liquid-based Pap (less likely to have obscuring components), test for HPV, or refer for colposcopy

**Expert opinion

† If client pregnant, repeat Pap postpartum.

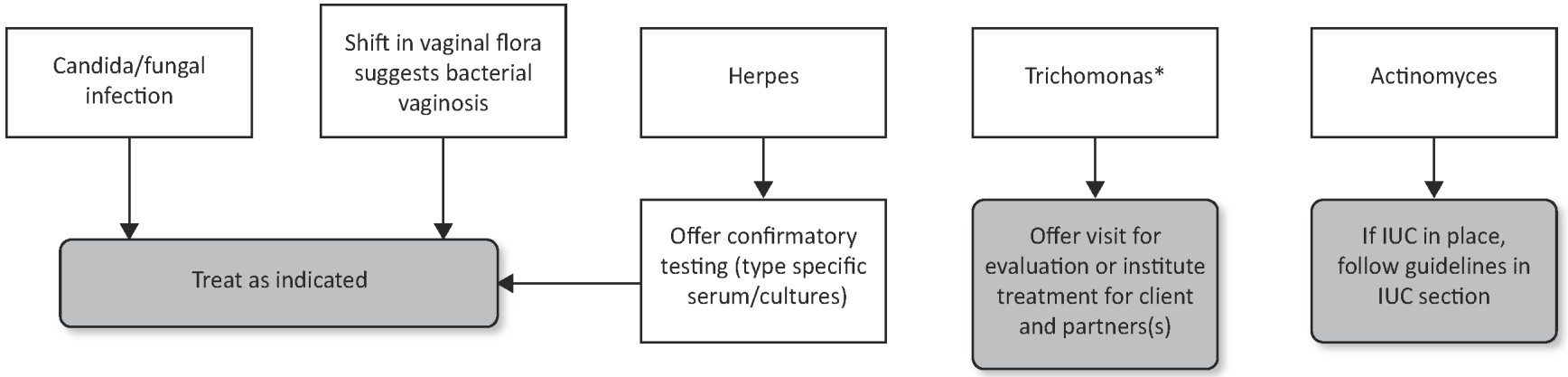
Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.3.d. Algorithm: Negative Pap with Borderline Cellularity or Partial Air Drying



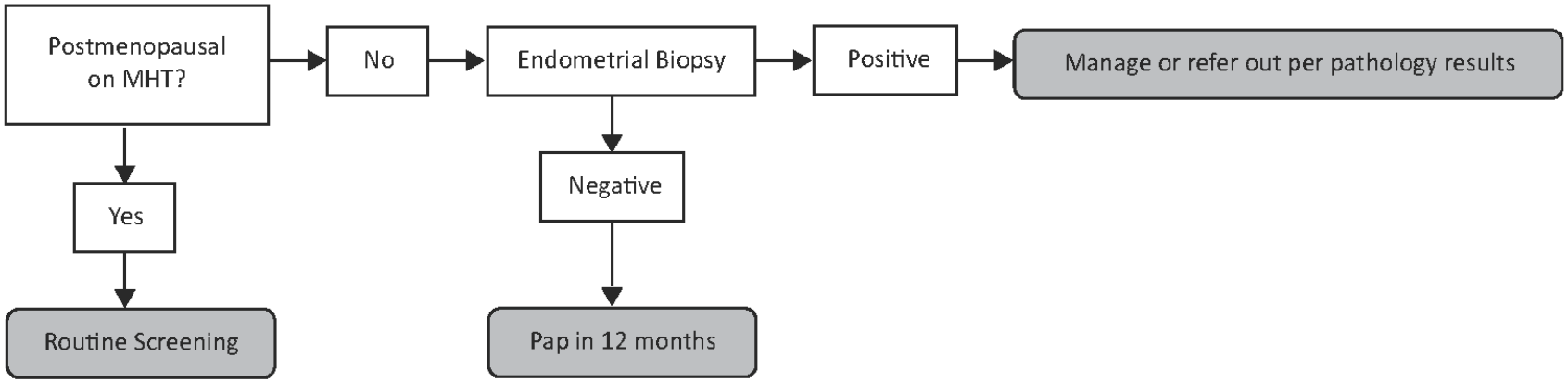
Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.3.e. Algorithm: Negative Pap with Specific Organism Identified



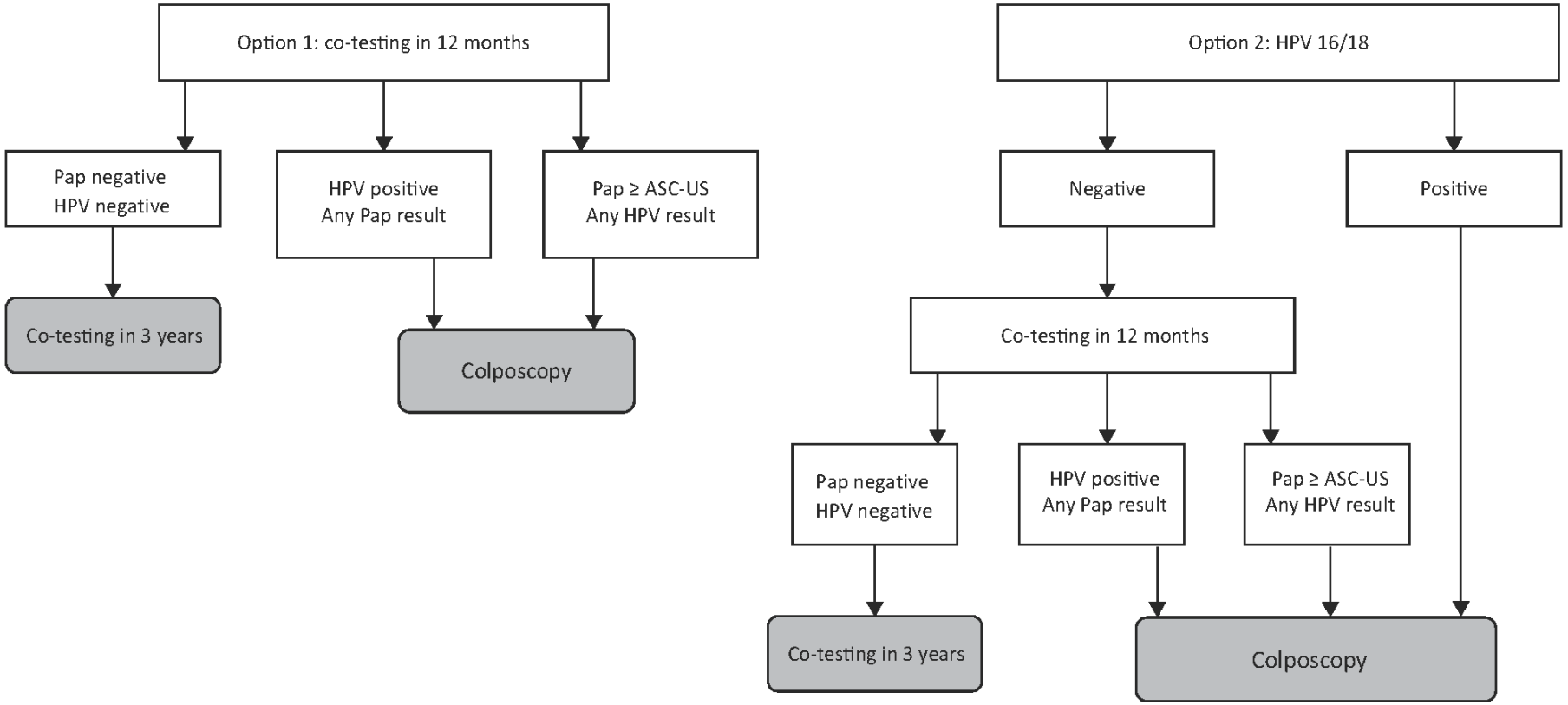
*Diagnosis is reliable.

4.3.f. Algorithm: Negative Pap with Endometrial Cells Present*



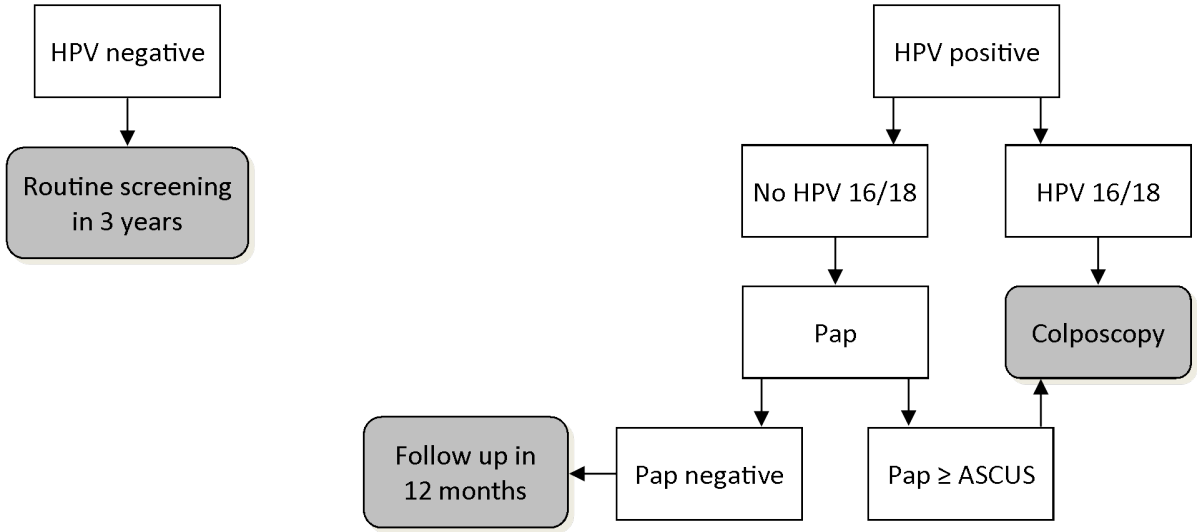
*Premenopausal or post-hysterectomy, routine follow-up.

4.3.g. Algorithm: Pap Negative and HPV Positive



Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

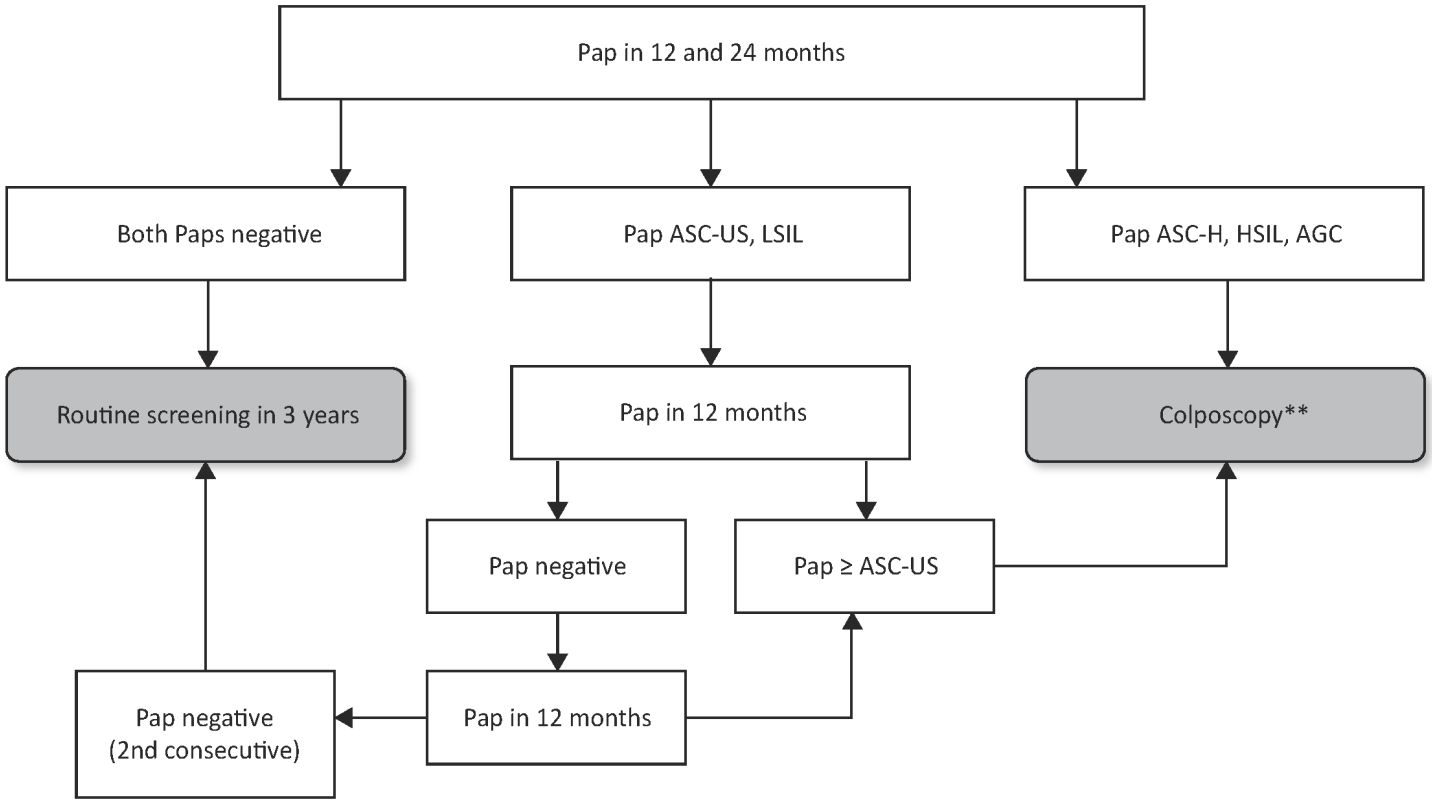
4.3.h. Algorithm: Primary HPV Screening (no Pap)[R5]



4.4 MANAGEMENT OF PAPS WITH SQUAMOUS CELL ABNORMALITIES

4.4.a. Algorithm: Pap ASC-US in Women 21-24*

- ✓ FYI — ASC-US Rates
- ✓ FYI — ASC-US Rates in Women 21-24

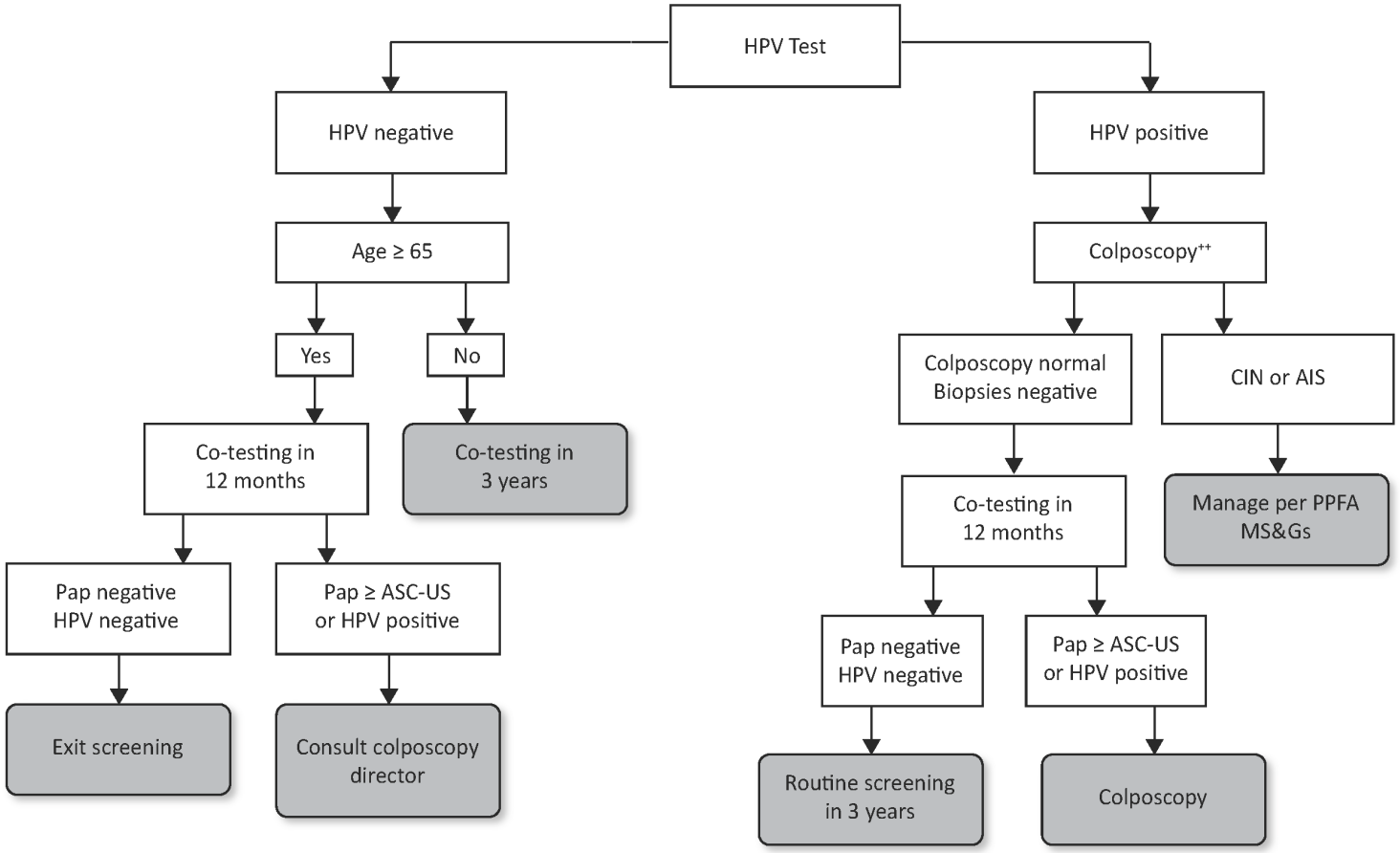


*Pregnancy – repeat Pap 6 weeks postpartum and 12 months later.
**ECS should be performed if no lesion seen or colposcopy is unsatisfactory.

Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.4.b. Algorithm: Pap ASC-US in Women 25 and Older*,**,†

✓ FYI — ASC-US Rates



*Postmenopausal women may be offered a course of estrogen cream. If prescribed, it should be completed 1 to 2 weeks prior to repeating the Pap.

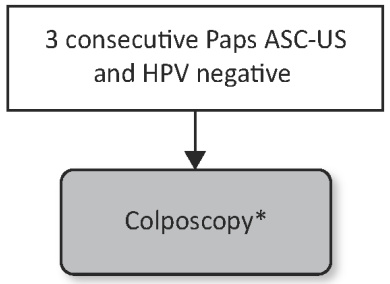
**If no HPV result, see ASCCP guidelines for management

†Pregnancy – same management as non pregnant but if HPV positive, acceptable to defer colposcopy until 6 weeks postpartum.

††ECS should be performed if no lesion seen or colposcopy is unsatisfactory.

Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

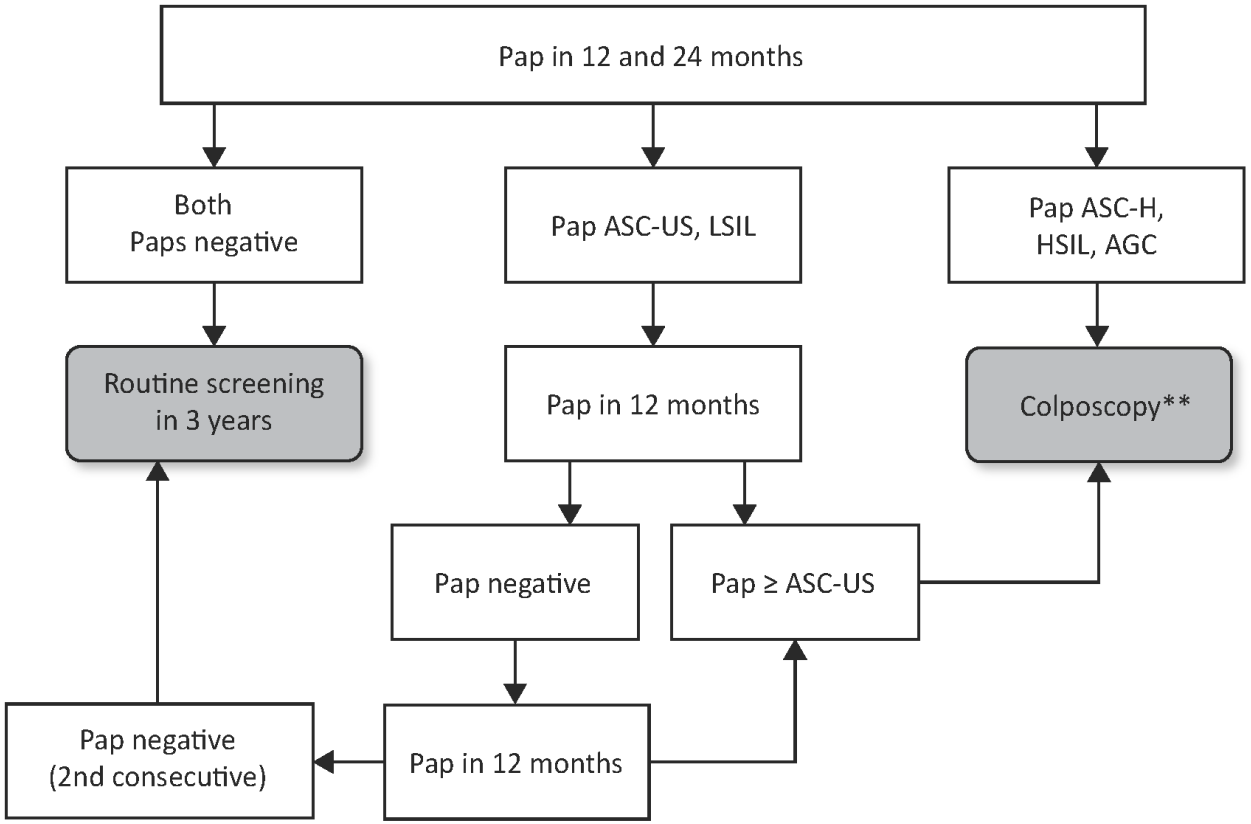
4.4.c. Algorithm: 3 Consecutive Pap ASC-US and HPV negative



*ECS should be performed if no lesion seen or colposcopy is unsatisfactory.

Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.4.d. Algorithm: Pap LSIL in Women 21-24*

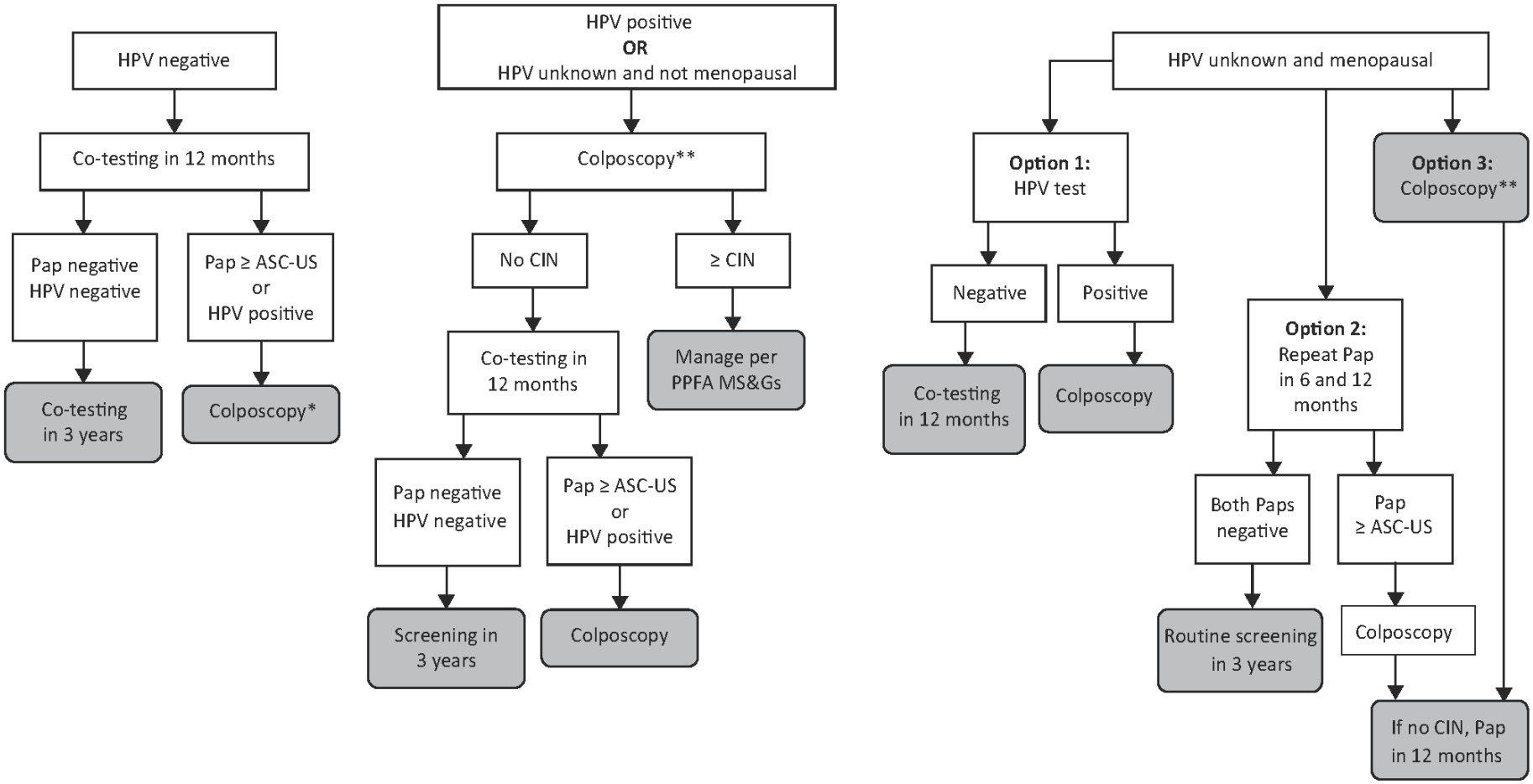


*Pregnancy – same management as non-pregnant but if colposcopy not done by third trimester, may defer until postpartum.
**ECS should be performed if no lesion seen or colposcopy is unsatisfactory. If ECS is needed, postpone until postpartum in pregnant women.

Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.4.e. Algorithm: Pap LSIL in Women 25 and Older*

✓ FYI — LSIL cannot r/o HSIL

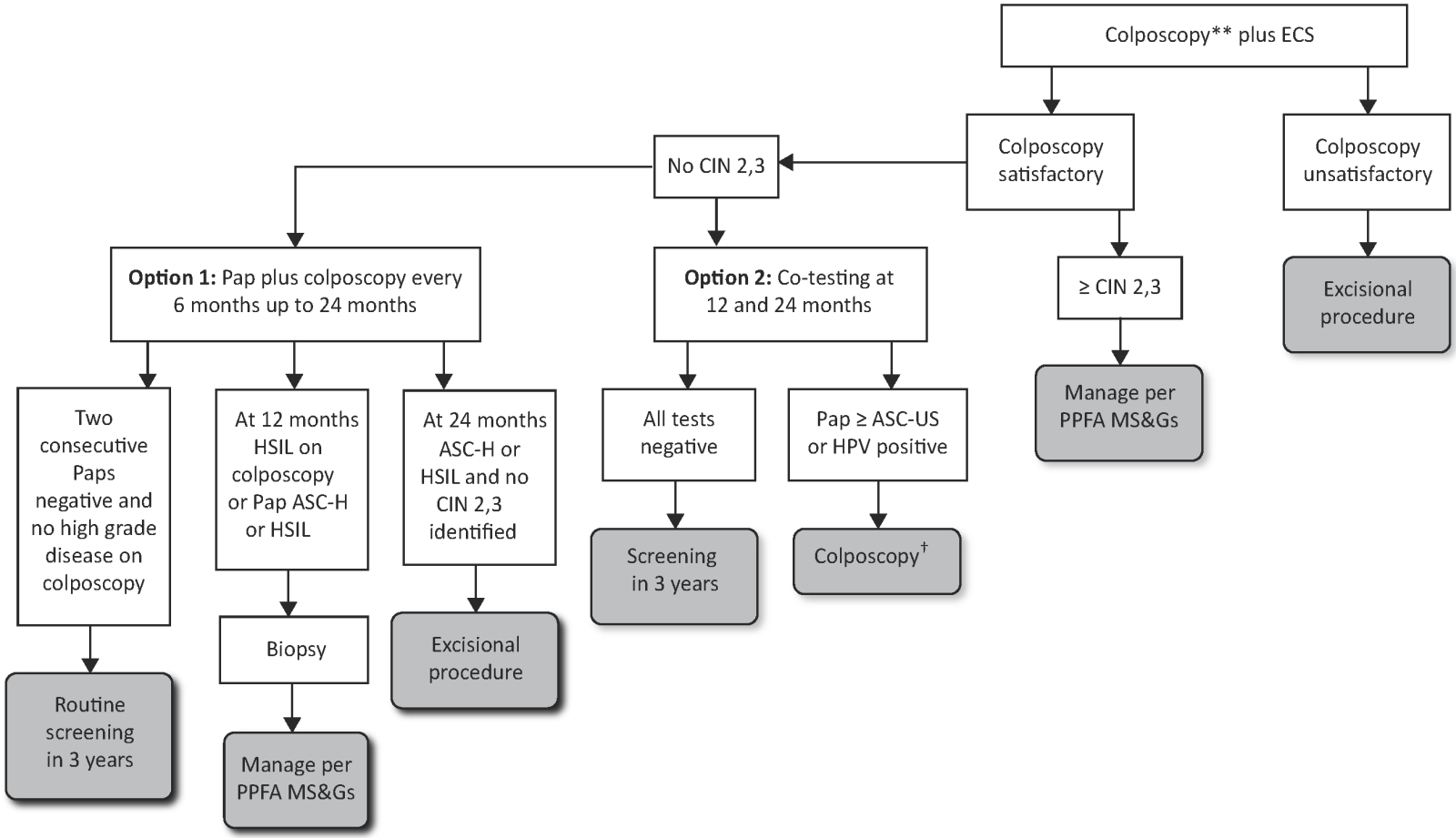


*Pregnancy – same management as non-pregnant but if colposcopy not done by third trimester, may defer until postpartum.

**ECS should be performed if no lesion seen or colposcopy unsatisfactory. If ECS is needed, postpone until postpartum in pregnant women.

Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.4.f. Algorithm: Pap ASC-H in Women 21-24*



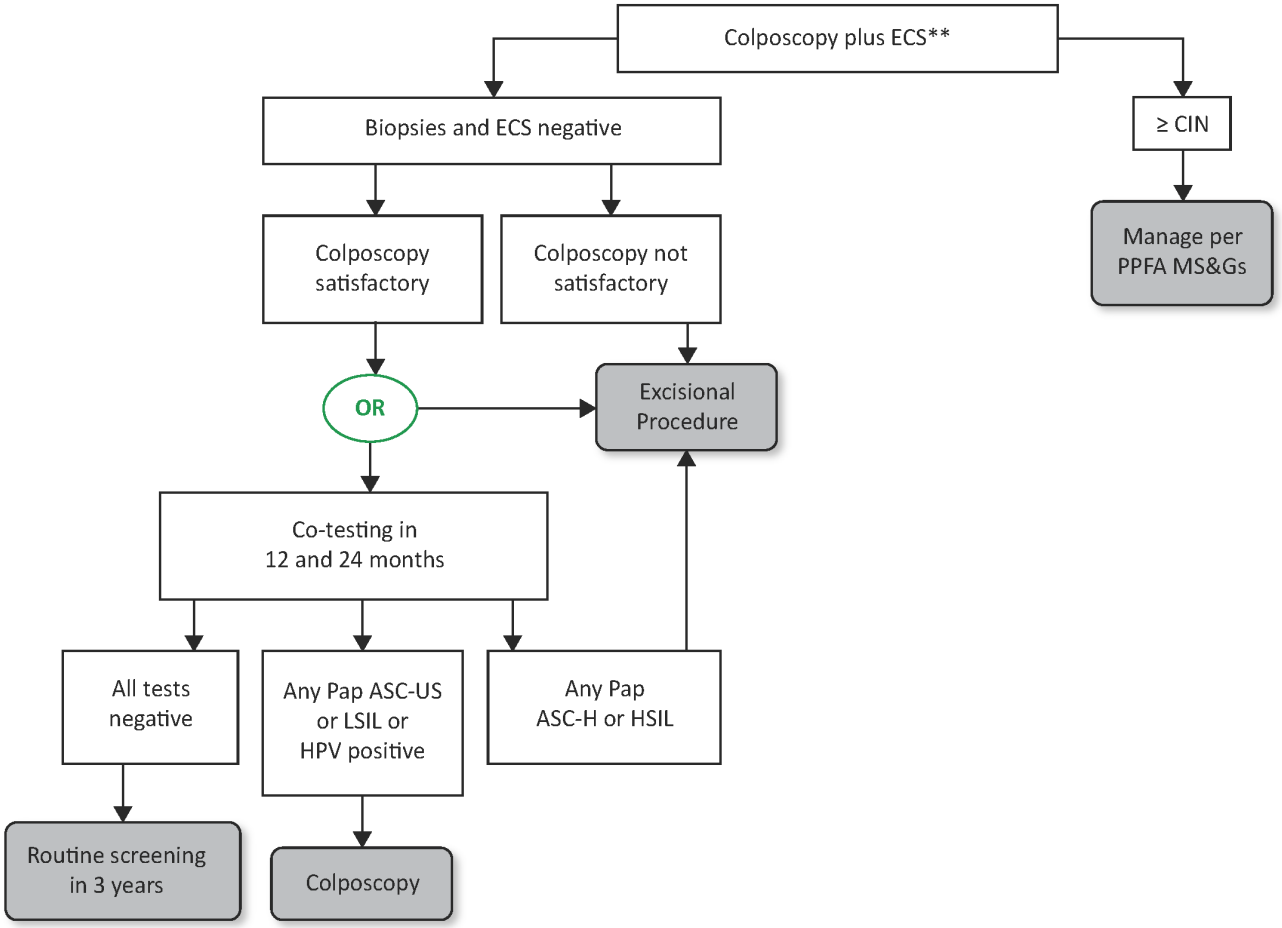
*Pregnancy – after 12 weeks gestation, colposcopy **must** be performed by physician colposcopist experienced with pregnant clients and privileged to see these clients or **must** refer out. According to ASCCP Guidelines, endocervical sampling should not be done in pregnancy. Biopsy any lesions suspicious for high grade or invasive disease. If excisional procedure necessary, refer out.

**If colposcopy is normal, random biopsies should be performed. Small four quadrant biopsies are suggested.

†If ASC-H or HSIL at 12 months, **must** biopsy. If ASC-H or HSIL at 2 years, **must** refer for excisional procedure.

Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.4.g. Algorithm: Pap ASC-H in Women 25 and Older*



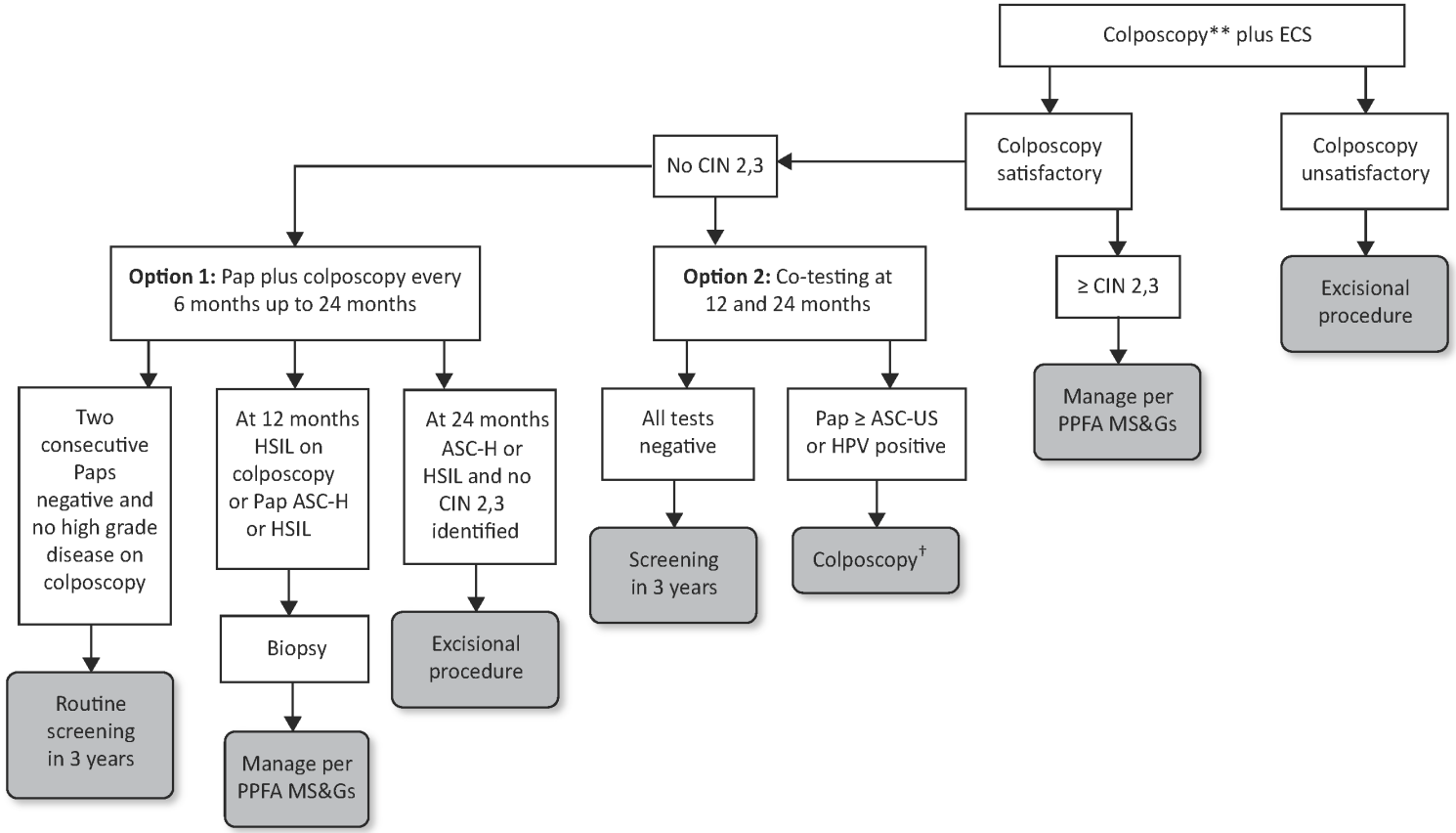
*Pregnancy – after 12 weeks gestation, colposcopy **must** be performed by physician colposcopist experienced with pregnant clients and privileged to see these clients or **must** refer out. According to ASCCP Guidelines, endocervical sampling should not be done in pregnancy. Biopsy any lesions suspicious for high grade or invasive disease. If excisional procedure necessary, refer out.

**If colposcopy is normal, random biopsies should be performed. Small four quadrant biopsies are suggested.

Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.4.h. Algorithm: Pap HSIL in Women 21 -24*

✓ FYI — Management of ASC-H and HSIL in Women 21-24 Post Colposcopy, Option 2



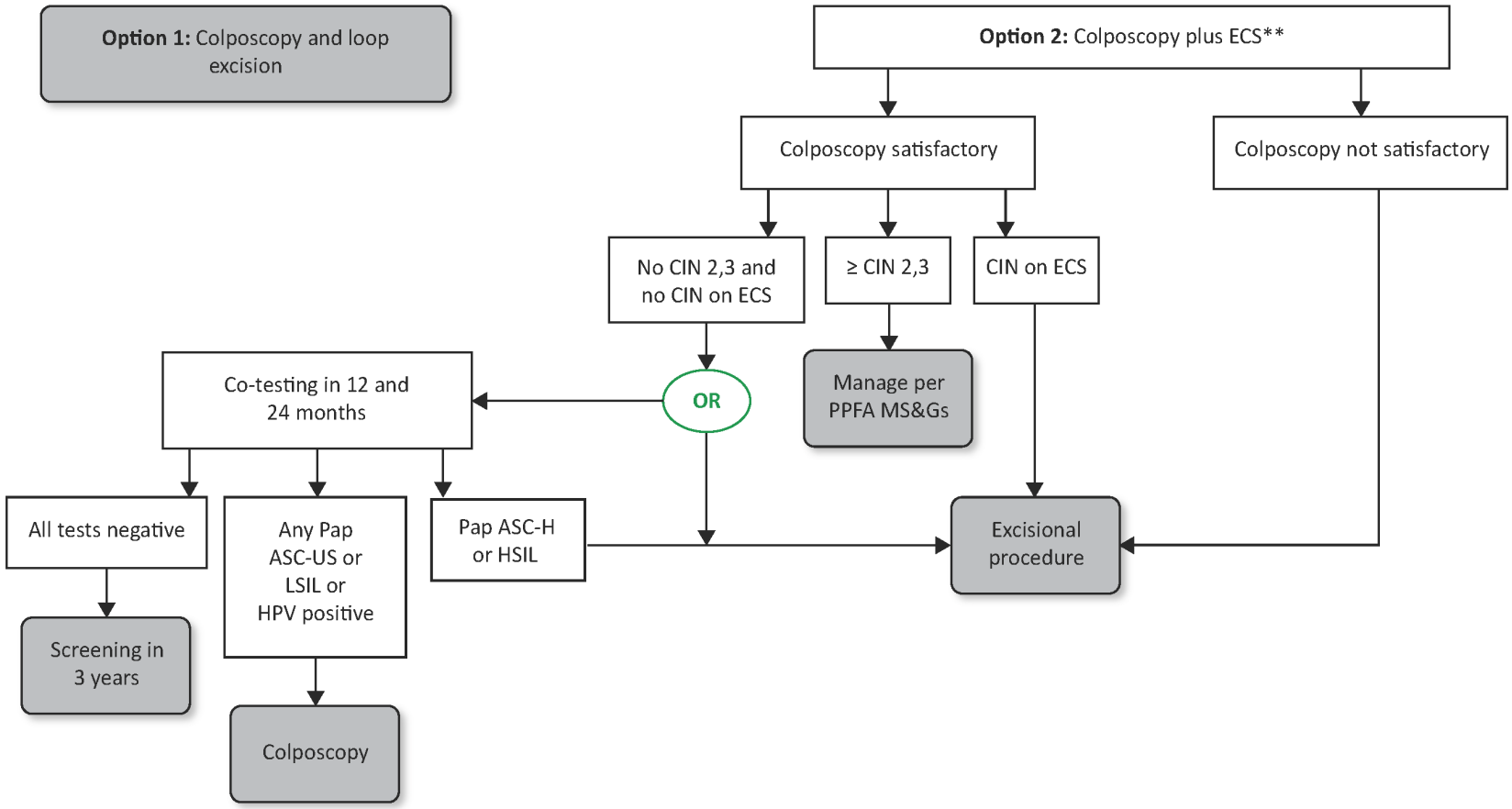
*Pregnancy – after 12 weeks gestation, colposcopy **must** be performed by physician colposcopist experienced with pregnant clients and privileged to see these clients or **must** refer out. According to ASCCP Guidelines, endocervical sampling should not be done in pregnancy. Biopsy any lesions suspicious for high grade or invasive disease. If excisional procedure necessary, refer out.

**If colposcopy is normal, random biopsies should be performed. Small four quadrant biopsies are suggested.

†If ASC-H or HSIL at 12 months, **must** biopsy. If ASC-H or HSIL at 2 years, **must** refer for excisional procedure.

Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.4.i. Algorithm: Pap HSIL (CIN 2, CIN 3, CA In Situ) in Women 25 and Older*

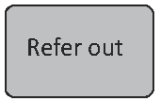


*Management in pregnancy – after 12 weeks gestation, colposcopy **must** be performed by physician colposcopist experienced with pregnant clients and privileged to see these clients or **must** refer out. According to ASCCP Guidelines, endocervical sampling should not be done in pregnancy. Biopsy any lesions suspicious for high grade or invasive disease. If excisional procedure necessary, refer out.

**If colposcopy is normal, random biopsies should be performed. Small four quadrant biopsies are suggested. If no CIN identified on biopsies or ECS, cytology and histology may be reviewed. If diagnosis is revised, manage according to the revised diagnosis.

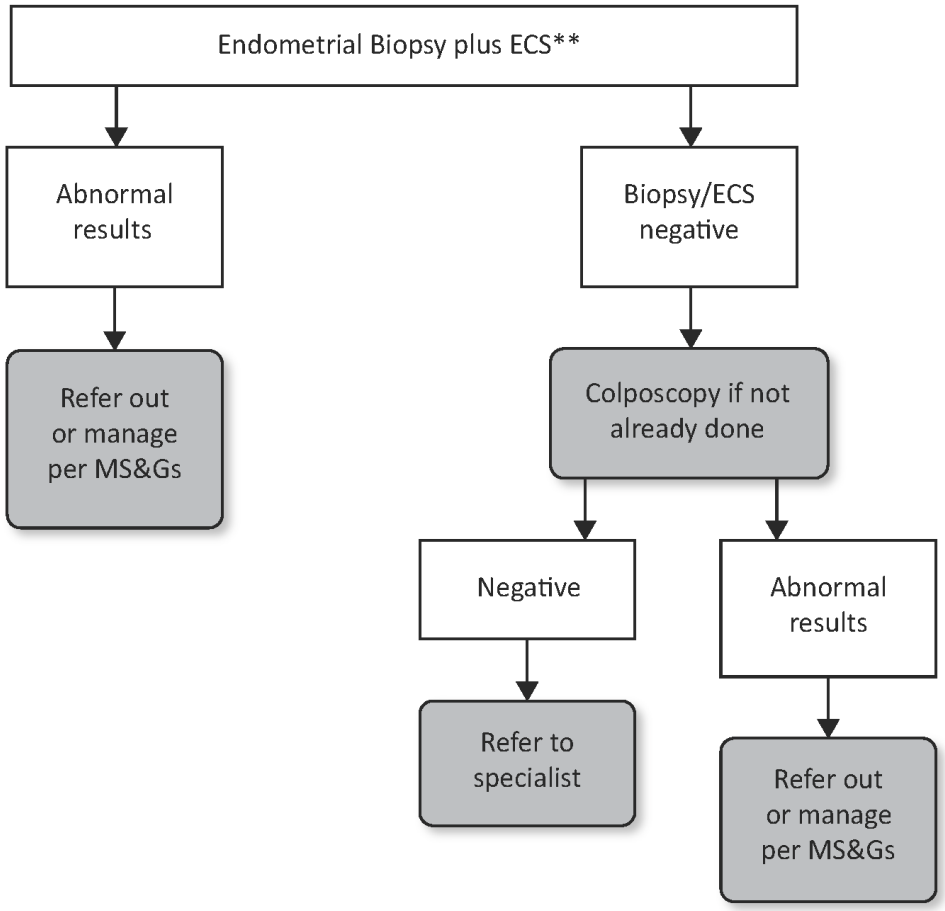
Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.4.j. Algorithm: Pap Squamous Cell Carcinoma



4.5 MANAGEMENT OF PAPS WITH GLANDULAR CELL ABNORMALITIES

4.5.a. Algorithm: Pap Atypical Glandular Cells (AGC) – Endometrial*

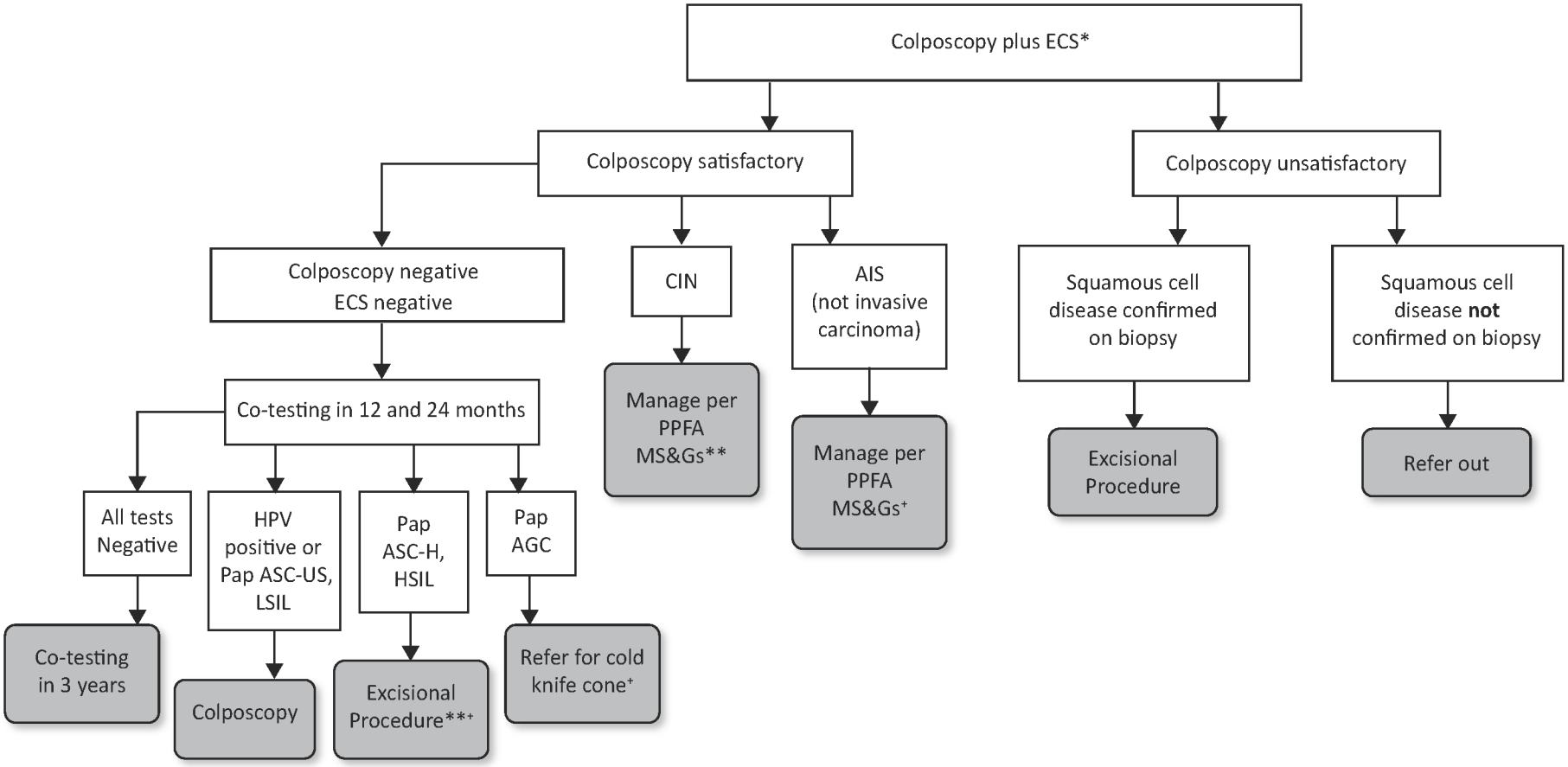


***Must** refer out if pregnant.

**Colposcopy may be done at same time.

Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.5.b. Algorithm: Pap Atypical Glandular Cells (AGC)- Endocervical or Not Otherwise Specified (NOS)



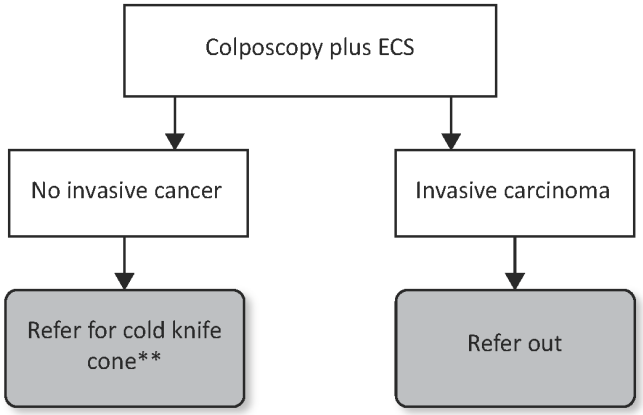
*If ≥ 35 or any abnormal bleeding or at increased risk for endometrial cancer **must** do endometrial biopsy. Initial work-up is same in pregnant women, but **must not** do ECS or endometrial biopsy.

**Ablative therapy is not a treatment option.

†Cold knife cone **must not** be done at affiliate unless approved for Level III GYN services.

Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

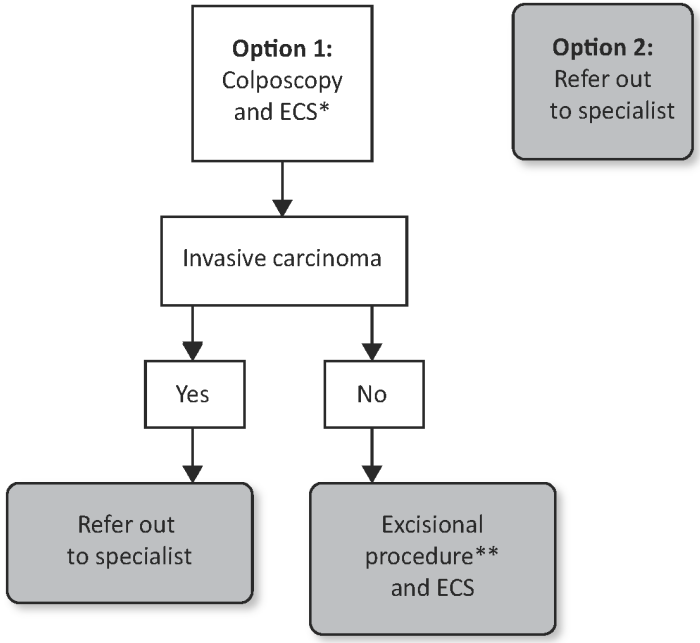
4.5.c. Algorithm: Pap Atypical Glandular Cells (AGC) – Favor Neoplasia or Pap Atypical Endocervical Cells – Favor Neoplasia*



***Must** refer pregnant women out of affiliate
Cold knife cone **must not be done by affiliate unless approved for Level III GYN services.

Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.5.d. Algorithm: Pap Adenocarcinoma in Situ (AIS) or Favor AIS

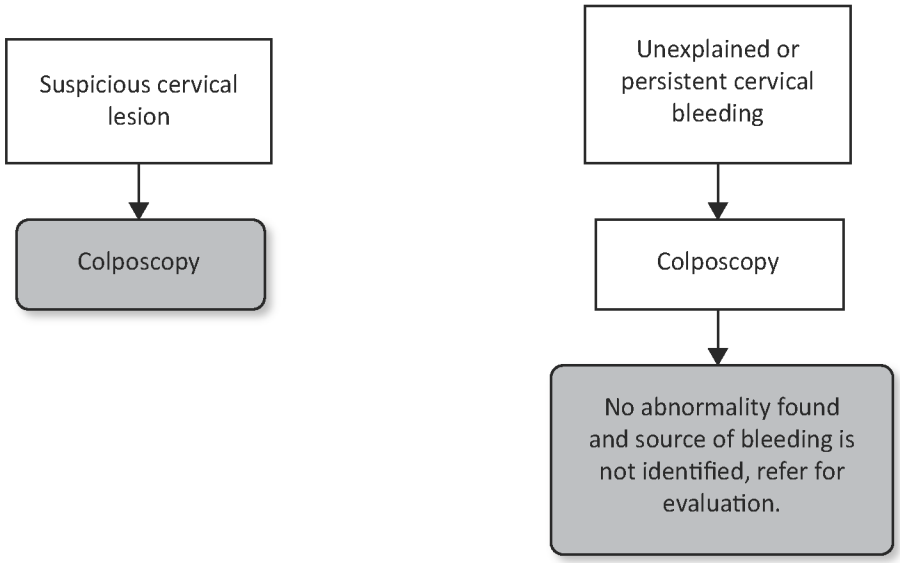


*Initial work-up is same in pregnant women, but per ASCCP Guidelines should not do ECS.
LEEP for AIS should be limited to experts. Excisional procedure should provide an intact specimen with interpretable margins. If margins are not free of disease, **must refer to specialist out of affiliate unless affiliate provides Level III GYN services. If colposcopy, biopsy, endocervical sampling, and excisional procedure are all normal, **must** refer out of affiliate to physician experienced in care of women with difficult Pap management problems.
Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.5.e. Algorithm: Pap Atypical Glandular Cells (AGC) with Origin Other than Cervix or Endometrium, for Example, Ovarian, Tubal, or Other Origin	4.5.f. Algorithm: Pap Invasive Adenocarcinoma
Refer out to oncologist	Refer out to specialist

4.6 MANAGEMENT OF ABNORMAL FINDINGS ON CLINICIAN EXAM

4.6.a. Algorithm: Abnormal Finding on Clinician Exam Regardless of Pap



Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.7 MANAGEMENT OF ABNORMAL PAPS AND FINDINGS ON CLINICIAN EXAM

4.7.a. Table: Colposcopy/Biopsy/ECS

When performing colposcopy/biopsy/ECS, table 4.7.a. **must** be followed.

History	Physical Examination	Laboratory Testing and Diagnostic Imaging	Colposcopic Evaluation
Must include ▪ Problem-specific history with particular attention to abnormal results and/or previous treatment(s)	**Must** include ▪ Visual examination (not necessarily colposcopic) of external genitalia and vagina	**Must** include ▪ Tests for STIs and pregnancy, as indicated ▪ Repeat Pap if more than 6 months have passed since referral Pap test was done	**Must** include ▪ Application of acetic acid and systematic visualization of the cervix and vagina, especially when no cervical lesion is identified ▪ Whether colposcopy is satisfactory or unsatisfactory ▪ Whether SCJ is within the endocervical canal and possible influence on management ▪ Abnormal patterns seen e.g., leukoplakia white epithelium, punctation, mosaicism, or atypical vessels ▪ Colposcopic impression

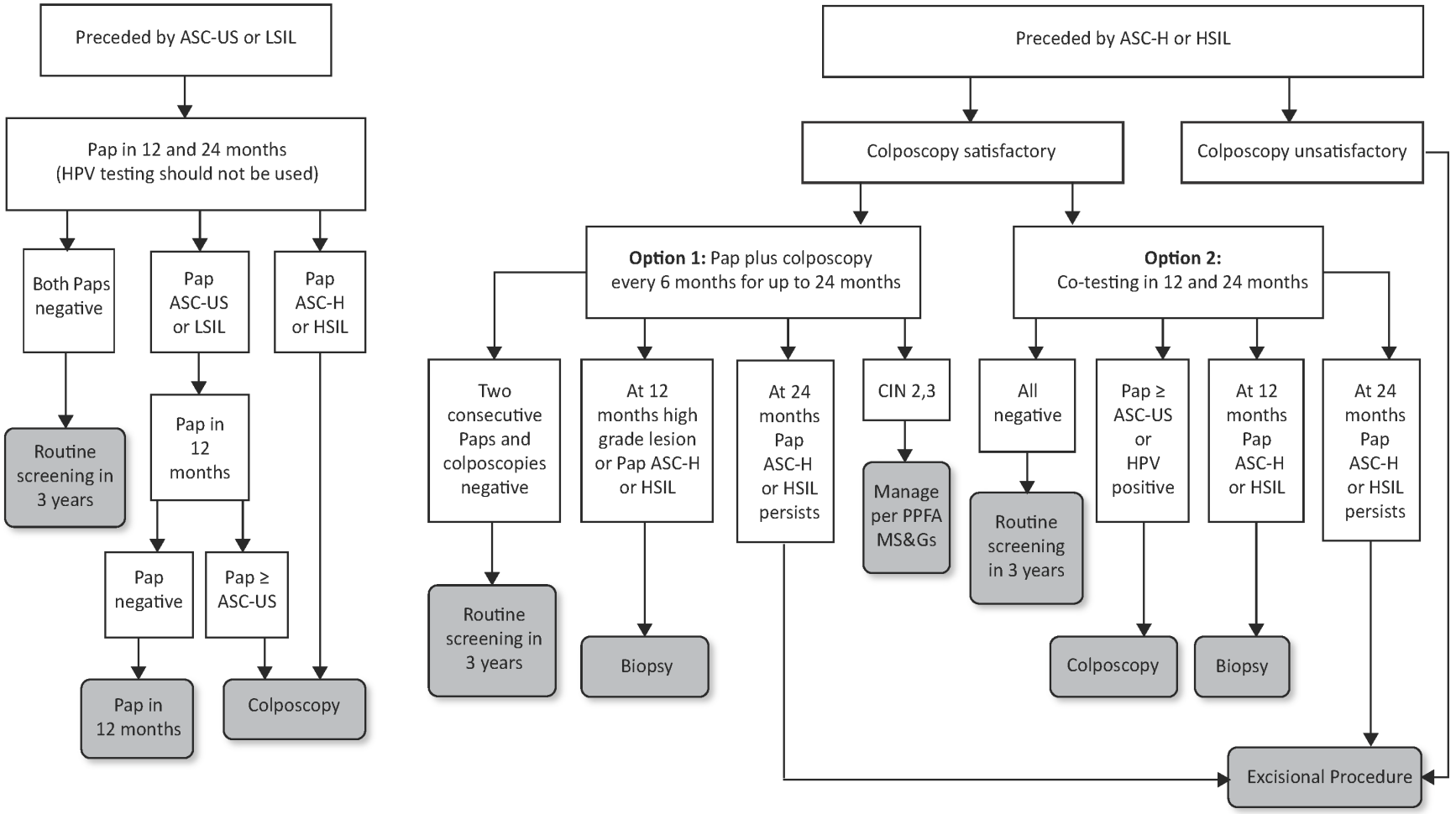
Important Information

Must refer to physician colposcopist if APC colposcopist suspects cancer or there is doubt about categorizing the lesion and the biopsies do not agree with the colposcopic impression.

4.8 MANAGEMENT OF ABNORMAL HISTOLOGY

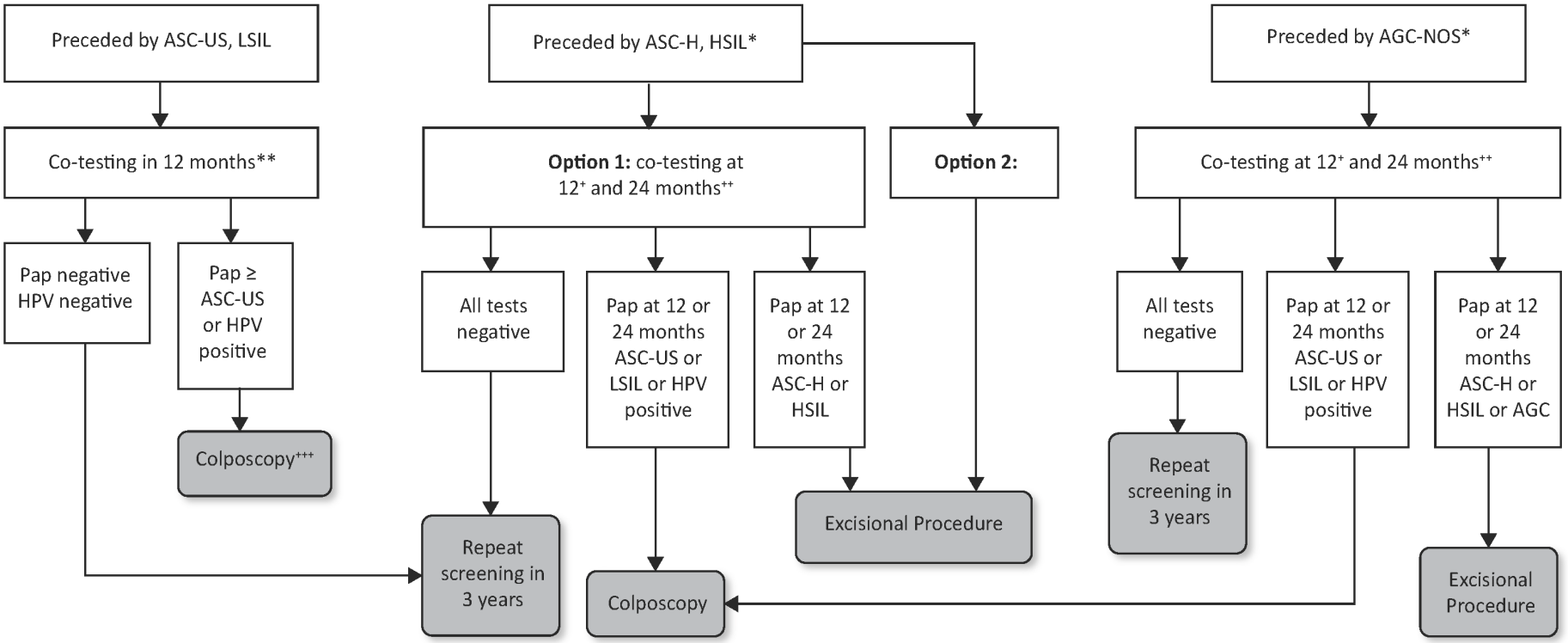
4.8.a. Algorithm: Histology CIN 1 or LSIL (Biopsy or ECS) in Women 21-24

✓ FYI — CIN with Comments



Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.8.b. Algorithm: Histology CIN 1 or LSIL in Women 25 and Older



*Cytology and histology may be reviewed. If diagnosis is revised, manage according to revised diagnosis.

**If CIN 1 on prior ECS, repeat ECS with co-testing.

+If CIN 1 on prior ECS, repeat ECS at 12 months.

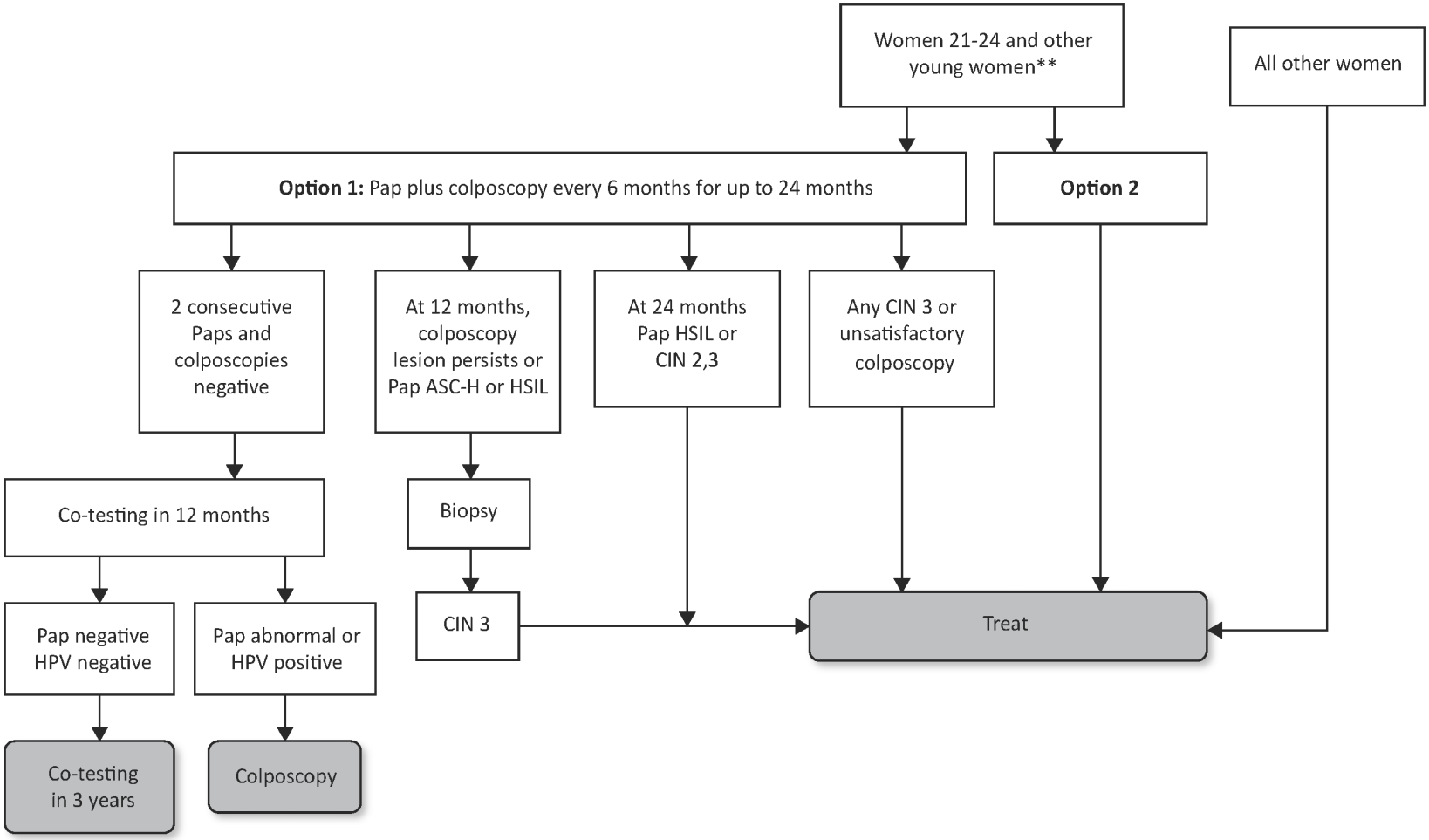
++Co-testing is an option only if colposcopy satisfactory and ECS negative for CIN. If colposcopy unsatisfactory, refer for excisional procedure.

+++If CIN 1 persists for 2 years, treat with LEEP or cryosurgery as indicated or continue to follow.

Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.8.c. Algorithm: Histology CIN 2,3 or HSIL*

✓ FYI — Young Women and Management of CIN 2,3



***Must** refer pregnant women to an outside specialist or to an affiliate colposcopist with privileges to see these women. No treatment is allowed within affiliate while client is pregnant.

****Must** treat the following: unsatisfactory colposcopy, ECS positive for CIN 2,3 or unable to grade dysplasia, CIN 3 is specified or referral Pap is AGC. Observation is preferred if CIN 2 is specified.

4.8.d. Algorithm: Histology Adenocarcinoma in Situ	4.8.e. Algorithm: Histology Adenocarcinoma or Squamous Cell Carcinoma
Excisional procedure* and ECS *LEEP for AIS should be limited to experts. Excisional procedure should provide an intact specimen with interpretable margins. If the margins are not free of disease, client **must** be referred to a specialist out of the affiliate unless affiliate provides Level III GYN services. If colposcopy, biopsy, endocervical sampling, and excisional procedure are all normal, **must** refer out of affiliate to physician experienced in the care of women with difficult Pap management problems.	Refer out to specialist

- ✓ FYI — Treatments
- ✓ FYI — Choice Loop Size Used for Excision

Important Information
LEEP **must** be performed under colposcopic guidance or following application of Lugol's solution.

4.8.f. Table: Contraindications and Special Conditions for Cryotherapy and LEEP

When choosing a treatment modality, Table 4.8.f **must** be followed.

Legend	
A	Contraindications — **must not** perform procedure
B	Conditions Requiring Special Consideration before Performing Procedure

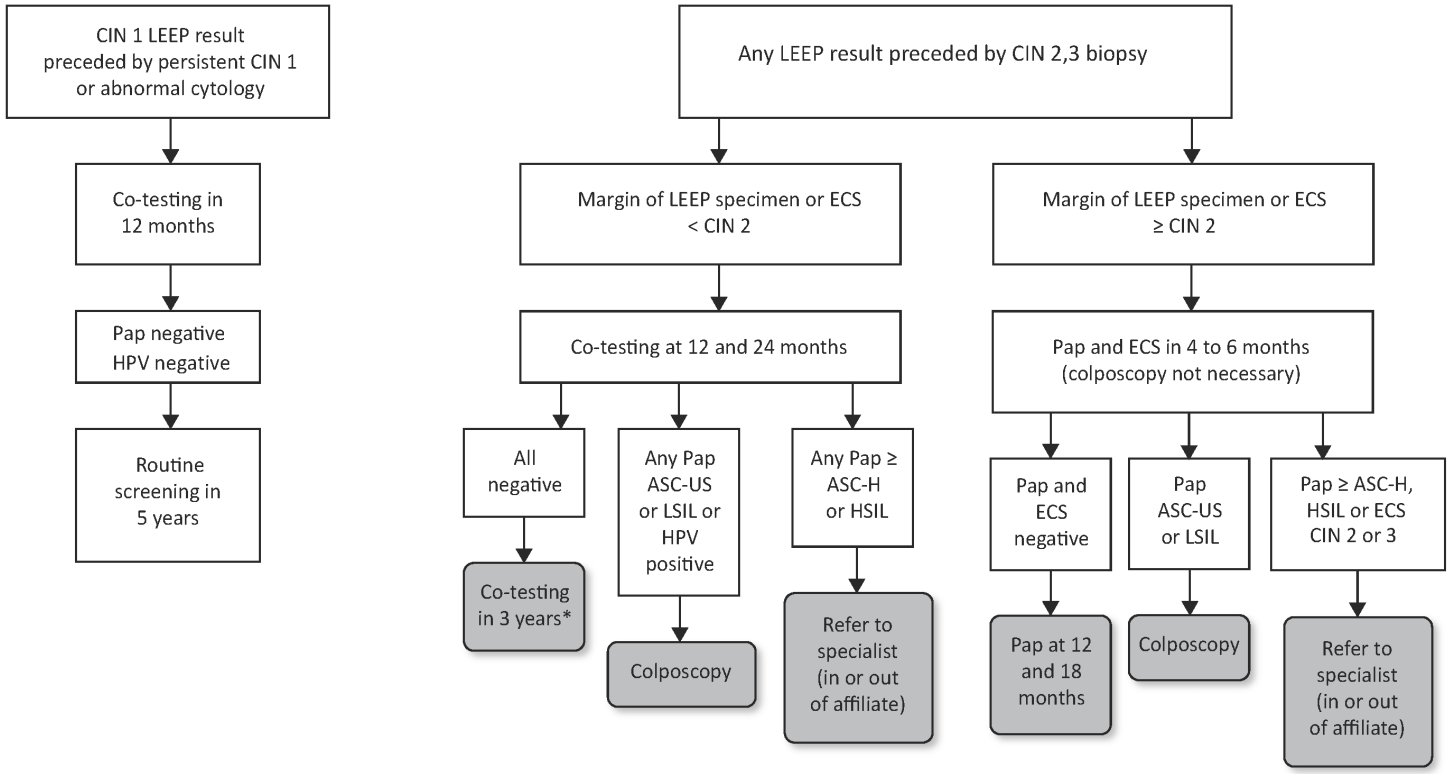
Condition/Signs/Symptoms	A	B
Biopsy or ECS		
▪ ~~Shows microinvasion, squamous carcinoma or adenocarcinoma~~ ▪ ECS shows squamous disease ≥ CIN 1	Cryotherapy LEEP	
▪ Shows glandular disease	Cryotherapy	
▪ Performed by providers outside of affiliate - written biopsy results **must** be obtained and reviewed and colposcopic evaluation **must** be performed prior to treatment		Cryotherapy LEEP

Condition/Signs/Symptoms	A	B
▪ ECS not previously done	Cryotherapy	
Cervicitis – acute; until gonorrhea and Chlamydia infection are excluded and/or treated	Cryotherapy LEEP	
Cervical lesion(s)		
▪ Involving more than 2 quadrants of the cervix — colposcopy **must** be performed by colposcopy program director prior to procedure. Clients **must** be informed of higher risk of treatment failure if lesion covers more than 2 quadrants of the cervix		Cryotherapy
▪ Not amenable to excision	LEEP	
▪ Adenocarcinoma in situ not amenable to excision as an intact specimen	LEEP	
▪ LOL or SCJ goes deeper than 4mm into endocervical canal	Cryotherapy	
Colposcopy unsatisfactory - LOL or SCJ not fully visualized	Cryotherapy	
Cryotherapy in past — **must** consult with colposcopy program director prior to procedure		Cryotherapy
Discrepancy (unexplained, persistent) of more than 1 grade between referral Pap test and biopsy results (e.g. cytology HSIL/CIN 3 and histology CIN 1)	Cryotherapy	
Gap of time between colposcopy and cryotherapy > 6 months, colposcopy **must** be repeated. ▪ Proceed with cryotherapy if there has been no significant change. ▪ If the lesion *has* progressed, perform biopsy and ECS as indicated.		Cryotherapy
Gap of time between HSIL biopsy and LEEP > 12 months, colposcopy **must** be performed. ▪ If lesion still present, LEEP **must** be performed. ▪ If lesion not present, may proceed with LEEP or immediately repeat Pap and ECS. HPV testing should be considered.		LEEP
IUC in place when LEEP is performed, inform client of risk of cutting string and what that implies for removal. ▪ Attempt to push IUC string up into canal to avoid cutting it. ▪ Alternatively, consider excision in two parts, e.g., working from three o'clock to center of cervix, then from nine o'clock to center.		LEEP
Pap - referral		
▪ AGC (atypical glandular or endocervical cells)	Cryotherapy	

Condition/Signs/Symptoms	A	B
▪ "Suspicious for" or "cannot rule out invasive cancer"	Cryotherapy	
Pregnancy	Cryotherapy LEEP	

4.9 MANAGEMENT POST LEEP OR POST CRYOTHERAPY

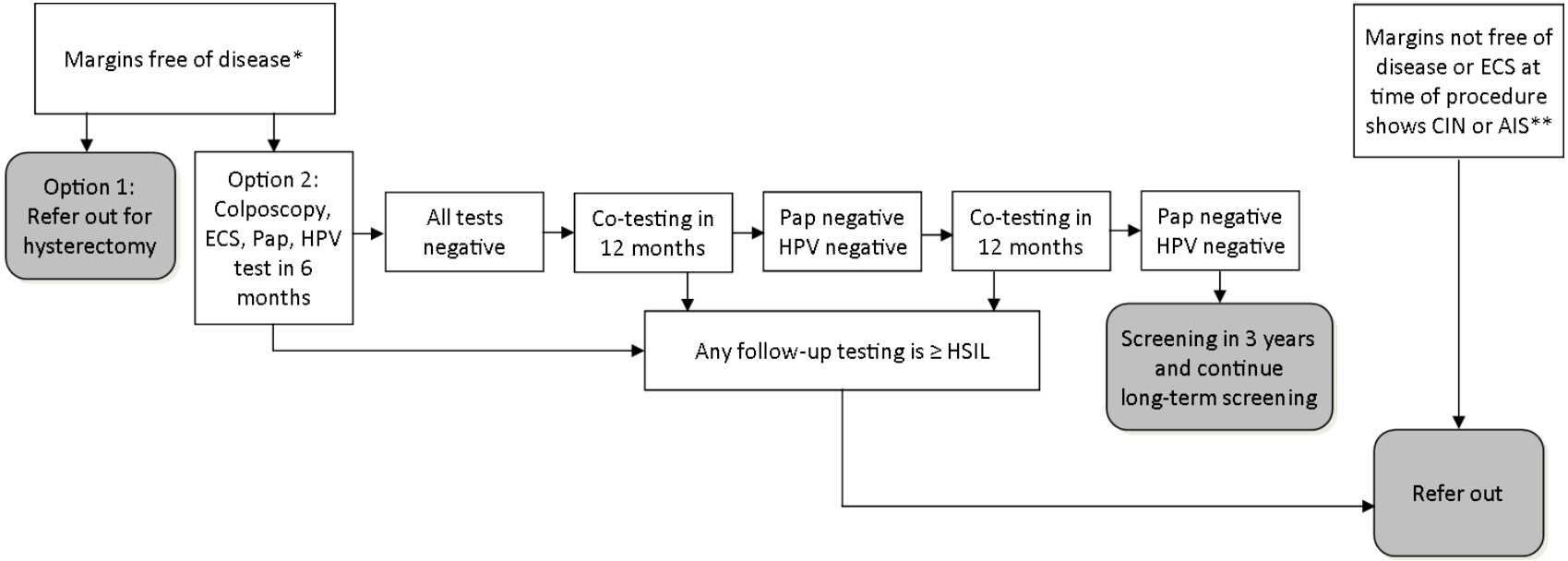
4.9.a. Algorithm: Post-Treatment Squamous Cell Disease – LEEP Histology CIN 1 and CIN 2,3



*Continue screening for at least 20 years.

Biopsies **must** be performed if a colposcopically abnormal area is seen (unless previously biopsied). Heterogeneous lesions should be biopsied in each area with a unique pattern, especially if abnormal vascular areas are seen.

4.9.b. Algorithm: Post Excision Histology AIS



*Discussions and documentation **must** include that women with AIS are at risk of disease progression even with negative margins, strict compliance with follow-up surveillance plan is important, and hysterectomy remains the treatment of choice for women who have completed childbearing.

**If procedure was done outside of affiliate, client cannot return to affiliate for Pap follow-up, unless she has 3 negative Paps.

†Referral is not required if affiliate provides Level III GYN services.

4.10 ADDITIONAL INFORMATION

4.10.a. Table: For Your Information

Section	Topic	Detail
4.2.b	General Information and Definitions	▪ Co-testing — Pap plus an HPV test. Can be used for screening in women 30 and older or for follow up of abnormal results. ▪ Genotyping – refers to typing for HPV 16 and 18 **About results** ▪ Unsatisfactory for evaluation – (reported as approximately 1% of Pap tests.[R2]) ▪ NIL — negative for intraepithelial lesion — used to report "normal" Pap test. NIL with endocervical cells or transformation zone components absent (reported as 10-20% of Paps and are higher in older women)[R2] ▪ ASC-US — atypical squamous cells of undetermined significance. A woman with this Pap finding will have a 5-17% chance of CIN 2 or 3 confirmed by biopsy with a very low risk of invasive cervical cancer (0.1–0.2 percent). ▪ LSIL — low-grade squamous intraepithelial lesion. 15-20% of women with LSIL on cervical cytology will have CIN 2 or 3 on a subsequent cervical biopsy. ▪ ASC-H — atypical squamous cells cannot exclude HSIL. A woman with this Pap finding will have a 24-94% chance of CIN 2 or 3 confirmed by biopsy. ▪ HSIL — high-grade squamous intraepithelial lesion. HSIL is a less common cytological finding, with an incidence of 0.7% in the U.S. There is a 53-66% chance of detecting CIN 2,3 on a single colposcopic exam and 84-97% chance of detecting CIN 2,3 with LEEP. There is a 1-2% chance of invasive carcinoma ▪ AGC, AGC favor neoplasia, AIS - glandular cell abnormalities that are less severe than adenocarcinoma are classified into 3 categories – atypical glandular cells, AGC favor neoplasia, and adenocarcinoma in situ. The origin of these abnormal glandular cells may be designated as endometrial, endocervical, or NOS (not otherwise specified). On very rare occasions, other sites may be designated. AGC favor neoplasia and AIS have progressively increasing risk of invasive disease relative to AGC-NOS. Some labs use the term atypical endocervical cells instead of atypical glandular cells-endocervical origin. The report may specifically say AGC-NOS or it may only say AGC. In either case if endocervical or

Section	Topic	Detail
		endometrial origin is not specified, manage as per AGC-NOS. ▪ CIN 2,3 — It has become more common for histology findings of high-grade disease to be reported as CIN 2,3 without further clarification. Some labs continue to specify either CIN 2 or CIN 3. If CIN 3 is specified, **must** treat as noted. **Performing colposcopy/ biopsy / endocervical sampling / endocervical evaluation, endometrial sampling** ▪ When the MS&Gs refer to colposcopy or for excisional procedure, it may be within or outside the affiliate. It will be specified in the MS&Gs when referral outside the affiliate is mandated. ▪ When colposcopy is mandated, it implies that biopsies will be taken as indicated. ▪ Unsatisfactory colposcopy is defined as one in which one cannot see the entire squamocolumnar junction (SCJ) or the limits of the lesion (LOL) are not seen. ▪ Cervical biopsy showing "endocervical gland neck involvement" or "extension into the endocervical glands" is not the same as an abnormal endocervical sampling. An abnormal endocervical sample may influence therapy options; extension into the endocervical glands should not. ▪ Cervical biopsies imply punch biopsy and/or endocervical sampling (ECS). ▪ ECS has replaced "endocervical curettage" and may be done with a curette or a cytobrush. Samples are sent for histological (not cytological) evaluation. ▪ Endocervical evaluation is a broader term that may include colposcopic evaluation of the endocervix with or without endocervical sampling. ▪ Endometrial sampling is tissue obtained by D&C or by using an endometrial sampling device. **Treatment modalities** ▪ Cryotherapy is used generically for any ablative method — laser, electrocautery, etc. ▪ LEEP is used interchangeably with excisional procedure.
4.2.a.	First time Screening for Women older than 30	In women older than 30 being screened for cervical cancer for the first time, consideration should be given to shortening the next screening interval. For example, if a Pap was done, consider repeating in 2 years (rather than 3). If co-testing was done, consider repeating in 3 years (rather than 5).

Section	Topic	Detail
4.2.a.	Managing young clients who had Pap testing before age 21	Although Pap screening in women younger than 21 is not recommended, there may be occasions in which adolescents have had a Pap. Refer to management guidelines for women 21-24. Women who began screening before age 21 and had a negative Pap can have their next screening Pap at age 21, or in 3 years if they were 18 or older at the time of the initial Pap.
4.4.a. 4.4.b.	ASC-US Rates	The average rate of ASC-US in the U.S. is under 5%, but due to demographic characteristics of our clients, higher rates are expected in the Planned Parenthood population. ASC-US rates exceeding 10% should be evaluated. The ASC-US-to-LSIL ratio should be in the 1.5-3.0: 1 range. The ASC-US/HPV-positivity ratio can be helpful in the evaluation of a laboratory's performance. In the ASC-US/LSIL Triage Study for Cervical Cancer (ALTS) this ratio was just over 50%. Ratios may vary greatly based upon the age of the population being screened; therefore the positivity ratio at Planned Parenthood may be higher due to the younger age of the screening pool. Unfortunately, there are no specific ratios that have been established as "the norm." Example of how to use the ASC-US/ HPV positivity ratio to help assess laboratories that are likely over-calling or under-calling ASC-US: If 80% of the affiliate's ASC-US Paps are HPV-positive it is likely that the lab is reading a lot of LSIL as ASC-US (under-calling LSIL), making HPV testing ineffective as a triage tool. (In ALTS about 83% of LSIL was HPV-positive, which is why reflex HPV testing is **not** used to triage who goes to colposcopy in women with LSIL Paps.) Conversely, if the affiliate's ASC-US/HPV-positivity ratio is 30% then the lab is likely over-calling ASC-US and reading too many normal Paps as ASC-US.
4.4.a.	ASC-US Management in Women 21-24	The preferred management of ASC-US in women age 21-24 is follow-up Paps. HPV reflex testing in this age group has been deleted as a management option from the PPFA MS&Gs. However, there may be times that an HPV test is performed inadvertently in a woman younger than 25. If that occurs, the following management may be used: ▪ If HPV-negative, return to routine screening in 3 years.

Section	Topic	Detail
		▪ If HPV-positive, repeat Pap in 12 and 24 months (referral to colposcopy or repeat HPV is NOT recommended). ○ If 2 consecutive Paps negative, return to routine screening in 3 years. ○ If at 12 months Pap ASC-US or LSIL, repeat Pap in 12 months. • If at 24 months Pap negative, repeat Pap in 12 months. • If at 24 months Pap ≥ ASC-US, refer to colposcopy. ○ If at 12 months Pap ASC-H, HSIL, or AGC, refer to colposcopy
4.4.h.	Management of ASC-H and HSIL in Women 21-24 post colposcopy, Option 2	Option 2, co-testing at 12 and 24 months, is not included in the recommendations from the 2012 ASCCP Consensus Conference for women 21-24 but it is the standard for women age 25 and older who are being followed. Since older women are at higher risk for CIN 3 and since Option 1, Pap and colposcopy at 6 month intervals for up to 24 months, is likely more costly and more invasive, both options are acceptable for women 21 and older in the PPFA MS&Gs.
4.4.e.	LSIL Cannot r/o HSIL	LSIL Cannot R/O HSIL should be an uncommon Pap result. Laboratories should be directed to stop using this designation or to only use it very sparingly. When LSIL Cannot r/o HSIL is reported from your laboratory, manage this result according to the standards for management of ASC-H. (Expert opinion.)
4.8	CIN with Comments	Occasionally cervical biopsies with findings of CIN will have one of the following comments: ▪ endocervical gland neck involvement ▪ gland neck involvement ▪ extension into adjacent endocervical glands This diagnosis does not indicate that the endocervical canal is involved with disease, nor does it imply cervical disease of glandular origin. These findings have no influence on choice of therapy. A comprehensive review of studies of the natural history of CIN 1 showed that 57% of lesions spontaneously regress and 11% of lesions progress. Overall, the rate of progression to invasive cervical cancer observed in these studies was 0.3%. The 36 month regression rate for CIN 1 in women under age 22 was 91%. [R3]

Section	Topic	Detail
		Since the risks associated with CIN 1 preceded by cytology showing HSIL or atypical glandular cells is higher than CIN 1 preceded by cytology read as ASC or LSIL, the management will be different for these two groups.
4.8.c.	Young Women and Management of CIN 2,3	The guidelines from the 2012 ASCCP Consensus Conference state: "In these guidelines, the term "young women" indicates those who after counseling by their clinicians consider the risks to future pregnancies of interventions for cervical abnormalities outweigh the risks of cancer during observation of those abnormalities. No specific age threshold is intended."[R2] Following consultation with subject matter experts, age 25 was chosen as the upper age limit in defining "**young women**" for the PPFA MS&Gs. However, affiliates have some age flexibility when determining if young women age 25 to 29 or older could be eligible for the conservative follow-up management option. Decisions about who is a reasonable candidate to follow conservatively should be made in consultation with the colposcopy program director and based on clinical judgment, taking into account the reliability of the client to adhere to follow-up regimen, the risk of progressive disease, and the risk of proposed treatment.
4.8.f.	Treatments	Recurrence rates for CIN (all grades) are similar for ablative and excisional procedures if the colposcopy is satisfactory.
4.8.f.	Choice of Loop Size used for Excision	Data are conflicting regarding the relationship between LEEP and preterm delivery. More recent literature implicates the depth of the excision as a significant contributor to preterm delivery, especially depth greater than 10mm. [R4]

4.10.b. Table: References

Section	R#	Reference
4.2.a. 4.3.h.	R5	Huh WK, Ault KA, Chelmow D, Davey D, Goulart RA, Garcia FAR, Kinney WK, Massad LS, Mayeaus EJ, Saslow D, Schiffman M, Wentzensen N, Lawson HW, Einstein MH. Use of primary high risk human papillomavirus testing for cervical cancer screening: Interim clinical guidance. Obstet Gynecol. 2015;125(2):330-337.
4.2.a.	R2	Massad, LS, Einstein M, Huh W, Katki H, Kinney W, Schiffman M, Solomon D, Wentzensen N, Lawson H for the 2012 ASCCP

Section	R#	Reference
4.10.a. (1) 4.10.a. (2)		Consensus Guidelines Conference. 2012 updated consensus guidelines for the management of abnormal cervical cancer screening tests and cancer precursors. Journal of Lower Genital Tract Disease;2013;17(5):S1-S27
4.10.a.	R3	Moscicki AB, Shiboski S, Hills NK, Powell KJ, Jay N, Hanson EN, Miller S, Canjura-Clayton LK, Farhat S, Broering JM, Darragh TM. Regression of low-grade squamous intra-epithelial lesions in young women. Lancet 2004; 364: 1678–83.
4.10.a.	R4	Nøhr B, Jensen A, Frederiksen K, Tabor A, Kjaer SK. Depth of cervical cone removed by loop electrosurgical excision and subsequent risk for spontaneous preterm delivery. Obstet Gynecol. 2009;114(6):1232–1238.
4.2.a.	R1	Saslow D et al. American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology Screening guidelines for the prevention and early detection of cervical cancer. Journal of Lower Genital Tract Disease 2012;16(3). Available at: http://journals.lww.com/jlgtd/PublishingImages/ASCCP%20Guidelines.pdf. Accessed May 17, 2012.
Throughout		Wright C et al. (Ed.) Basic and advanced colposcopy. Part Two. A practical handbook for treatment. 2nd edition. Houston, Biomedical Communications, 1995.
Throughout		Wright TC, Massad LS, Dunton CJ, Spitzer M, Wilkinson EJ, Solomon D, for the 2006 American Society for Colposcopy and Cervical Pathology–sponsored Consensus Conference. 2006 consensus guidelines for the management of women with cervical intraepithelial neoplasia or adenocarcinoma in situ. Am J Obstet Gynecol. 2007;Oct;197(4):340-5

4.10.c. Table: Additional Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIIC	CI Pap and HPV Test CIIC Colposcopy and Biopsy CIIC Cryotherapy CIIC LEEP	Part 3, Chapter 02_04
	CIIC Endometrial Biopsy	Part 3, Chapter 02_08

4.10.d. Table: Additional Resources for Staff

Type	Resource	Location
Job Tools	✓ ASCCP Algorithms Mobile App	
Training	**CAL Courses** Cervical Cancer Screenings and Management of Selected Cervical Abnormalities Dana's Story: Anatomy of a Cervical Cancer Case	
	PPFA 2014 VOICE Cases Studies in Abnormal Cervical Cytology	To be posted on Extranet
Sample Forms	Sample Letter Pap Notification Sample Letter Pap Notification Needs Tests	Part 3, Chapter 01_08

CHAPTER 5: CONTRACEPTION - PERMANENT

Revised June 2014

Chapter 5 Table of Contents

5.1 HYSTEROSCOPIC TUBAL STERILIZATION (HTS)

5.1.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

5.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer	Should give
CI Before and After Your HTS			●		
CI Hysterosalpingogram					●
CIIC Hysteroscopic Tubal Sterilization (HTS)		●	●		
Client user card for Essure, as indicated			●		
Referral for follow-up hysterosalpingogram (HSG)		●	●		
Release When Test/Service/Consultation Will Not Be Obtained As Recommended		Once			
Request for Surgery or Special Procedures		●		●	
Written information about any medication dispensed (package insert may be used)			●		

Important Information - Informed Consent and Sterilization

Special care **must** be taken to ensure that women considering sterilization are not subjected to duress or to coercion of any kind and that all such decisions are reached on the basis of full information and free discussion. Information that the client needs to make an informed decision **must** be presented in an objective and non-judgmental manner and in language and terminology that she can best understand. She **must** be given the

- opportunity to ask questions and get answers at any time during the process
- option of being accompanied during the education session by a person of her own choosing, who also is free to ask questions
- option of deciding not to have the procedure without penalty or denial of other services

5.1.2 Contraindications and Special Conditions

I. Client selection **must** be determined according to Table 5.1.b. Possible contraindications or special conditions **must** be reported to the surgeon prior to the procedure.

5.1.b. Table: Contraindications and Special Conditions for HTS

LEGEND	
A	**Musts**/Shoulds
B	Contraindications — **must** not perform
C	Special Conditions Requiring Further Evaluation (pre-existing conditions that may complicate surgery). These conditions require affiliate protocols for management or consultation with the physician/surgeon performing the procedure.

Conditions/Signs/Symptoms	A	B	C
Allergy			
▪ To contrast media		●	
Asthma	All clients who report a history of asthma should be instructed to ▪ take regularly scheduled doses of asthma medication prior to procedure ▪ bring asthma medication to procedure		●
Cardiovascular disease - including ischemic heart disease and congenital anomalies			●
Cervicitis			
▪ On the day of scheduled procedure – untreated or suspected		●	
Hypertension			
▪ BP > 140/90			●
▪ Presently under treatment with medications			●
Illnesses/Conditions that may			
▪ Cause immune deficiency or poor healing			●
▪ Require endometrial ablation using radio frequency, or electrosurgery on the			●

Conditions/Signs/Symptoms	A	B	C
uterine cornua and proximal fallopian types			
▪ Predispose to infective endocarditis (IE)	**Must** follow the current recommendations of the American Heart Association (AHA) ✓ AHA Guidelines: Prevention of Infective Endocarditis		●
Medication/Therapy			
▪ Immunosuppressive (e.g., systemic corticosteroids or chemotherapy) – current use			●
PID – acute			
▪ On the day of scheduled procedure – untreated or suspected		●	
Postpartum			
▪ Delivery or termination of a pregnancy (pregnancy loss or abortion) < 6 weeks before placement		●	
Pregnancy – suspected or confirmed		●	
Tubal sterilization - previous		●	
Uterus/adnexa			
▪ Abnormal bleeding – undiagnosed		●	
○ At time of pre-operative exam			
○ On day of scheduled procedure		●	
▪ Anatomical variant and/or pathology making the client unsuitable for hysteroscopic delivery and/or placement of device (i.e., large fibroids, etc.) – known			●
▪ Salpingectomy or salpingo-oophorectomy			●
▪ Unicornuate uterus – known or suspected			●
▪ Unilateral device placement - includes clients with previously diagnosed contralateral proximal tubal occlusion			●

5.1.3 Medical Screening and Evaluation

5.1.c. Table: Evaluation Prior to HTS

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
must be done within 6 weeks prior to procedure and should include ▪ Past illnesses ▪ Previous surgery ▪ Current medications, including contraception ▪ Allergies to medications, antiseptic solutions, latex and contrast media ▪ Any substance abuse or addictions ▪ Asthma	**Must** include ▪ Temperature, if symptomatic of infection ▪ BP ▪ Abdominal palpation ▪ Pelvic exam ▪ Additional exam as indicated by history or laboratory findings	**Must** include ▪ Negative pregnancy test within 24 hours prior to procedure ▪ GC/CT testing according to CDC guidelines ✓ CDC STD Treatment Guidelines

5.1.4 Timing of Procedure

I. Should be performed during the early proliferative phase of the menstrual cycle to decrease the potential of an undiagnosed (luteal phase) pregnancy and enhances visualization of the fallopian tube ostia.
II. Consider prescribing hormonal contraception 2 months prior to the procedure to thin the endometrium and allow the procedure to be performed at any time during the cycle.
III. Should not be attempted during menstruation.

5.1.5 Pre-Sterilization Procedures

I. Prior to procedure — the physician performing the procedure **must**
   A. Review and update history, especially recent illness, interim contraception, plans for continuation of contraception, and the LNMP.
   B. If pre-operative pelvic exam was done by another clinician, perform a pelvic exam to evaluate uterine size and position and the presence of adnexal masses or fixation.
   C. Confirm that the sterilization is voluntarily requested.
   D. Sign the physician's section of the state or federal sterilization consent, if necessary.

5.1.6 Procedure

- ✓ FYI – Use of NSAIDs
- ✓ FYI – Prevention of Infection in HTS

I. Fluid Volume Management
   A. **Must** account for all fluid used.
   B. Consider an under the buttock drape funnel collection system for fluid tracking.
   C. Consider use of pressure cuff to assist in steady flow.
   D. If procedure is extended for any reason, special care will need to be taken to prevent complications associated with hypervolemia.

5.1.7 Post-Procedure Management

I. Client Discharge Criteria
   A. For recovery area care and discharge criteria, see Chapter 17 Recovery Area Care.
   B. Before leaving, the client **must** receive and understand postoperative instructions.

5.1.8 Follow-up

I. Hysterosalpingogram (HSG) — Advise client to schedule HSG 3 months following the procedure:
   A. The client may be instructed to discontinue use of alternative contraception only if there is evidence of bilateral occlusion of the fallopian tubes
   B. If micro-insert location is satisfactory but occlusion of fallopian tubes is not complete at 3-month HSG, client should remain on alternative contraception for 3 more months and have repeat HSG.
   C. If occlusion is again not complete, client **must** be advised she cannot rely on the micro-inserts for contraception and alternate contraception **must** be offered.

5.1.9 Management of HTS Related Complications

- ✓ Refer to ARMS Emergency Manual for the management of acute emergencies.

5.1.d. Table: Management of HTS-Related Complications

Condition	Timing	Management
Fluid overload, suspected*	Intraoperative Postoperative	▪ Discontinue hysteroscopic procedure along with fluid infusion. ▪ Monitor o Urine output o BP o Pulse oximeter o Body temperature o Lung fields for crackling or rales o EKG for cardiac arrhythmia o Hgb for hemodilution ▪ May provide Lasix 20 to 40 mg IV. ▪ Discontinue IV infusion after administration of Lasix. ▪ Elevate client's head and place client in sitting position. ▪ If client is unstable, or there is concern about ability to adequately treat fluid overload or associated complications, **must** transfer to hospital
Infection	Postoperative	Follow CDC guidelines.
Procedure failure	Intraoperative Postoperative	▪ **Must** inform client o Permanent contraception has not been completed o Whether or not a second attempt is warranted ▪ If first attempt failed because tube could not be visualized and/or tubal spasm suspected, should offer second procedure. ▪ If client opts for second procedure, tube could not be cannulated on the first attempt, and tubal spasm is not suspected, consider HSG after her next menses to determine tubal patency: ▪ If tubal patency observed, should offer client a second attempt at placement. ▪ If a second attempt at placement fails, client is unlikely to have success with subsequent attempts. ▪ If a client undergoes follow-up HSG in order to qualify for second procedure, it is not a substitute for the required 3-month HSG. ▪ If client chooses laparoscopic sterilization both fallopian tubes should be clipped or coagulated, even if one tube contains Essure
*For healthy clients the maximum fluid deficit of 1000 mL is suggested when using hypotonic solutions. The maximum limit for isotonic solutions like normal saline and Ringer's lactate is unclear, but 2500 mL has been advocated in previous AAGL Guidelines.		

5.2 TRANSABDOMINAL TUBAL STERILIZATION

5.2.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

5.2.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
CI Before and After Transabdominal Tubal Sterilization			●	
CIIC Transabdominal Tubal Sterilization		●	●	
Request for Surgery or Special Procedure		●		●
Written information about any medication dispensed (package insert may be used)			●	

Important Information - Informed Consent and Sterilization

Special care **must** be taken to ensure that women considering sterilization are not subjected to duress or to coercion of any kind and that all such decisions are reached on the basis of full information and free discussion. Information that the client needs to make an informed decision **must** be presented in an objective and non-judgmental manner and in language and terminology that she can best understand. She **must** be given the

- opportunity to ask questions and get answers at any time during the process
- option of being accompanied during the education session by a person of her own choosing, who also is free to ask questions
- option of deciding not to have the procedure without penalty or denial of other services

5.2.2 Contraindications and Special Conditions

I. Client selection **must** be determined according to Table 5.2.b. Possible contraindications or special conditions **must** be reported to the surgeon prior to the procedure.

5.2.b. Table: Contraindications and Special Conditions for Transabdominal Tubal Sterilization

LEGEND	
A	**Musts**/shoulds
B	Contraindications — **must** not perform
C	Special Conditions Requiring Further Evaluation (pre-existing conditions that may complicate surgery). These conditions require affiliate protocols for management or consultation with the physician/surgeon performing the procedure.

Conditions/Signs/Symptoms	A	B	C
Anemia			●
Anti-coagulant therapy			●
Asthma	All clients who report a history of asthma should be instructed to ▪ take regularly scheduled doses of asthma medication prior to procedure ▪ bring asthma medication to procedure		●
Bleeding diathesis			●
Cardiovascular disease			●
Diabetes			●
Hypertension			
▪ BP > 140/90			●
▪ Presently under treatment with medications			●
Illnesses/Conditions that may			
▪ Cause immune deficiency or poor healing - chronic			●
▪ Require operative laparoscopy, laparotomy or hysterectomy in the near future			●
▪ Predispose to infective endocarditis (IE)	**Must** follow the current recommendations of the American Heart Association (AHA). ✓ AHA Guidelines: Prevention of Infective Endocarditis		●

Conditions/Signs/Symptoms	A	B	C
Obesity			●
PID			
▪ On day of scheduled procedure – untreated or suspected		●	
▪ Treated with antibiotics in the past year			●
▪ Recurrent (> 2 episodes ever)			●
Peritonitis – previous, especially ruptured appendix			●
Renal disease – chronic			●
Reproductive history			
▪ Sterilization procedure - previous failure			●
Surgical history			
▪ More than 1 laparotomy for any reason, including cesarean section, tubal surgery, etc.			●
Systemic Lupus Erythematosus (SLE)			●

5.2.3 Medical Screening and Evaluation

5.2.c. Table: Evaluation Prior to Transabdominal Tubal Sterilization

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Must be done within 6 weeks prior to procedure and should include ▪ Past illnesses ▪ Previous surgery ▪ Current medical conditions ▪ Allergies to medications, antiseptic solutions, and any components of the occlusive device or equipment used to perform the procedure ▪ Any substance abuse or addictions ▪ Asthma	**Must** include ▪ Temperature ▪ BP ▪ Heart and lung exam ▪ Abdominal palpation ▪ Pelvic exam ▪ Additional exam as indicated by history or laboratory findings	**Must** include ▪ Hgb or Hct ▪ Negative pregnancy test within 24 hours prior to procedure ▪ GC/CT according to CDC Guidelines ✓ CDC STD Treatment Guidelines

5.2.4 Pre-Sterilization Procedures

I. Day of Surgery — the following **must** be done:
   A. Review and update history, especially recent illness, current contraception, and LNMP.
   B. If pre-operative pelvic exam was done by another clinician, perform a pelvic exam to evaluate uterine size and position and the presence of adnexal masses or fixation.
   C. Confirm that the sterilization is voluntarily requested.
   D. Sign the physician's section of the state or federal sterilization consent, if necessary.

5.2.5 Procedure

I. Verification of Occlusion — To verify that the fallopian tubes are being occluded, the fimbriated end of each tube **must** be identified, if possible, before and after occlusion.
II. Tissue Management — When the surgeon elects to remove sections of the fallopian tubes, they **must** be sent to the laboratory for tissue identification.

5.2.6 Post-Procedure Management

I. Client Discharge Criteria
   A. For recovery area care and discharge criteria, see Chapter 17 Recovery Area Care.
   B. Before leaving, the client **must** receive and understand postoperative instructions.

5.2.7 Management of Transabdominal Tubal Sterilization Complications

✓ **Must** refer to ARMS Emergency Manual for management of acute emergencies.

5.2.d. Table: Management of Complications

Complication	Timing	Findings/Management
Bleeding, anterior abdominal wall (trocar sites)	Intraoperative Postoperative	Management ▪ Cauterize bleeding from intra-abdominal side through auxiliary trocar. ▪ Apply pressure to external bleeding sites. ▪ Cauterize or suture if pressure unsuccessful.

Complication	Timing	Findings/Management	
Bleeding, cervical (from uterine manipulator)	Intraoperative Postoperative	Management ▪ Apply pressure. ▪ Apply Monsel's solution. ▪ Suture.	
Bleeding, other pelvic structure	Intraoperative	Management ▪ Suture, cauterize or clip laparoscopically. ▪ Laparotomy may be necessary if unable to visualize bleeding site or unable to control bleeding laparoscopically.	
Burn, anterior abdominal wall	Intraoperative	Management ▪ Routine wound care to prevent infection. ▪ Consider resection of more extensive burned skin for better cosmetic result.	
Burn, pelvic structures (other than tubes)	Intraoperative	Management ▪ Burns to most pelvic structures do not require treatment. ▪ Burns to bladder or ureter require intraoperative consultation with a urologist. ▪ If a urologist is not consulted, specifically describe injury, lack of proximity to trigone, reason for performing or not performing cystoscopy plus plans for post-operative drainage.	
Gas (air or CO2) embolism	Intraoperative	Findings ▪ Oxygen saturation – decreasing ▪ Pulse - decreased or absent ▪ Respirations - decreased or absent ▪ Consciousness – failing or absent ▪ BP – failing or absent	Management ▪ Discontinue administration of gas. ▪ Administer oxygen. ▪ CPR/BLS and emergency transport.
Gastrointestinal tract injury (Burn, perforation or laceration)	Intraoperative Postoperative (Intestinal burns may not manifest until post-operative day 5 to 10)	Findings ▪ Intestinal burns unrecognized at surgery may result in perforation several days later. If pain or fever accompanied by localized or generalized signs of peritonitis begin 5 to 10 days postoperative, perforation secondary to	Management ▪ All burns, lacerations or significant perforations require laparotomy and layered repair. ▪ Consultation with surgeon skilled in repair of intestinal injuries **must** be obtained if operating surgeon is not qualified to do so. ▪ Consultation is encouraged in all cases.

Complication	Timing	Findings/Management	
		burn should be considered.	▪ Clients with signs of delayed perforation require immediate consultation with staff physician and, in most cases, immediate transfer to a hospital ER. ▪ Antibiotic coverage is required for peritoneal contamination with bowel contents.
Infection	Postoperative	▪ Follow CDC STD Treatment Guidelines ✓ CDC STD Treatment Guidelines	
Occlusive Device Problem - applied to the wrong structure	Intraoperative	Management ▪ If applied to non-vital structure, no need to remove unless it can be done easily and removed laparoscopically without causing significant bleeding or trauma. ▪ If applied to intestine, bladder or major vessel and there is possibility of obstruction or necrosis, should remove, laparoscopically if possible, otherwise by laparotomy.	
Occlusive Device Problem - occlusion failure	Postoperative (may be delayed)	Management ▪ Management for unblocked tube. ▪ Client is instructed to use another form of contraception. ▪ Plan second attempt to occlude unblocked tube.	
Perforation, uterus (by uterine manipulator or trocar)	Intraoperative	Management ▪ Remove uterine manipulator if responsible. ▪ If no bleeding from perforation site, no treatment necessary. ▪ Bleeding from midline perforations usually can be controlled with cautery or suturing laparoscopically. ▪ Laparotomy may be necessary for lateral perforations. ▪ Antibiotic coverage usually indicated.	
Subcutaneous emphysema, massive	Intraoperative	Findings ▪ Abdominal wall crepitus ▪ Gas leaking from incision ▪ Inability to insert laparoscope into	Management ▪ Express gas from subcutaneous tissue by holding incision open with blunt instrument and from subfascial area through laparoscopic sheath.

Complication	Timing	Findings/Management	
		peritoneal cavity ▪ Observation of gas-dissected subcutaneous tissue or muscle with laparoscope	▪ If emphysema is not excessive or can be reduced, attempts may be made to reestablish pneumoperitoneum either with insufflation needle or by direct insertion of laparoscopic sheath. ▪ If unable to reestablish pneumoperitoneum, procedure **must** be abandoned or open procedure attempted.
Wound infection	Postoperative	Management ▪ Open, culture, debride and irrigate incision. ▪ Teach client to clean and pack incision 2 to 3 times daily. ▪ Recheck in 3 to 4 days. ▪ Most wound infections resolve within 1 week. ▪ Antibiotics are not indicated for most superficial infections if adequately debrided, drained, cleaned and packed with wet to dry dressings (if defect is large enough for packing). ▪ Consult with staff physician for infections that do not resolve in 7 days. ▪ Consult with staff physician for suspected subfascial infections that usually require hospitalization and intravenous antibiotic therapy.	

5.2.8 Follow-up

I. A follow-up examination **must** be scheduled at the affiliate or through referral approximately 1 week post procedure, if suture removal is necessary. If no suture removal is needed, the client **must** be instructed to make an appointment within 6 weeks.

5.3 VASECTOMY

5.3.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

5.3.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
CI Before and After Your Vasectomy			●	
CIIC Vasectomy		●	●	
Release When Test/Service/Consultation Will Not Be Obtained As Recommended		Once		
Request for Surgery or Special Procedure		●		●
Written information about any medication dispensed (package insert may be used)			●	

Important Information - Informed Consent and Vasectomy

Special care **must** be exercised to ensure that men considering sterilization are not subjected to duress or to coercion, express or implied, of any kind, and that all such decisions are reached on the basis of full information and free discussion. During the client education and informed consent process, the client **must** have the

- opportunity to ask questions and to clarify points at any time during the process
- option of being accompanied by a person of his own choosing, who also is free to ask questions
- option of deciding not to have the procedure, without penalty or denial of other services

5.3.2 Contraindications and Special Conditions

I. Client selection **must** be determined according to Table 5.3.b. Possible contraindications or special conditions **must** be reported to the surgeon prior to the procedure.

5.3.b. Table: Contraindications and Special Conditions for Vasectomy

LEGEND	
A	**Musts**/Shoulds
B	Contraindications — vasectomy **must** not be provided
C	Special Conditions Requiring Further Evaluation — Conditions that may complicate surgery require management by affiliate protocols or consultation with the clinician performing the procedure.

Conditions/Signs/Symptoms	A	B	C
Anemia			●
Anti-coagulant therapy			●
Azoospermia			●
Blood disorders – including any disease that interferes with normal blood clotting			●
Chronic medical illness that may cause immune deficiency or poor healing			●
Diabetes			●
Heart disease			●
Hernia – inguinal			●
Hydrocele			●
Hypertension - BP > 140/90 or presently under treatment with medications			●
Infection – genital tract, scrotal skin or systemic infection, if present on day of scheduled surgery	▪ Procedure **must** be postponed. ▪ Consult with surgeon or physician designee and re-evaluate after treatment for rescheduling.	●	
Scrotal abnormality			●
Surgery – previous inguinal or scrotal surgery			●
Testicular abnormality			●
Varicocele			●
Vasectomy in past that failed			●

5.3.3 Medical Screening and Evaluation

5.3.c. Table: Evaluation Prior to Vasectomy

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Must include ▪ Past illnesses ▪ Previous inguinal or scrotal surgery ▪ Previous or current scrotal abnormality or trauma ▪ Current medical conditions and medications ▪ Allergies to medications (particularly local anesthetics), antiseptic solutions, and latex ▪ Substance abuse or addictions	**Must** include ▪ Genital exam, with specific evaluation for hydrocele, hernia, and skin conditions ▪ Abdominal palpation, if indicated ▪ Additional exam as indicated by history or laboratory findings	Perform as indicated ▪ Hgb or Hct ▪ GC/CT according to CDC Guidelines ✓ CDC STD Treatment Guidelines ▪ Additional tests per history or laboratory findings

5.3.4 Pre-Sterilization Procedures

I. Prior to surgery — the provider **must**
   A. Review and update the history, especially recent illness
   B. Examine the client for signs of genital tract, scrotal skin, or systemic infection
   C. Confirm that the sterilization is voluntarily requested
   D. Sign the physician's section of the state or federal sterilization consent, if necessary

5.3.5 Sterilization Procedures

I. Vas Isolation
   A. Isolation of the vas deferens should be performed using either a minimally invasive or no-scalpel technique.
   B. A single midline or bilateral incisions may be used based on the preference of the surgeon

II. Vas Occlusion
   A. Preferred Methods of Occlusion
      1. Mucosal cautery, with or without fascial interposition, and without ligatures or clips applied
      2. Open ended vasectomy leaving the testicular end unoccluded, using mucosal cautery on the abdominal end with fascial interposition

3. Non-divisional method of extended electrocautery (Marie Stopes technique)

B. Other Acceptable Methods of Occlusion (based on surgeon experience and prior success)
   1. Ligation of both ends with or without fascial interposition
   2. Clips on both ends with or without fascial interposition

5.3.6 Post-Procedure Management

I. Tissue Management
   A. When a surgeon elects to remove sections of the vas, they **must** be treated as all other surgical specimens under state law or, if there is no relevant state law tissue removed may be sent for histological confirmation at the discretion of the surgeon. Since azoospermia is the gold standard for determining the success of a vasectomy, the removed tissue does not need to be kept.

II. Client Discharge Criteria
   A. For recovery area care and discharge criteria, see Chapter 17 Recovery Area Care.
   B. Before leaving, the client **must** receive and understand postoperative instructions.

5.3.7 Management of Post-Vasectomy Complications

5.3.d. Table: Management of Post-Vasectomy Complications

Condition	Treatment/Follow-up
Hematoma	**Treatment** — immediate symptomatic relief measures include ▪ Ice packs ▪ Elevation of scrotal sac ▪ Analgesic or anti-inflammatory medication (acetaminophen/ibuprofen/naproxen sodium). If these are insufficiently effective, a small quantity of narcotic/acetaminophen analgesics may be prescribed after consultation with the surgeon, vasectomy director or medical director. ▪ Pelvic rest for 7 to 10 days **Follow-up** ▪ Clinician evaluation at the time of reported hematoma and 48 hours after, as indicated. ▪ If no resolution at the time of follow-up, refer to urologist for further treatment and evaluation.

Condition	Treatment/Follow-up
Infection / inflammation	**Treatment** ▪ Observation only with recommended pelvic rest for 7 to 10 days ▪ Antibiotics for surgical incision infection o Cephalexin 500mg TID x 7 days o Dicloxacillin 500mg QID x 7 days • If allergy to PCN ◊ Erythromycin 250mg QID x 7 days ◊ Doxycycline 100mg BID x 7 days ◊ Trimethoprim/Sulfamethoxazole DS BID x 7 days ▪ Analgesic or anti-inflammatory medication (see analgesic or anti-inflammatory medication above) ▪ Rarely, surgical treatment for abscess drainage
Acute/Chronic Pain	**Treatment** ▪ Keep penis/scrotum in place using supportive underwear ▪ Analgesic or anti-inflammatory medication (see analgesic or anti-inflammatory medication above) ▪ Pelvic rest o If < 1 week post surgery, continue to use ice packs as needed. o If ≥ 1 week post surgery, use warm packs or soaks as an alternative. In some instances, alternating between warm and cold provides the best relief. **Follow-up** ▪ Acute pain — expectant management. If no resolution, refer to urologist. ▪ Chronic pain (> 3 months) — Usually requires referral to urologist.
Spermatic Granuloma / Spermatocele	**Evaluation** — Ultrasound may be required to differentiate spermatocele from hydrocele. **Treatment** – Rarely requires treatment. **Follow up** — Refer for surgery if cyst becomes large and / or symptomatic.

Condition	Treatment/Follow-up
Adhesions / Fistula	**Follow-up** For adhesions, referral to performing surgeon or vasectomy director for treatment is acceptable if they are experienced in correcting this complication. Otherwise, refer out to urologist for treatment. For fistula, refer out to surgeon for evaluation and treatment.

5.3.8 Follow-up

I. Post-procedure medical visit
   A. **Must** be offered, either at the affiliate or through another medical provider.

✓ Refer to ARMS Emergency Manual for management of acute emergencies.

5.3.9 Post-Vasectomy Semen Analysis (PVSA)

✓ FYI – Home Testing for Azoospermia

I. At least one PVSA **must** show azoospermia before the client is advised that contraceptive measures may be discontinued. A post-operative evaluation for the persistence of sperm **must** be performed > 12 weeks post-vasectomy. The semen sample should be taken by masturbation.
II. PVSA on a fresh specimen may be performed at the affiliate using provider-performed microscopy by a qualified clinician or at an outside laboratory.
   A. Affiliate performed: semen **must** be collected in a sterile container without the use of a condom or lubricants and kept at body temperature.
      1. Ensure specimen is labeled with client's name, date, and time.
      2. Specimen **must** not be centrifuged.
      3. Specimen **must** be examined within 2 hours of collection.
      4. At least 10 high power fields (hpf) should be examined
   B. Laboratory performed: If the specimen is sent to an outside lab, only a non-concentrated (non-centrifuged) study should be performed. The lab should be asked to only report on the specimen in this form. If a study includes examination of a concentrated (centrifuged) specimen, that portion of the results should be disregarded, regardless of whether or not sperm are noted as present.

III. PVSA on a non-fresh specimen: A preliminary screen using a non-fresh semen specimen (either mailed or dropped off) provided > 12 weeks post-vasectomy may be used to determine if sperm are present. This is intended primarily for situations where it may be difficult for a client to produce a fresh semen specimen (especially in large affiliates with low population density).
   A. If no sperm are present, the procedure is considered successful and no further testing is required.
   B. If ≥ 1 sperm/hpf are present, the client may provide a second non-fresh semen specimen 1 month later. If no sperm are present in the second specimen, the procedure is considered successful and no further testing is required.
   C. If any sperm are present in the second non-fresh semen specimen, repeat testing with a fresh specimen **must** be performed.

IV. If any motile sperm are detected after 12 weeks, the client **must** be told that he is not considered infertile and that he should return for another PVSA after 1 month.

V. If any motile sperm are present on re-examination, a repeat procedure **must** be offered to the client.

VI. The persistence of rare non-motile sperm following a vasectomy has been reported in the literature. Pregnancies have not been reported in these cases, and the procedure is considered successful if the PVSA shows ≤100,000 non-motile sperm/mL and no motile sperm.

5.4 ADDITIONAL INFORMATION

5.4.a. Table: For Your Information

Section	Topic	Detail
5.1.6	Use of NSAIDs	The use of NSAIDs 30 to 60 minutes prior to HTS has been shown in early studies with Essure to improve bilateral placement rate. This is hypothesized to be due to a decreased incidence of tubal spasm at the time of the procedure.
5.1.6	Prevention of Infection in HTS	Although infection is an unlikely complication, hysteroscopy should be avoided in the presence of gross cervical infection, uterine infection, or salpingitis. Infection may be prevented by ▪ Administration of prophylactic antibiotics when indications exist. ▪ Use of oral antibiotics at the discretion of the physician when o Length of procedure is excessive. o Application of the instruments or sterilization device causes excessive manipulation or possible trauma to the uterus or fallopian tube.
5.3.9	Home Testing for Azoospermia	In 2009, the National Medical Committee advised that SpermCheck Vasectomy, a home test for oligospermia, is not acceptable to determine vasectomy effectiveness.

5.4.b. Table: References

Section	Reference
5.1	AAGL. "AAGL Practice Report: Practice Guidelines for the Management of Hysteroscopic Distending Media." Journal of Minimally Invasive Gynecology 20, no. 2 (March/April 2013). http://www.aagl.org/wp-content/uploads/2013/03/aagl-Practice-Guidelines-for-the-Management-of-Hysteroscopic-Distending-Media.pdf
5.1	Conceptus. "Essure package label." March 19, 2012. http://www.essuremd.com/App_Themes/BaseTheme/PDFs/Link%20Essure%20IFU.pdf (accessed June 14, 2014).
5.3	American Urological Association. Vasectomy: AUA Guideline. 2012. http://www.auanet.org/common/pdf/education/clinical-guidance/Vasectomy.pdf Accessed: April 15, 2014.

5.4.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIIC	CI Before and After Your HTS CI Before and After Your Tubal CI Before and After Your Vasectomy CI Hysterosalpingogram CIIC Hysteroscopic Tubal Sterilization CIIC Transabdominal Tubal Sterilization CIIC Vasectomy	Part 3, Chapter 02_05

5.4.d. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ Handbook for Introducing Hysteroscopic Tubal Sterilization	
Training	✓ PPFA Essure Workshop Presentations	
	CAL Courses Permanent Contraception Series	

CHAPTER 6: CONTRACEPTION – REVERSIBLE

Revised June 2014

Chapter 6 Table of Contents

6.1 CHOOSING A METHOD

The following table **must** be used when choosing a contraceptive method for clients with medical conditions. If a condition is not listed, a method can be prescribed. For women who develop a medical condition while on a method, turn to the section of the Standards for that particular method.

6.1.a. Table: Choosing a Method

Legend	
A	**Musts**
B	Contraindications — **must** not prescribe
C	Special Conditions Requiring Further Evaluation — Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral **must** be based on protocols approved by the medical director or in consultation with the medical director or affiliate physician. ***Must** give Special Conditions CIIC
D	Other considerations - condition should be considered in risk/benefit analysis when choosing the method
E	Other considerations - method may add a non-contraceptive benefit for a specific condition

Condition	A	B	C	D	E
PERSONAL CHARACTERISTICS AND REPRODUCTIVE HISTORY					
Allergies					
▪ Copper — known or suspected		CU IUC			
▪ Latex (does not apply to non-latex barrier methods)		Diaphragm Condom			
▪ Spermicide (does not apply to condoms without spermicide)		Diaphragm Cap Condom			
Bariatric surgery – Malabsorptive procedures only (Roux-en-Y gastric bypass, biliopancreatic diversion)			COC POP		
Immobility — chronic, for example, due to wheelchair use				CHC	
Conditions that make predicting the fertile days of menstrual cycle difficult			FAM		

Condition	A	B	C	D	E
Inability to abstain or use alternative contraceptive methods during fertile days				FAM	
Postabortion					
▪ < 42 days post midtrimester abortion		Diaphragm Cap			
▪ < 3 months post endometritis or septic abortion		IUC			
Postpartum — Not breastfeeding					
▪ < 21 days		CHC			
▪ ≥ 21 to 42 days, with other risk factors for VTE only. ✓ FYI – VTE Risk Profile			CHC		
▪ <42 days		Diaphragm Cap			
▪ < 3 months post endometritis		IUC			
Postpartum —Breastfeeding					
▪ < 21 days		CHC			
▪ ≥ 21days < 28 days — with or without other risk factors for VTE			CHC		
▪ ≥ 28 days to 42 days — with other risk factors for VTE only			CHC		
▪ <42 days		Diaphragm Cap			
▪ < 3 months post endometritis		IUC			
Smoking — age ≥ 35 years		CHC			
ANEMIAS					
Iron deficiency anemia					CHC LngIUC
Hct < 30 % or Hgb < 10 gm/dl			CuIUC[1]		

Condition	A	B	C	D	E
Sickle cell disease[2]					DMPA
CARDIOVASCULAR DISEASE					
Arterial cardiovascular disease[3] — multiple risk factors for	**Must** follow affiliate protocols for women with 2 or more risk factors		CHC* DMPA*		
Bleeding disorder - impaired coagulation		CuIUC			
DVT/PE					
▪ Adverse venous thromboembolism (VTE) risk profile ✓ FYI – VTE Risk Profile	**Must** consider risk profile when 2 or more risk factors exist		CHC		
▪ History of DVT/PE, not on anticoagulant therapy — higher risk for recurrence ▪ (≥ 1 risk factor(s))[4]		CHC[5]			
▪ History of DVT/PE, not on anticoagulant therapy – lower risk for recurrence (no risk factors)[4]			CHC*		
▪ Acute DVT/PE		CHC			
▪ History of DVT/PE, on anticoagulant therapy		CHC			
▪ Major surgery (anticipated or recent) with prolonged immobilization		CHC			
Hyperlipidemia — known/reported by client Total cholesterol ≥240 mg/dL or LDL cholesterol ≥160 mg/dL or HDL cholesterol <40 mg/dL or triglycerides in the range of 200-499 mg/dL			CHC		
Hypertension					
▪ Systolic ≥ 160 mm Hg or diastolic ≥ 100 mm Hg		CHC	DMPA*		
▪ Systolic 140-159 mm Hg or diastolic 90-99 mm Hg			CHC*		
▪ Adequately controlled hypertension: <140/<90			CHC*		
▪ And vascular disease		CHC	DMPA*		

Condition	A	B	C	D	E
Ischemic heart disease – current or h/o		CHC	DMPA*		
Peripartum cardiomyopathy		CHC			
Stroke — history of CVA		CHC	DMPA*		
Thrombogenic mutations[6] — known/reported by client		CHC			
Valvular heart disease — complicated (pulmonary hypertension, risk of atrial fibrillation, history of subacute bacterial endocarditis)		CHC			
RHEUMATIC DISEASES					
▪ Systemic lupus erythematosus *(SLE)* ✓ FYI SLE					
▪ When antiphospholipid antibodies are positive or unknown.		CHC[7]	DMPA*[8] Implant*[9] POP*[9] LngIUC*[9]		
▪ If severe thrombocytopenia			DMPA[9] CuIUC[10]		
MUSCULOSKELETAL					
▪ Osteoporosis — conditions that increase risk (NMC 2005)[11] ✓ FYI - Risk Factors for Osteoporosis			DMPA		
▪ Osteoporosis / fragility fractures[12] — known ✓ FYI - Risk Factors for Osteoporosis	**Must** obtain documentation from treating healthcare provider or subspecialist that client has been evaluated that use of DMPA is approved and time frame for use is stipulated		DMPA*		

Condition	A	B	C	D	E
NEUROLOGIC CONDITIONS					
Headache with focal neurological symptoms or with symptoms suggesting cerebral ischemia	**Must** refer for evaluation	CHC			
Meningioma — currently being treated	**Must** consult with oncologist or neurosurgeon		CHC DMPA Implant POP		
Migraine with aura[13] — with or without headache at any age		CHC			
Migraine without aura (simple migraine) — women ≥ age 35 only			CHC		
Seizure disorders[14]					DMPA
REPRODUCTIVE TRACT INFECTIONS AND DISORDERS					
Anatomic Conditions					
▪ Distortion of the uterine cavity such that proper placement is prevented[15]		IUC			
▪ Congenital uterine anomalies (bicornuate, septate, etc.)		IUC			
▪ Large or obstructive myomata		IUC			
▪ Small uterine cavity with sounding less than 6.0 cm (NMC 2010)[16]			IUC		
▪ Markedly distorted cervical anatomy		Cap			
▪ Uterine prolapsed		Diaphragm			
▪ Conditions that put the Ring at risk of expulsion including vaginal stenosis, pelvic organ prolapse, rectocele, cystocele and severe constipation				Ring only	
Anovulation — chronic		FAM			CHC

Condition	A	B	C	D	E
Breast Disease					
▪ Breast cancer – current and past		CHC DMPA Implant POP LngIUC			
▪ Undiagnosed mass	**Must** initiate breast mass evaluation as soon as possible		CHC* DMPA* Implant* POP* LngIUC*		
Cervical cancer — known, has not been treated		Cap IUC			
Cervical dysplasia — high grade		Cap			
Dysmenorrhea — severe				CuIUC	CHC LngIUC
Endometrial cancer — known		IUC			
Gestational Trophoblastic Disease (history)					
▪ With persistently elevated β-hCG levels or malignant disease		IUC			
▪ With decreasing or undetectable hCG levels			IUC		
Infections — not STI/PID					
▪ Known pelvic tuberculosis		IUC			
▪ History of pelvic actinomycosis — Symptomatic, confirmed by a culture (not asymptomatic colonization) ✓ FYI - Actinomyces on Pap and it's time to Replace the IUC		IUC			

Condition	A	B	C	D	E
✓ FYI — Actinomyces					
▪ History of toxic shock syndrome		Diaphragm Cap			
▪ Recent history of frequent lower urinary tract infections, especially if associated with prior diaphragm use			Diaphragm Cap		
PID and STIs					
▪ Known or suspected untreated chlamydia, gonorrhea, mucopurulent cervicitis, PID		IUC[17]			
▪ Increased risk for PID or sexually transmitted infections (STIs)[18]			IUC		
▪ Unresolved bacterial vaginosis				IUC	
Perimenopausal symptoms					CHC
Pregnancy or suspicion of pregnancy		IUC			
Uterine perforation from IUC/hx IUC expulsion					
▪ Known or suspected perforation occurring with placement of uterine sound during current procedure		IUC			
▪ Previous IUC intolerance, expulsion, failure				IUC	
Vaginal bleeding					
▪ Menorrhagia				CuIUC	LngIUC
▪ Abnormal, unexplained	For CHC, DMPA, Implant, Pops ▪ **Must** evaluate abnormal bleeding ▪ Women ≥ age 45 ○ With risk factors for endometrial cancer[19] — **must** perform endometrial biopsy prior	IUC	CHC DMPA Implant POP		

Condition	A	B	C	D	E
	to initiation of method. May start method prior to obtaining results. ○ Without risk factors for endometrial cancer — should perform endometrial biopsy. May start method prior to biopsy. ▪ Women < age 45 with risk factors for endometrial cancer[19]– should perform endometrial biopsy. May start method prior to biopsy.				
HIV/AIDS					
AIDS		Diaphragm Cap			
High risk for HIV		Diaphragm Cap			
HIV infection		Diaphragm Cap			
ENDOCRINE CONDITIONS					
Adrenal insufficiency — predisposes for hyperkalemia			DRSP only		
Diabetes					
▪ Nephropathy/retinopathy/neuropathy		CHC	DMPA		
▪ Other vascular disease or diabetes of > 20 years duration		CHC	DMPA		

Condition	A	B	C	D	E
▪ Without clinical vascular disease	As risk factors increase in number or severity, it is less appropriate to prescribe CHCs. The healthcare provider managing the client's diabetes should be consulted before the client is initiated on CHCs. If the client is prehypertensive or hypertensive, the diabetes care provider **must** be consulted.		CHC*		
GASTROINTESTINAL CONDITIONS					
Gallbladder disease — active (specifically excluding history of cholecystectomy) and past cholestasis related to CHC use			CHC		
Inflammatory Bowel Disease — ulcerative colitis and Crohn disease for women at increased risk for VTE such as active or extensive disease, surgery, immobilization, corticosteroid use, vitamin deficiencies, fluid depletion			CHC[20]		
Liver Disease					
▪ Viral hepatitis – acute or flare		CHC[21]			
▪ Cirrhosis - severe ✓ FYI - Assessing for Severity of Cirrhosis by Using the Child Pugh Scoring System		CHC[21]	DMPA[22] Implant[22] POP[22] LngIUC[22]		
▪ End stage liver disease		CHC	DMPA POP LngIUC		

Condition	A	B	C	D	E
Liver tumors					
▪ Benign — history of or current hepatocellular adenoma		CHC	DMPA[23] Implant[23] POP[23] LngIUC[23]		
▪ Malignant — history of or current hepatoma		CHC	DMPA Implant POP LngIUC		
METABOLIC CONDITIONS					
Wilson's Disease		CUIUC			
RENAL CONDITIONS					
Renal insufficiency — Predisposes for hyperkalemia			DRSP only		
SOLID ORGAN TRANSPLANTATION					
Complicated — graft failure (acute or chronic), rejection, cardiac allograft vasculopathy, Budd-Chiari Syndrome		CHC[24]	IUC		
DRUG INTERACTIONS					
Medication(s) that may decrease contraceptive efficacy or method may interact with medication ✓ FYI — Systemic Antibiotics	See Table 6.1.b		CHC DRSP FAM Implant POP		

✓ FYI — Women with Significant Medical Conditions

6.1.b. Table: Special Conditions Drug Interaction

Drugs known to increase liver enzyme metabolism/ decrease contraceptive effectiveness of CHC, Implant, and POPS	Drugs with questionable effects	Drugs known not to affect liver enzyme metabolism or contraceptive effectiveness
Anti Epilepsy Drugs (AEDs) — may also be used to treat certain psychiatric illnesses, headaches, chronic pain and other conditions. When prescribing COCs, a preparation containing a minimum of 30 µg EE monophasic pill should be used. Inform the healthcare provider who prescribed the client's AED, when possible, when CHC is initiated, as it may interfere with the AED.		
Carbamazepine (Tegretol, Equetro, Carbetrol) Oxcarbazepine (Trileptal) Phenobarbital Phenytoin (Dilantin) Primidone (Mysoline) Topiramate if >200 mg/day (Topamax) ~~Lamotrigine (Lamictal) (monotherapy)~~	Felbamate (Felbatol) FYI — CHCs may reduce bioavailability of lamotrigine (Lamictal).	Gabapentin (Neurontin) Tiagabine (Gabitril) Levetiracetam (Keppra) Valproic Acid (Depakote) Zonisamide (Zonegran) Vigabatrin (Sabril) Ethosuximide (Zarontin) Benzodiazepines
Anti-Mycobacterials (Drug used to treat tuberculosis)		
Rifampin Rifampicin Rifamate		INH (not in combination with Rifampin)
Others		
Griseofulvin (anti-fungal) St John's Wort		Ketoconazole (anti-fungal) Fluconazole (anti-fungal)

Anti-HIVs — For up to date information go to http://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf (Accessed May, 2013)	
↓ Effectiveness of CHC	↑ Steroid levels/ No efficacy concern
Atazanavir + ritonavir – use OC containing at least 35 mcg of EE Darunavir + ritonavir – use alternative method or back up Fosamprenavir + ritonavir – use alternative method or back up Lopinavir + ritonavir – use alternative method or back up Saquinavir + ritonavir – use alternative method or back up Tipranavir + ritonavir – use alternative method or back up	Atazanavir – use OC w/no more than 30 mcg EE Fosamprenavir – use alternative method
Atazanavir + ritonavir – OCs containing progestins other than norethindrone or norgestimate have not been studied. Atazanavir - OCs containing less than 25 mcg of ethinyl estradiol or progestins other than norethindrone or norgestimate have not been studied.	

Drospirenone-only: Medications that may increase serum potassium when used for long-term treatment for chronic conditions or diseases. If drospirenone is prescribed to a woman taking any of the medications that predispose to hyperkalemia on a daily, long-term basis, the package insert states that the client should have her potassium level checked during the first month of OC use.

Ace inhibitors	Angiotensin-II receptor antagonists	Potassium-sparing diuretics	NSAIDS	Other
Captopril (Capoten) Enalapril (Vasotec) lisinopril (Zestril)	Losartan potassium (Cozaar) Valsartan (Diovan) Irbesartan (Avapro)	Spironolactone	Ibuprofen (Motrin, Advil) Naprosyn (Aleve)	Heparin

FAM only: use of certain medications may interfere with interpretation of fertility signs. Examples include: lithium, tricyclic antidepressants, anti-anxiety medications, some antibiotics, and anti-inflammatory drugs. (US MEC)

6.2 COMBINED HORMONAL CONTRACEPTIVES (CHCS)

Combined Oral Contraceptive [COC], Contraceptive Vaginal Ring [CVR], Transdermal Contraceptive Patch [TCP]

6.2.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

6.2.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
CI How To Use The Patch			At first RX	
CI How To Use The Pill			At first RX	
CI How To Use The Ring			At first RX	
CIIC HC Special Conditions*			At first RX and every renewal, if applicable	
CIIC Pill Patch and Ring			At first RX and with every update of CIIC	
Package insert			At first RX	annually
Release When Test/Service/Consultation Will Not Be Obtained		Once		
Written information on all available contraceptive methods			If starting an Rx method for the first time	To all others seeking a new method/change
*Diabetes, chronic hypertension, BP 140-159/90-99, history of DVT/PE with low risk of recurrence, multiple cardiovascular risk factors, undiagnosed breast mass				

6.2.b. Prescribing Combined Hormonal Contraceptives

I. Prescription — limited to 13 months supply before the next risk assessment. Clinician discretion may be used to prescribe additional cycles. Monophasic COCs and CVR may be provided continuously in a manner to be determined by the individual clinical situation.

✓ When initiating or switching to CHC, **must** follow Table 6.1.a. Choosing a Method

✓ See Table 6.9.a. Requirements for Initial Prescribing/Providing/Dispensing and Renewal

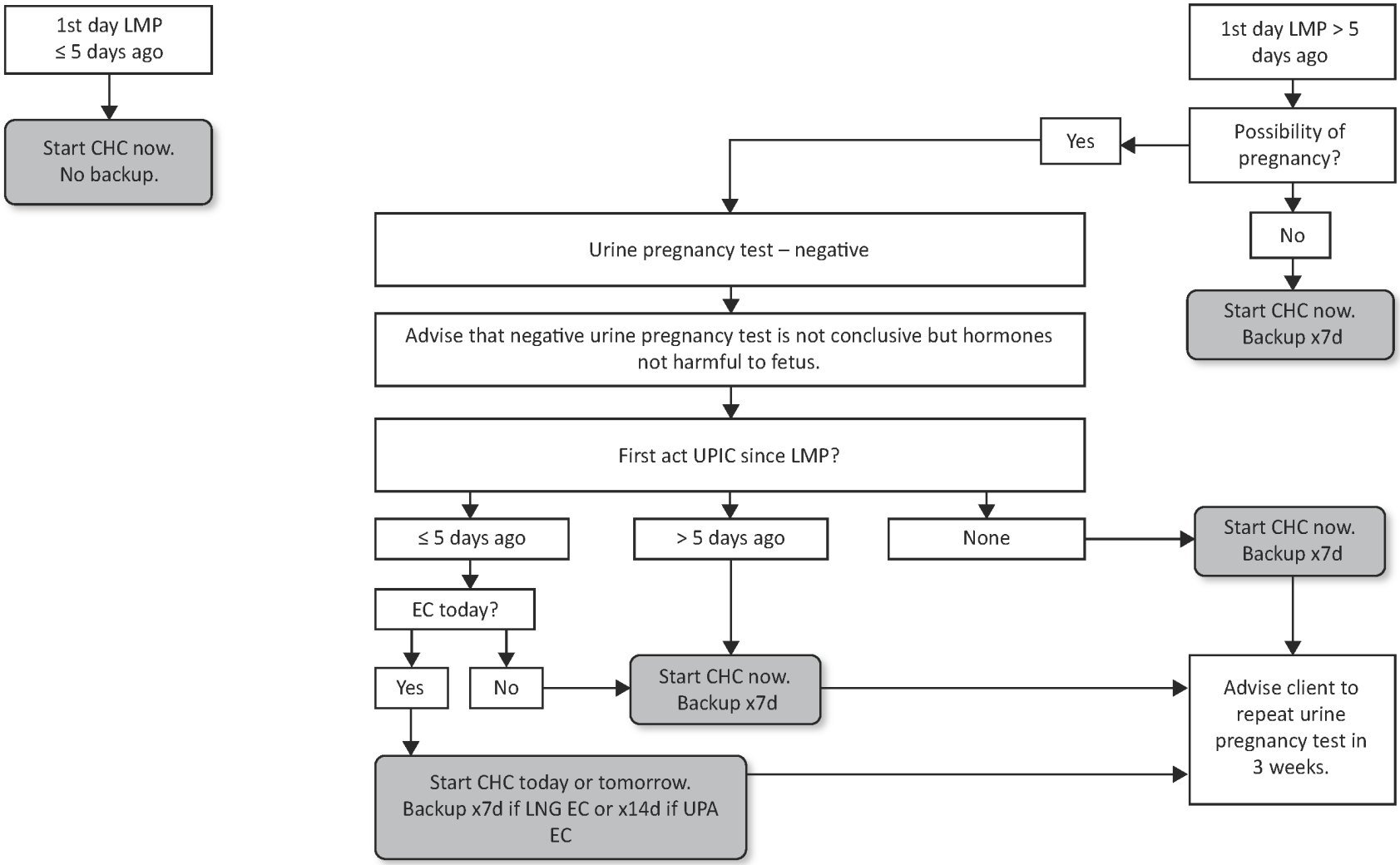
✓ FYI — Extended Use of the Patch and the Ring

6.2.c. Table: Timing of Initiation

Current Method	Initiate CHC	Back Up
No effective contraception Barrier methods	▪ Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history? ▪ If possibility of pregnancy is suspected, **must** perform urine pregnancy test. ▪ If pregnancy test is negative, initiate CHC and advise client to repeat urine test in 3 weeks. (See Algorithm 6.2.d.)	▪ If ≤ 5 days since onset of menses, none. ▪ If > 5 days since onset of menses, backup for 7 days.
Current correct use of hormonal contraception (HC) (For LNG IUC see below)	~~Continuous use pill, patch, ring, on day of implant removal, when DMPA injection due~~	None
	~~Cyclic use of pills, patch, ring~~	~~Backup for 7 days.~~
	If switching from DMPA and it had been initiated > 7 days after onset of menses, **must** perform urine pregnancy test before prescribing CHC.	
IUC	Any time in cycle ▪ ≤ 5 days since onset of menses	None
	▪ > 5 days and no IC this cycle	Backup for 7 days
	▪ > 5 days and has had IC this cycle, ~~three~~ options	
	○ Start CHC, remove IUC ≥ 7 days later	None
	~~○ Abstain or use barrier ≥ 7 days, remove IUC, start CHC~~	~~None~~
	○ Remove IUC, provide EC, start CHC	~~Backup for 7 days~~

Current Method	Initiate CHC	Back Up
Post-EC Pills	Immediately — same day as EC or the following day ▪ If > 7 days since onset of menses, perform a urine pregnancy test prior to initiation. ▪ Advise client to repeat pregnancy test in 3 weeks.	Backup for 7 days after LNG EC or 14 days after UPA EC
Post-surgical procedure for spontaneous or elective abortion and post early pregnancy failure – no procedure	≤ 7 days post procedure or passing pregnancy (when day known)	None, if initiated that day. Otherwise back-up for 7 days
	> 7 days or unknown~~, see "no effective contraception" above.~~	See "no effective contraception" above
Post-medication abortion	May initiate prior to confirmation of termination of pregnancy.	
	Day of misoprostol up to 7 days after mifepristone	None
	> 7 days after mifepristone and before resuming IC	Back-up for 7 days
Post-delivery after 24 weeks gestation – breastfeeding	May only initiate if ≥ 21 days postpartum (US MEC 4) ▪ 21-42 days postpartum see Table 6.1.a. Choosing a Method If menses has resumed, see "no effective contraception" above.	If < 6 months postpartum, amenorrheic, and vast majority of feeds are breastfeeds, none. Otherwise if ≥ 21 days postpartum and menses has not resumed menses, backup for 7 days.
Post-delivery after 24 weeks gestation – not breastfeeding	May only initiate if ≥ 21 days postpartum (USMEC 4) ▪ 21-42 days postpartum see Table 6.1.a. Choosing a Method If menses has resumed, see "no effective contraception" above.	If menses has not resumed, backup for 7 days.

6.2.d. Algorithm: Quick Start for CHC



I. Follow-up for CHC-Related Medical Visits
   A. History — review changes in personal history, headaches, signs of migraine aura, pain or swelling in legs, chest pain, shortness of breath, abdominal pain, and jaundice
   B. Examination/Laboratory Testing
      1. BP **must** be taken, if indicated (i.e., headache related visit)
      2. Other physical exam and laboratory testing **must** be performed, as indicated

II. Management Of Deviations

✓ U.S. SPR Guidelines for Management of Deviations from the Recommended Regimens for Pill, Patch, Ring

III. Management of Women Who Develop Side Effects and Complications

6.2.e. Table: Condition/Signs/Symptoms That Develop While on CHC

Legend	
A	Contraindications — **must** discontinue
B	Special Conditions Requiring Further Evaluation — Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral **must** be based on protocols approved by the medical director or in consultation with the medical director or affiliate physician. ***Must** give Special Conditions CIIC
C	Other considerations - condition should be considered in risk/benefit analysis for continuing method

Condition/Signs/Symptoms	A	B	C
Bleeding – irregular (extended or continuous use and/or cyclic use) ✓ FYI - Managing Unscheduled Bleeding in COC, DMPA, and IUC Users		●**	
Breast cancer – histologically proven malignancy or strong evidence of malignancy (e.g. BI-RADS 5)	●		
Breast mass (undiagnosed) – may continue CHC. **Must** initiate evaluation as soon as possible.*		●	
Diarrhea ✓ CDC recommended steps after vomiting or diarrhea while using combined oral contraceptives			
Headache			
▪ Non-migrainous – mild or severe (USMEC 2)			●
▪ Migraine aura or symptoms suggesting cerebral ischemia (USMEC 4)	●		

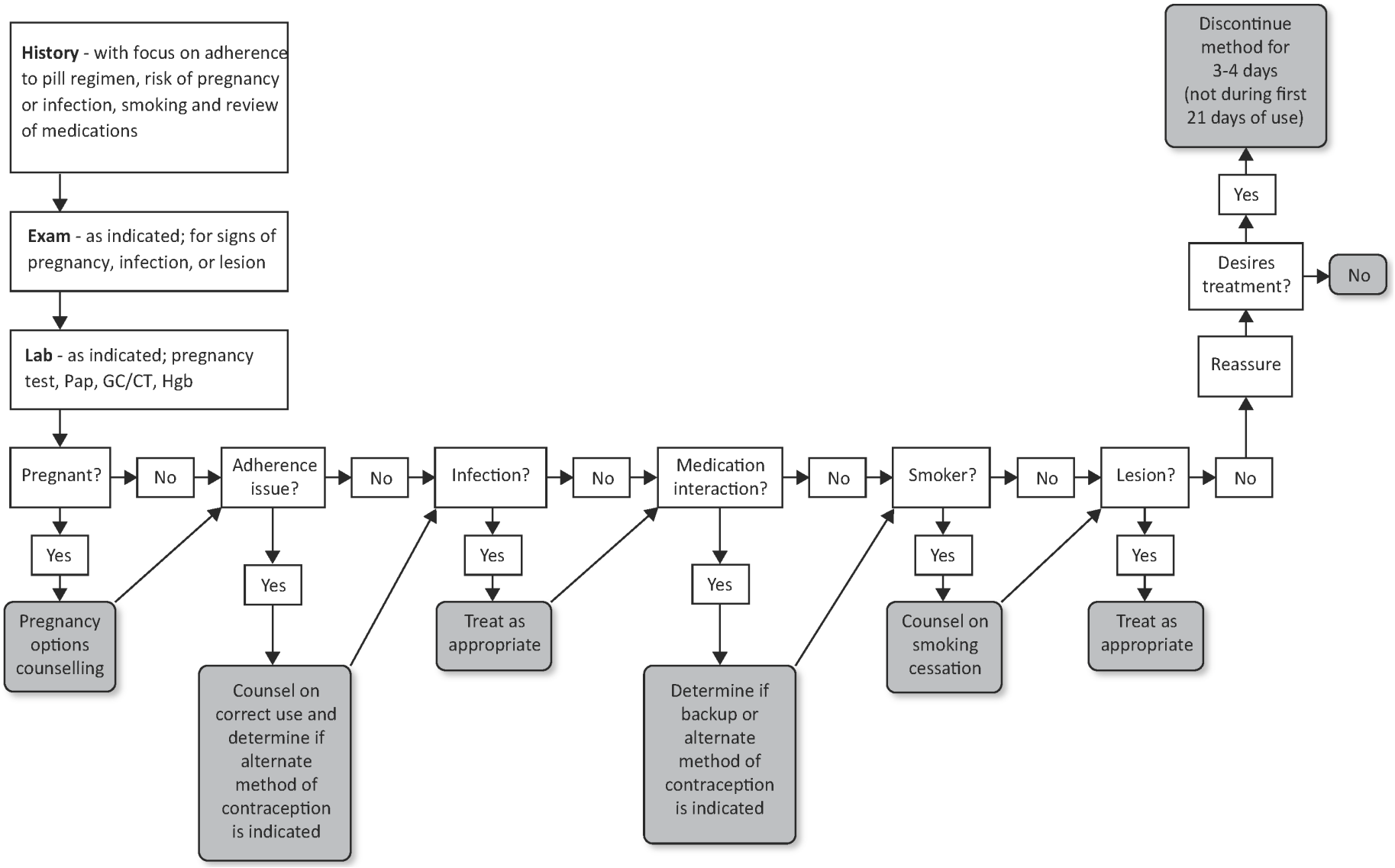
Condition/Signs/Symptoms	A	B	C
▪ Migraine without aura in women ≥ 35 (USMEC 4)	●		
▪ Migraine without aura in women < 35 (USMEC 3)		●	
Hepatitis - acute or flare (US MEC 2)			●
Hypertension* – If a woman with diabetes or chronic kidney disease develops a systolic blood pressure >120 or diastolic > 80, her disease management provider **must** be consulted.		●**	
Ischemic heart disease	●		
Pregnancy	●		
Thrombophlebitis†, pulmonary embolus, cerebrovascular disorders, or retinal thrombosis	●		
Vomiting ✓ CDC recommended steps after vomiting or diarrhea while using combined oral contraceptives			

* **Must** give Special Conditions CIIC

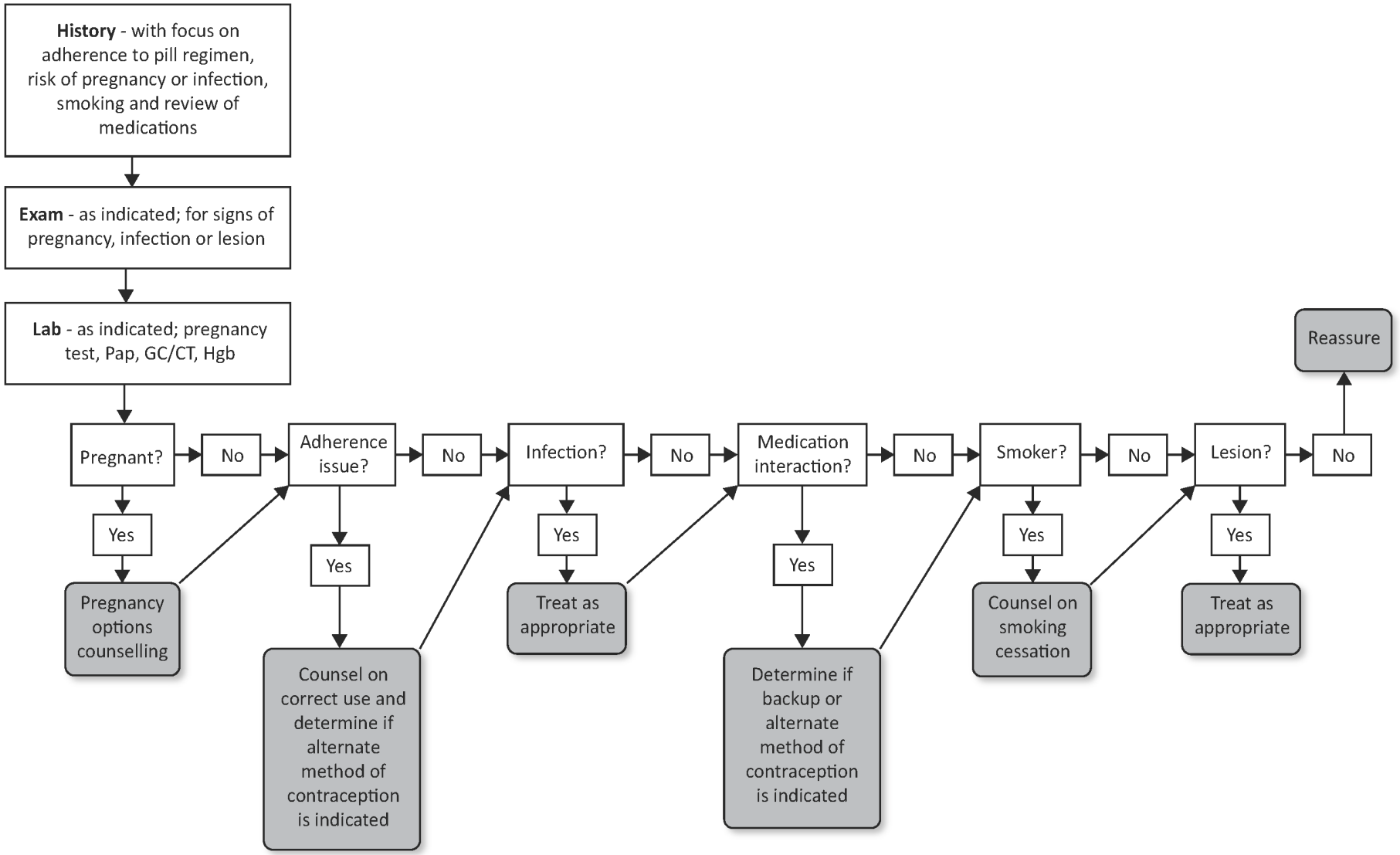
**See flow diagrams 6.2.f. to 6.2.h.

†If it is determined that client has superficial thrombophlebitis, CHC is not contraindicated

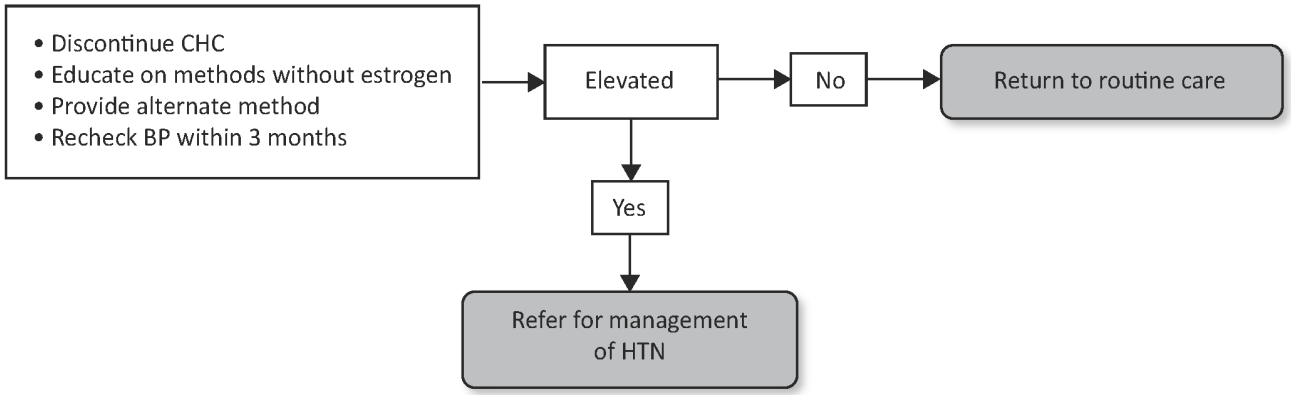
6.2.f. Flow Diagram: Evaluation and Management of Irregular Bleeding with Extended or Continuous Use of CHC



6.2.g. Flow Diagram: Evaluation and Management of Irregular Bleeding with Cyclic Use of CHC



6.2.h. Flow Diagram: Management of a Client Who Develops Elevated Blood Pressure After Initiating CHC



6.3 CONTRACEPTIVE IMPLANTS

6.3.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

6.3.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
CI After Insertion of the Implant			At each insertion	
CI After Taking Out the Implant			At each removal	
CIIC HC Special Conditions*			At each insertion	
CIIC Implant		●	At each insertion	
CIIC Taking Out the Implant		●	At each removal	
Package insert			At each insertion	
Product User Card			At each insertion	
Release When Test/Service/Consultation Will Not Be Obtained		Once		

Document	Document #	**Must** sign	**Must** give	**Must** offer
Request for Surgery or Special Procedure		•		At each insertion and removal
Written information on all available contraceptive methods			If starting an Rx method for the first time	To all others seeking a new method/change
*Systemic lupus erythematosus (SLE) — when antiphospholipid antibodies are positive or unknown; undiagnosed breast mass				

6.3.2 Prescribing Implants

I. Prescription — Single rod implant marketed in the US can be used for up to 3 years.

✓ When initiating or switching to the contraceptive implant, **must** follow Table 6.1.a. Choosing a Method

✓ See Table 6.9.a. Requirements for Initial Prescribing/Providing/Dispensing and Renewal

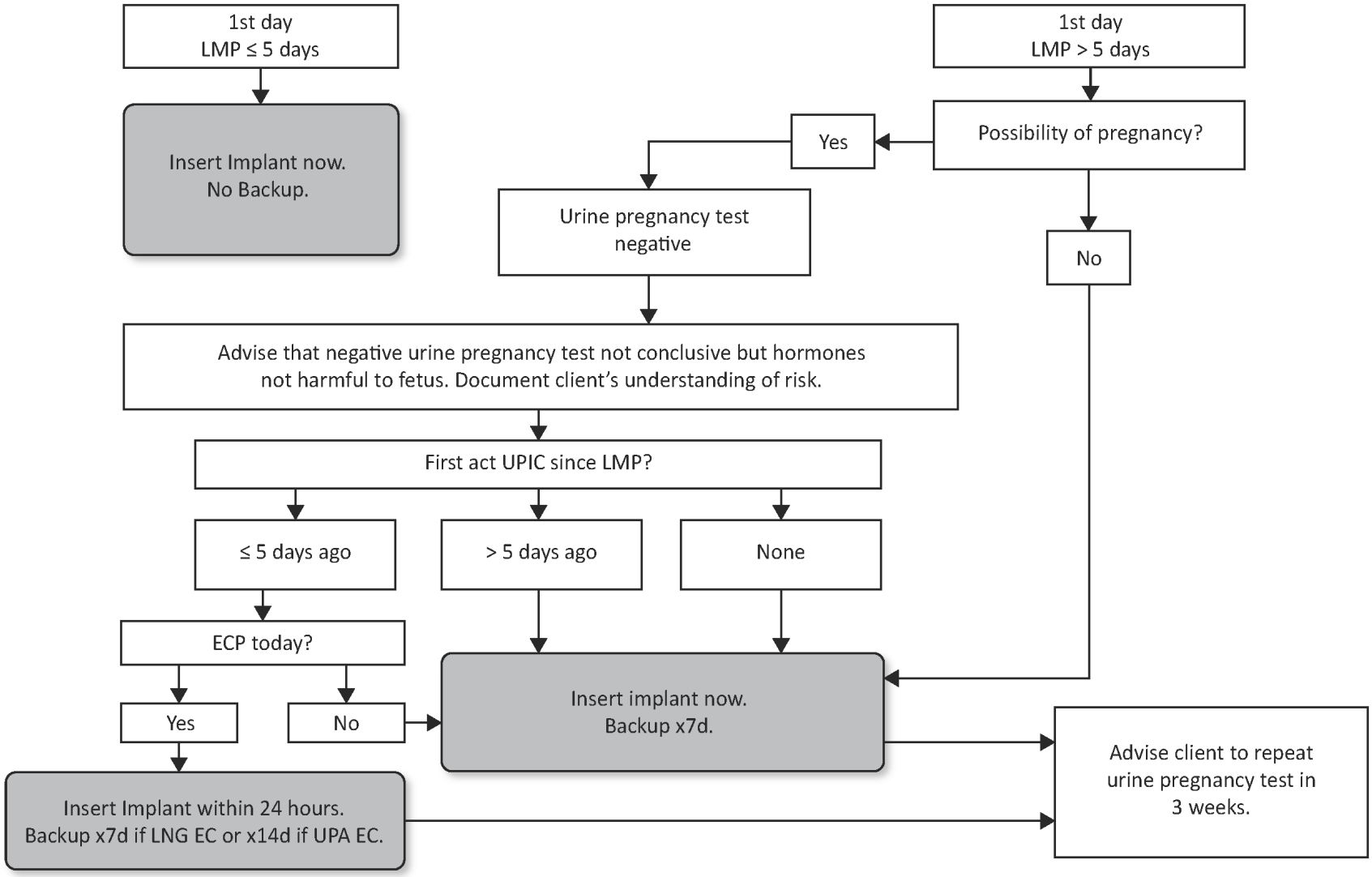
6.3.b. Table: Timing of Initiation - Implants

Current Method	Insert Implant	Backup
No effective contraception in current cycle Barrier methods	▪ Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history? ▪ If possibility of pregnancy is suspected, **must** perform urine pregnancy test. ▪ If pregnancy test is negative and client understands risk of possible very early pregnancy, insert implant and advise client to repeat urine test in 3 weeks. (See Algorithm 6.3.c.)	▪ If ≤ 5 days since onset of menses, none. ▪ If > 5 days since menstrual bleeding started, backup for 7 days.
Current correct use of hormonal contraception	Any time in cycle (pill, patch or ring) or when DMPA injection due If switching from DMPA and it had been initiated > 5 days after onset of menses, **must** perform urine pregnancy test before inserting implant.	Backup for 7 days

Current Method	Insert Implant	Backup
IUC	▪ Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history?	
	▪ ≤ 5 days since onset of menses	None, may remove IUC at time of insertion.
	▪ 5 days since onset of menses and has not had IC this cycle	Backup for 7 days
	▪ > 5 days since onset of menses and has had IC this cycle. ~~Three~~ options	
	○ Insert implant and remove IUC ≥7 days later.	None
	○ ~~Abstain or use barrier for ≥7 days before implant inserted and IUC removed.~~	~~None~~
	○ Insert implant, remove IUC, and provide EC.	~~Backup for 7 days~~
Post-EC Pills	Immediately — same day as EC or the following day ▪ If > 5 days since onset of menses, perform a urine pregnancy test prior to insertion of implant. ▪ Advise client to repeat pregnancy test if no menses in 3 weeks.	Backup for 7 days after LNG EC or 14 days after UPA EC
Post-surgical procedure for elective or spontaneous abortion and post early pregnancy failure – no procedure	▪ ≤ 7 days post procedure or passing pregnancy (when day known)	None, if inserted that day. Otherwise, backup for 7 days.
	▪ > 7 days or unknown~~, see "no effective contraception" above.~~	See "no effective contraception" above
Post-medication abortion	May insert prior to confirmation of termination pregnancy	
	▪ Day of misoprostol up to 7 days after mifepristone	None
	▪ > 7 days after mifepristone and before resuming intercourse	Backup for 7 days.

Current Method	Insert Implant	Backup
Post-delivery after 24 weeks – breastfeeding	▪ Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history? If menses has resumed, see "no effective contraception" above.	▪ If <21 days postpartum, none. ▪ If < 6 months postpartum, amenorrheic, and vast majority of feeds are breastfeeds, none. Otherwise if ≥ 21 days postpartum and menses has not resumed, backup for 7 days.
Post-delivery after 24 weeks – not breastfeeding	▪ Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history? If menses has resumed, see "no effective contraception" above.	▪ If <21 days postpartum, none. ▪ If ≥ 21 days postpartum and menses has not resumed, backup for 7 days.

6.3.c. Algorithm: Quick Start for Contraceptive Implants



I. Insertion - The manufacturer's instructions for insertion **must** be followed.
   A. Placement **must** be confirmed by palpating implant after insertion.
   B. If the implant cannot be palpated post insertion, client **must** be advised to use a non-hormonal method of contraception until placement is verified.

6.3.3 Follow-up for Implant-Related Medical Visits

I. Client should be queried about changes in personal history, possible side effects, and her menstrual cycle/bleeding pattern.
   A. Physical exam and laboratory testing **must** be performed, as indicated.
   B. Presence of implant **must** be documented in client's record.

6.3.4 Guidelines for Management of Side Effects And Complications

6.3.d. Table: Condition/Signs/Symptoms That Develop While Using the Implant

Legend	
A	Contraindications — **must** discontinue
B	Special Conditions Requiring Further Evaluation — Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral **must** be based on protocols approved by the medical director or in consultation with the medical director or affiliate physician. ***Must** give Special Conditions CIIC
C	Other considerations - condition should be considered in risk/benefit analysis for continuing method

Condition/Signs/Symptoms	A	B	C
Amenorrhea		●**	
Bleeding – irregular ✓ FYI - Expected Bleeding Patterns		●**	
Breast cancer – histologically proven malignancy or strong evidence of malignancy (e.g. BI-RADS 5) (USMEC 4)	●		
Breast mass (undiagnosed) – may continue Implant. **Must** initiate evaluation as soon as possible.* (USMEC 2)		●	
Expulsion†			

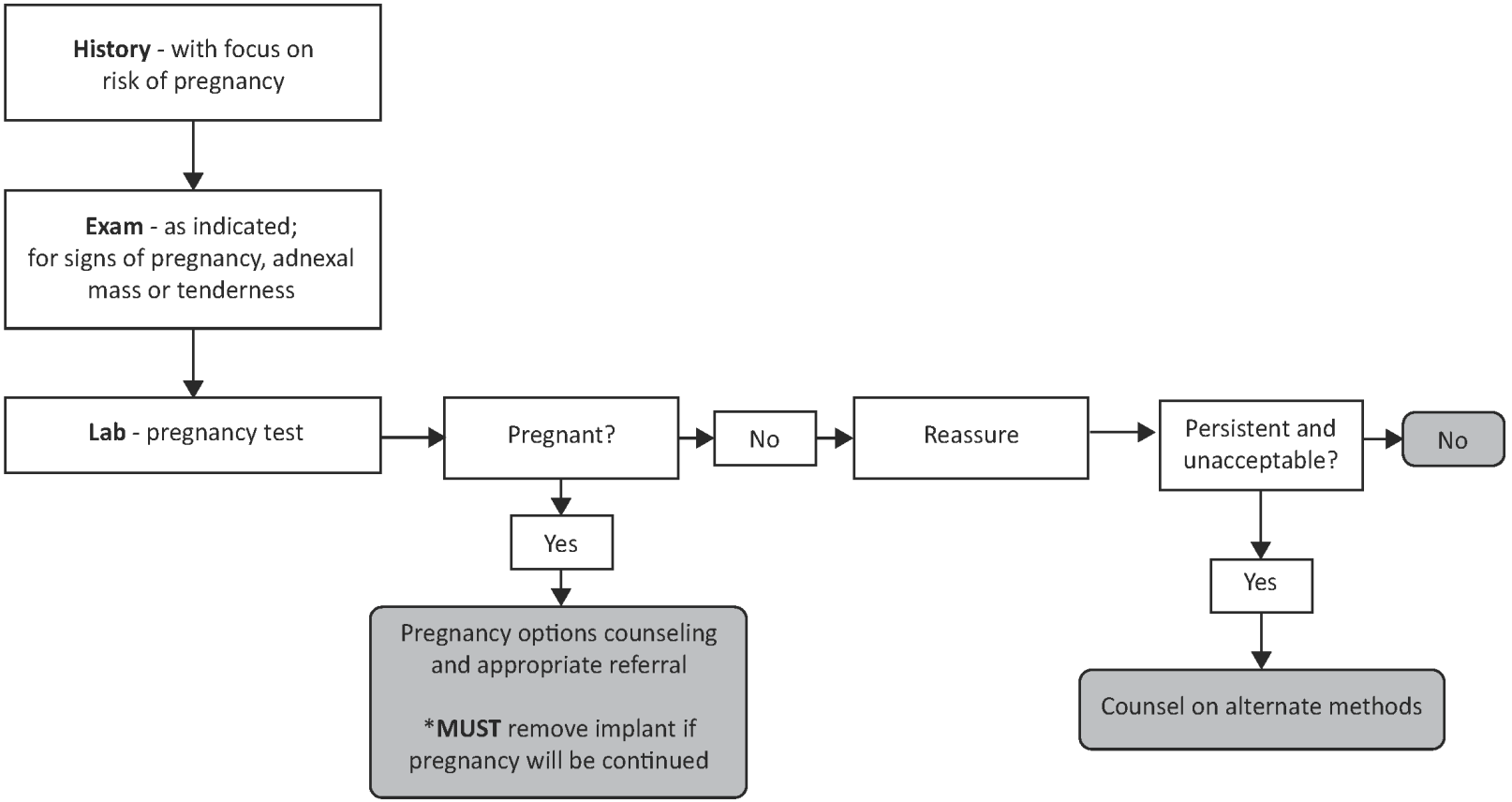
Condition/Signs/Symptoms	A	B	C
Headache			
▪ Non-migrainous - mild or severe (USMEC 2)			●**
▪ Migraine without aura (USMEC 2, continuation)			●**
▪ Migraine aura (USMEC 3, continuation)		●	
Implant nonpalpable**			
Insertion site complications			●**
Ischemic heart disease (US MEC 3, continuation)		●	
Stroke (USMEC 3, continuation)		●	

* **Must** give Special Conditions CIIC.

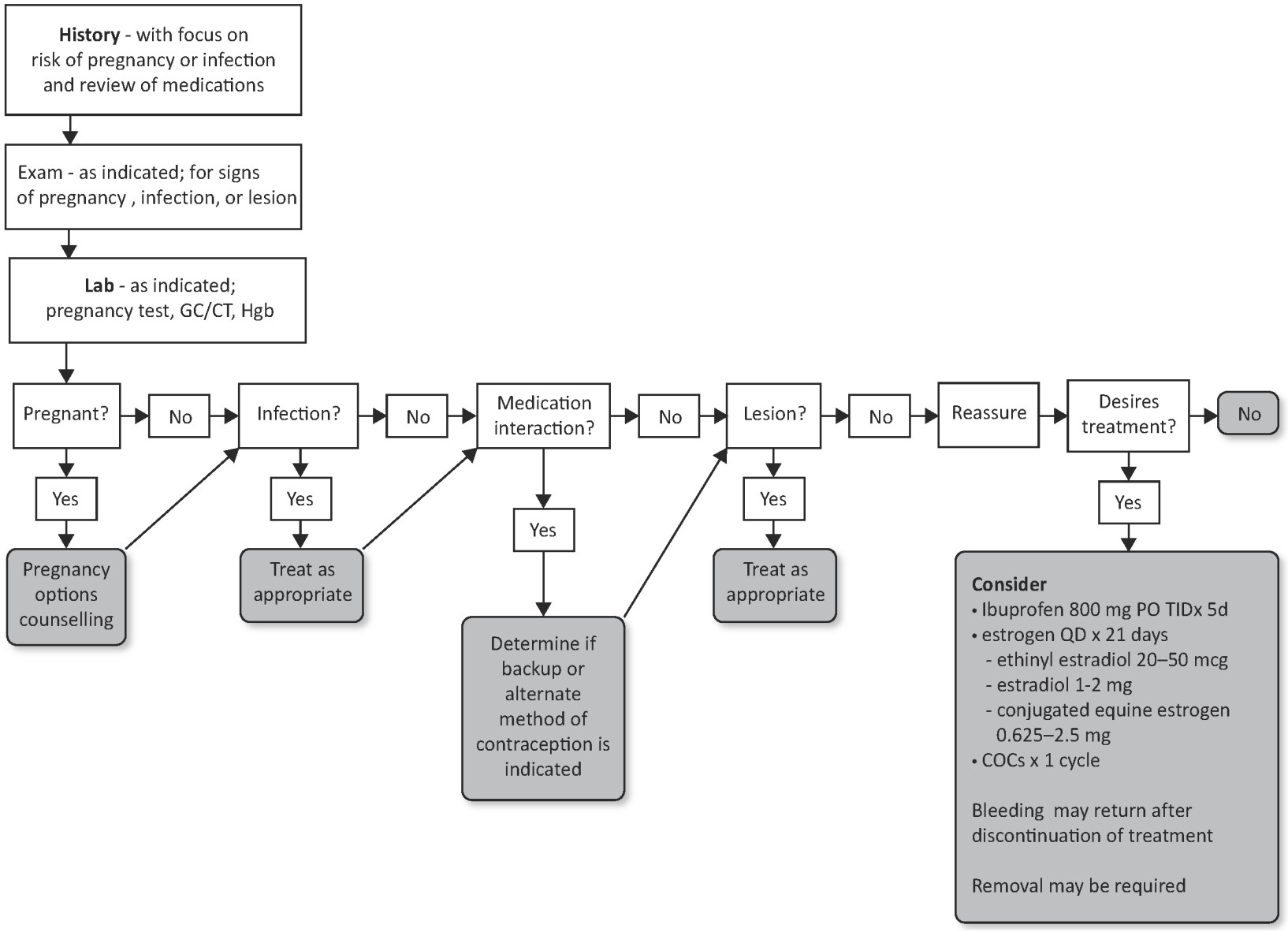
**See flow diagrams 6.3.e. – 6.3.i

[†]If partial expulsion, gently remove implant with hemostat. Clean incision with antiseptic and close with steri-strip. If bleeding, apply pressure dressing. Advise use of another method of contraception until replacement implant inserted. Offer EC if appropriate. Replacement implant can be inserted in a different site.

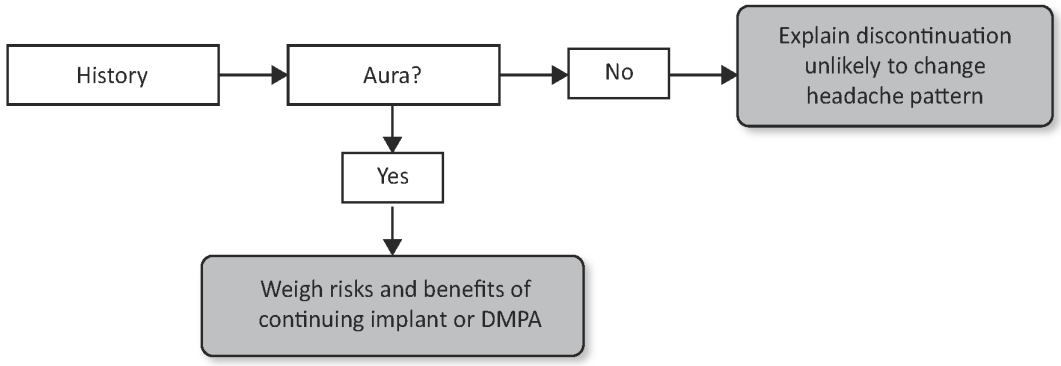
6.3.e. Flow Diagram: Amenorrhea – Contraceptive Implants



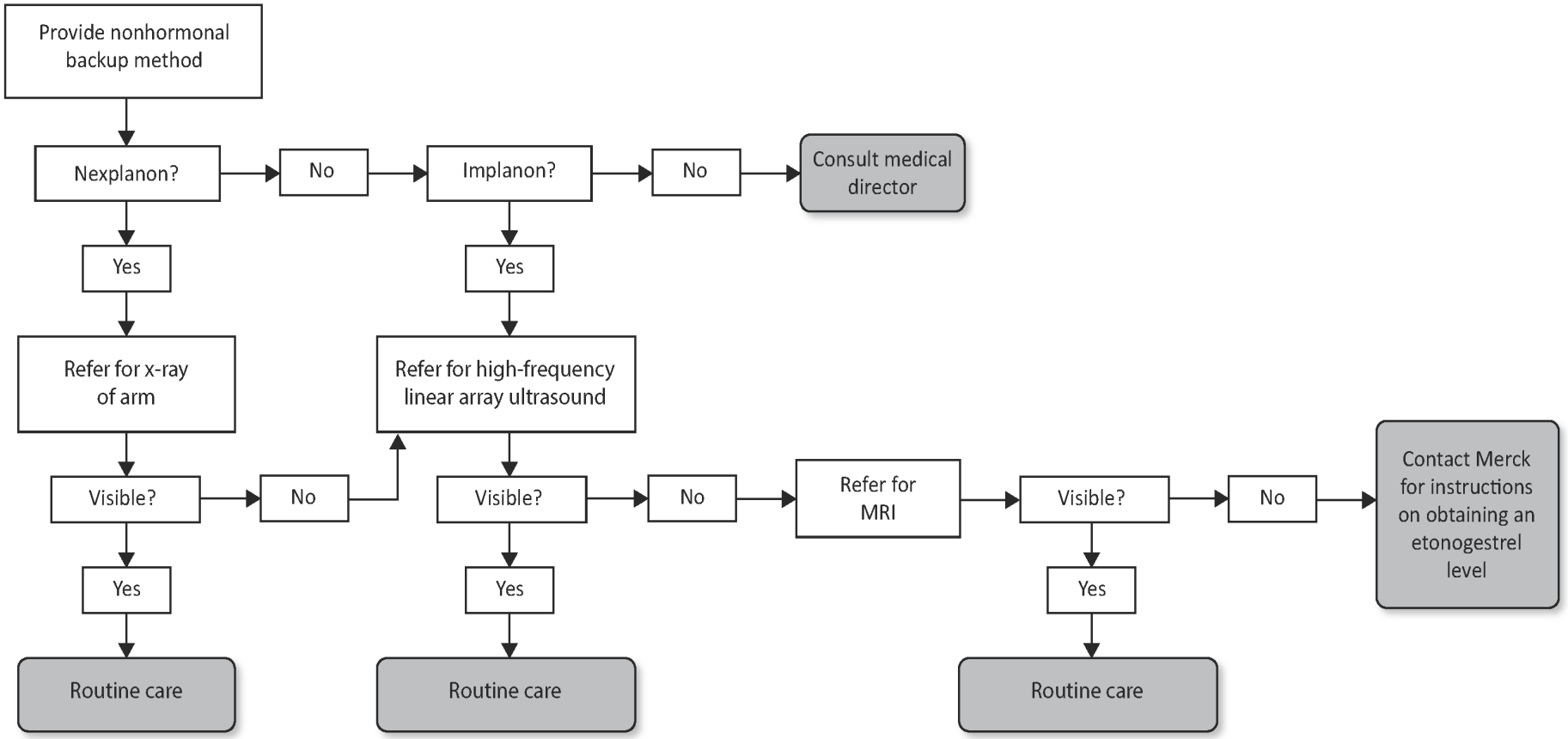
6.3.f. Flow Diagram: Irregular Bleeding – Contraceptive Implants



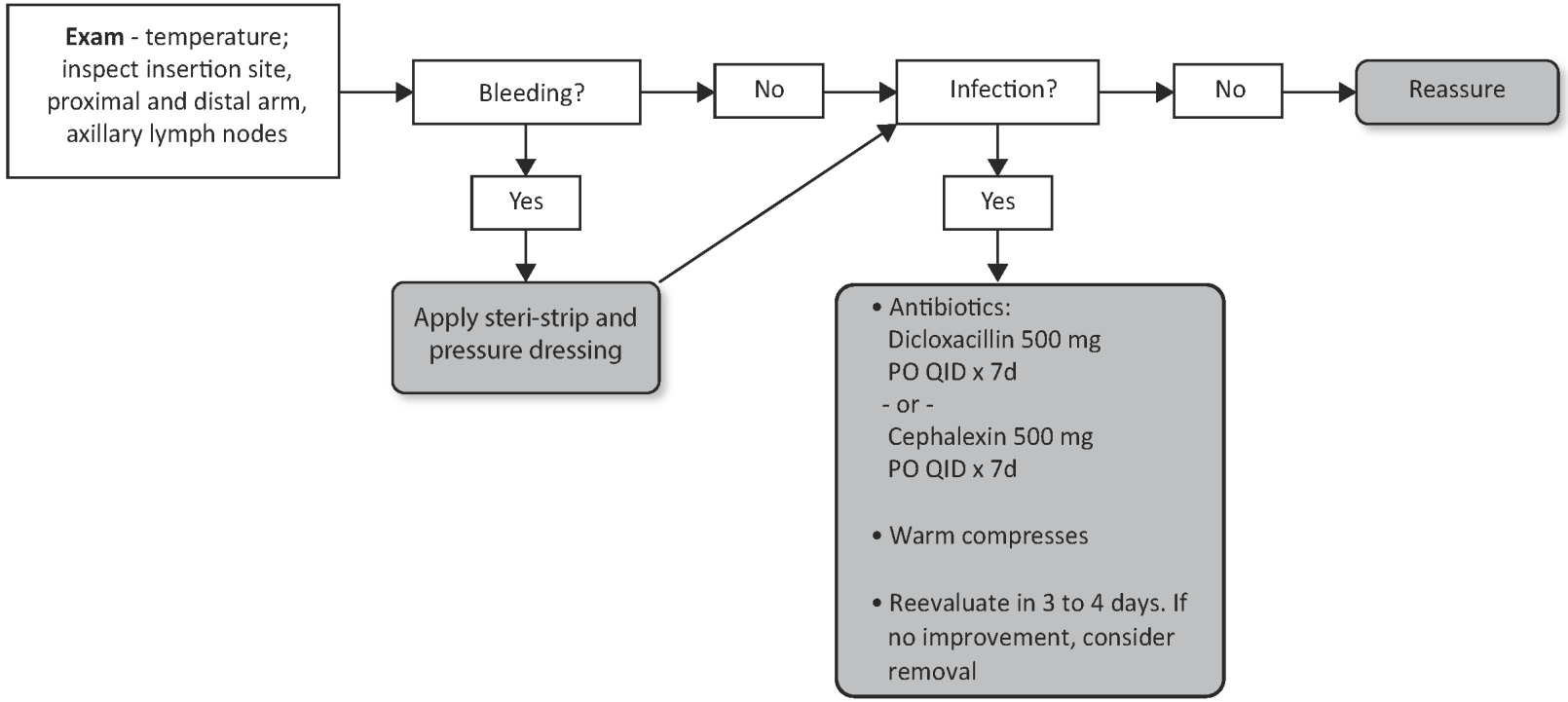
6.3.g. Flow Diagram: Headache – Contraceptive Implants



6.3.h. Flow Diagram: Nonpalpable Implant – Contraceptive Implants



6.3.i. Flow Diagram: Insertion Site Complication – Contraceptive Implants



6.3.5 Removal of Implant

I. Duration of Use
   A. Implant **must** be removed by the end of the third year of use. Unless pregnancy is desired, an alternative method of contraception **must** be offered.
   B. Another implant may be inserted immediately after removal through the same incision and in a track parallel to the one removed.

II. Procedure - The manufacturer's instructions for removal **must** be followed.

6.4 DMPA

6.4.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record

✓ See Administrative Chapter 4 Client Education and Informed Consent

6.4.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** Sign	**Must** Give	**Must** Offer
CIIC DMPA			At first RX and with every update of CIIC	
CIIC HC Special Conditions*			At first RX and every renewal	
Package insert			At first RX	annually
Release When Test/Service/Consultation Will Not Be Obtained		Once		
Written information on all available contraceptive methods			If starting an Rx method for the first time	To all others seeking a new method/change
~~Written instructions for use~~			~~At first RX~~	
*Osteoporosis; fragility fractures; BP ≥ 160/100; multiple cardiovascular risk factors; systemic lupus erythematosus (SLE) — when antiphospholipid antibodies are positive or unknown and/or severe thrombocytopenia; undiagnosed breast mass				

6.4.2 Prescribing DMPA

I. Prescription — limited to 5 injections before the next risk assessment. Clinician discretion may be used to prescribe one additional dose. Available products include
   A. 1 cc crystalline suspension of 150 mg depot medroxyprogesterone acetate that is injected intramuscularly (IM) every 3 months
   B. Low dose (depo-subQ provera 104) formulation of 104 mg medroxyprogesterone acetate in a 0.65 ml solution that is injected subcutaneously (SubQ) every 3 months

✓ When initiating or switching to DMPA, **must** follow Table 6.1.a. Choosing A Method

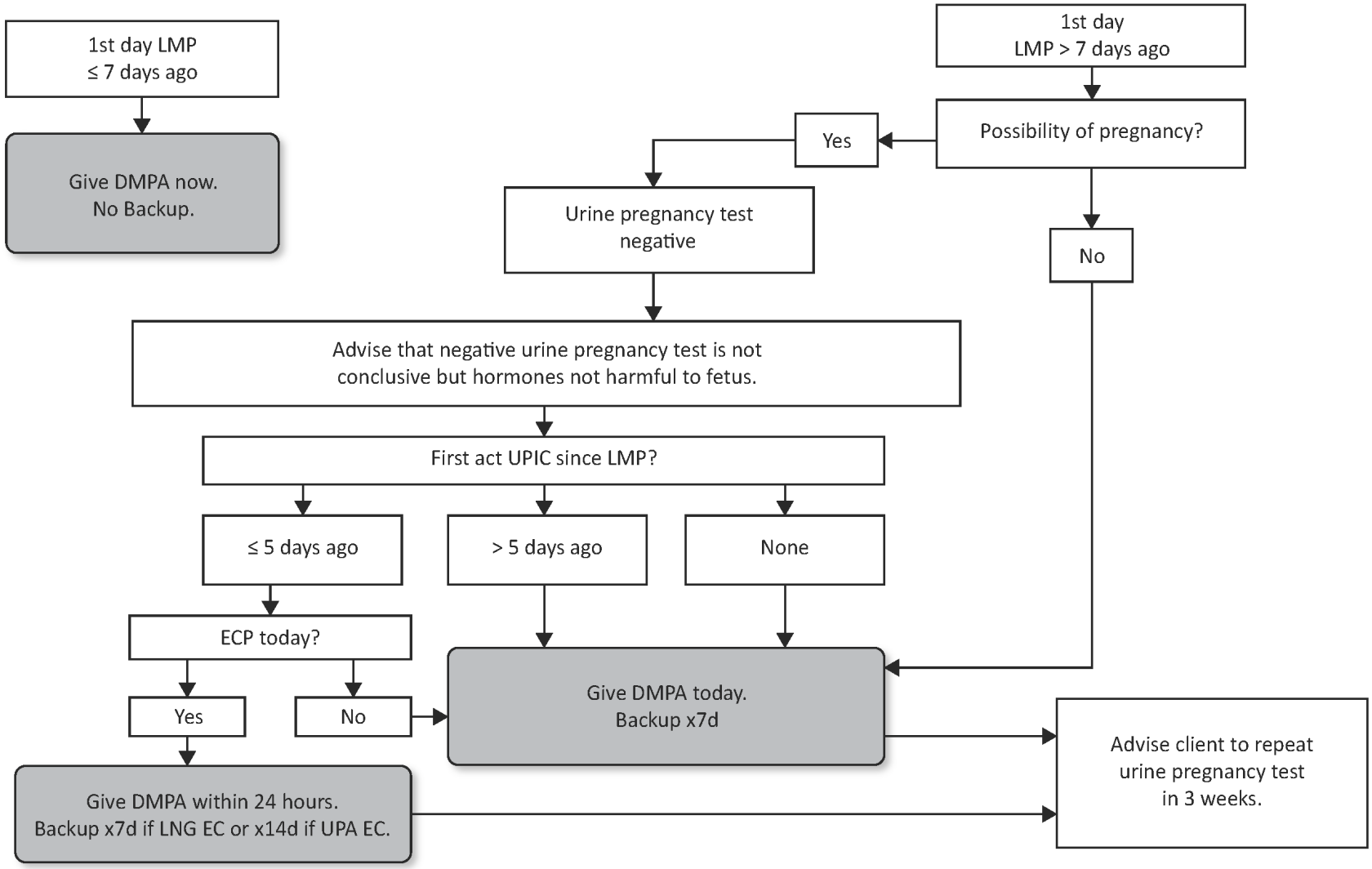
✓ See Table 6.9.a. Requirements for Initial Prescribing/Providing/Dispensing and Renewal

6.4.b. Table: Timing of Initiation - DMPA

Current Method	Initiate DMPA (First Injection)	Backup
No effective contraception in current cycle Barrier Methods	▪ Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history? ▪ If possibility of pregnancy is suspected, **must** perform urine pregnancy test. If negative, give DMPA and advise client to repeat pregnancy test in 3 weeks. ▪ If DMPA initiated > 7 days after onset of menses in sexually active client, **must** perform urine pregnancy test before next DMPA injection.	▪ If ≤ 7 days since onset of menses, none. ▪ If >7 days since onset of menses, backup for 7 days.
Current correct use of hormonal contraception (HC) (for LNG IUC see below)	Any time in cycle (pill, patch, ring) or on day of implant removal	Backup for 7 days
IUC	Any time in cycle	
	▪ ≤7 days since onset of menses	None, may remove IUC at time of injection
	▪ >7 days since onset of menses and has not had IC this cycle	Backup for 7 days
	▪ >7 days since onset of menses and has had IC this cycle. ~~Three~~ options	
	○ Give DMPA and remove IUC ≥7 days later.	None
	○ ~~Abstain or use barrier for ≥7 days before IUC removed and DMPA given. Perform urine pregnancy test before next DMPA injection.~~	~~None~~
	○ Give DMPA, remove IUC, provide EC. Perform urine pregnancy test before next DMPA injection.	~~Backup for 7 days~~

Current Method	Initiate DMPA (First Injection)	Backup
Post-EC Pills	▪ Immediately – same day as EC or the following day ▪ If > 7 days since onset of menses, perform urine pregnancy test prior to initiation. ▪ Advise client to repeat pregnancy test in 3 weeks. ▪ **Must** perform urine pregnancy test before next DMPA injection.	Backup for 7 days after LNG EC or 14 days after UPA EC
Post-surgical procedure for elective or spontaneous abortion and post-early pregnancy failure — no procedure	▪ ≤ 7 days post procedure or passing pregnancy (when day known)	None, if initiated that day. Otherwise backup for 7 days.
	▪ > 7 days or unknown~~, see "no effective contraception" above.~~	See "no effective contraception" above
Post-medication abortion	May initiate prior to confirmation of pregnancy termination	
	▪ Day of misoprostol up to 7 days after mifepristone	None
	▪ > 7 days after mifepristone and before resuming intercourse	Backup for 7 days
Post-delivery after 24 weeks - breastfeeding	▪ Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history? If menses has resumed, see "no effective contraception" above.	▪ If <21 days postpartum, none. ▪ If < 6 months postpartum, amenorrheic, and vast majority of feeds are breastfeeds, none. ▪ Otherwise if ≥ 21 days postpartum and menses has not resumed, backup for 7 days.
Post-delivery after 24 weeks – not breastfeeding	▪ Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history? If menses has resumed, see "no effective contraception" above.	▪ If <21 days postpartum, none. ▪ If ≥21 days postpartum and menses has not resumed, backup for 7 days.

6.4.c. Algorithm: Quick Start for DMPA



I. Injection Guidelines
   A. The manufacturer's instructions for injection **must** be followed.
   B. It is not acceptable to use the 400mg/ml concentration for contraceptive purposes.
   C. DMPA may only be prescribed/dispensed for injection at the clinical site.

6.4.3 Follow-up

I. DMPA Re-Injection Visit
   A. Every 13 0/7 weeks
   B. Client should be queried about changes in personal history, possible side effects, and her menstrual cycle / bleeding pattern over the previous 3 months.
   C. Repeat injection may be given as early as 10 weeks from the last dose.
   D. If client returns more than 13 weeks from the last dose, the injection may be given for up to a two week grace period (for up to a total of 15 weeks from last dose). Evaluation for pregnancy is not required.
   E. Urine pregnancy test **must** be done prior to re-injection in the following circumstances:
      1. When DMPA is initiated > 7 days after onset of menses in sexually active client - before next injection
      2. When IUC is removed and DMPA initiated > 7 days after onset of menses in a sexually active client - before next injection
      3. When DMPA is initiated immediately after ECP use – before next injection

6.4.4 Guidelines for Management of Side Effects and Complications

6.4.a. Table: Conditions/Signs/Symptoms That Develop While on DMPA

Legend	
A	Contraindications — **must** discontinue
B	Special Conditions Requiring Further Evaluation — Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral **must** be based on protocols approved by the medical director or in consultation with the medical director or affiliate physician. ***Must** give Special Conditions CIIC
C	Other considerations - condition should be considered in risk/benefit analysis when continuing the method

Condition/Signs/Symptoms	A	B	C
Amenorrhea - sudden			●**
▪ Bleeding – unscheduled ✓ FYI - Managing Unscheduled Bleeding in COC, DMPA, and IUC Users		●**	
▪ Light or spotting		●**	
▪ Heavy or prolonged		●**	
Breast cancer – histologically proven malignancy or strong evidence of malignancy (e.g. BI-RADS 5)	●		
Breast mass (undiagnosed) – may continue DMPA. **Must** initiate evaluation as soon as possible.*		●	
Estrogen deficiency – symptomatic†			●
Headaches			
▪ Non-migrainous - mild or severe (US MEC 2)			●**
▪ Migraine aura (USMEC 3)		●**	
Injection site complications			●**
Menopause – nearing menopause and won't have opportunity to rebuild bone density†† ✓ FYI - Hormonal Contraception and Bone Health			●
Systemic Lupus Erythematosus (SLE) (US MEC 3)*		●	
Weight change			●

* **Must** give Special Conditions CIIC.

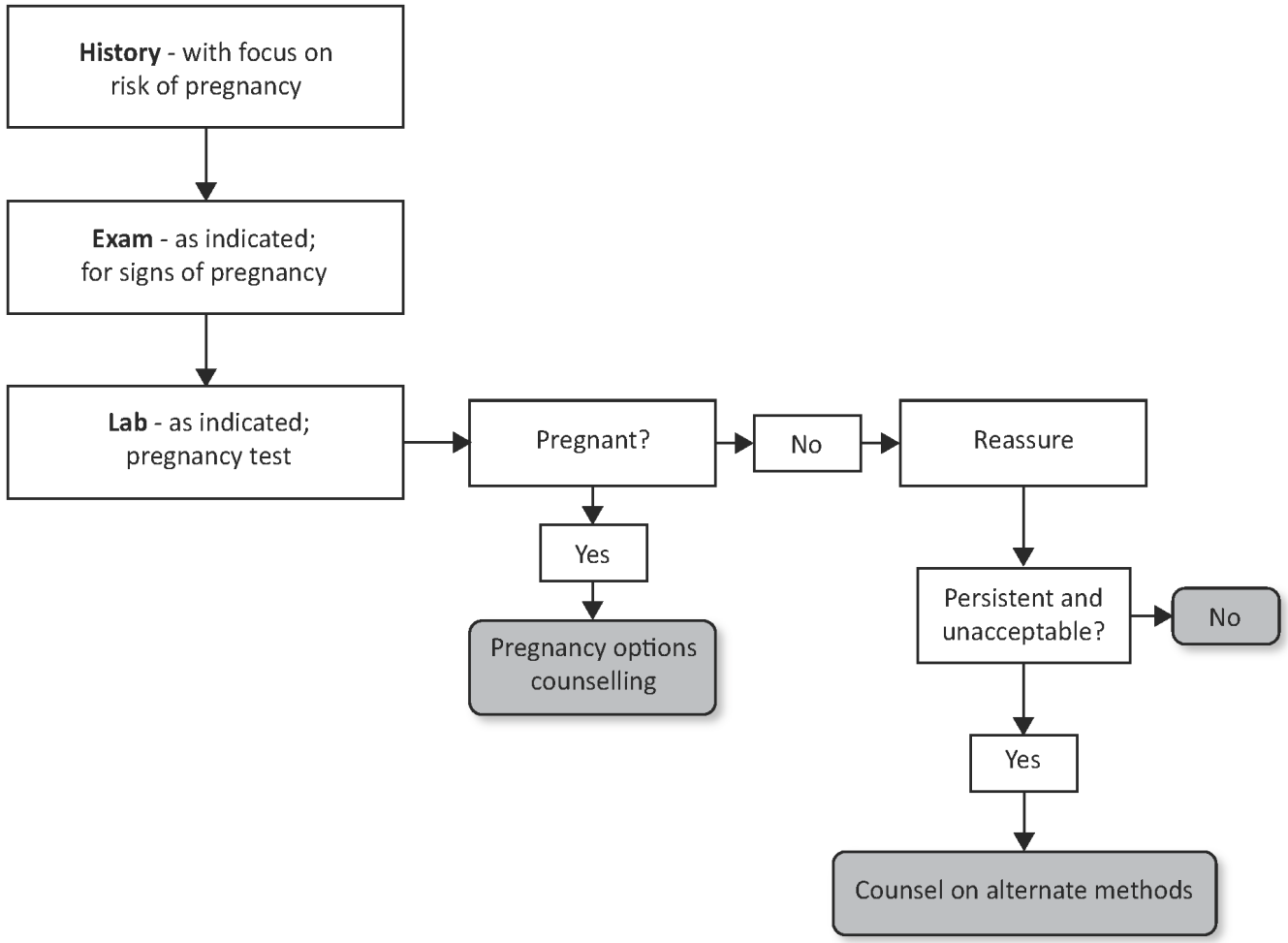
**See flow diagrams 6.3.g., 6.3.i, 6.4.b., 6.4.c., 6.4.d.

†May prescribe estrogen supplementation if not contraindicated. Recommended regimens to relieve symptoms include oral estrogen (CEE or esterified estrogen 0.3 – 0.625 mg or micronized estradiol 0.5-1.0 mg) and transdermal estradiol (50 µg)

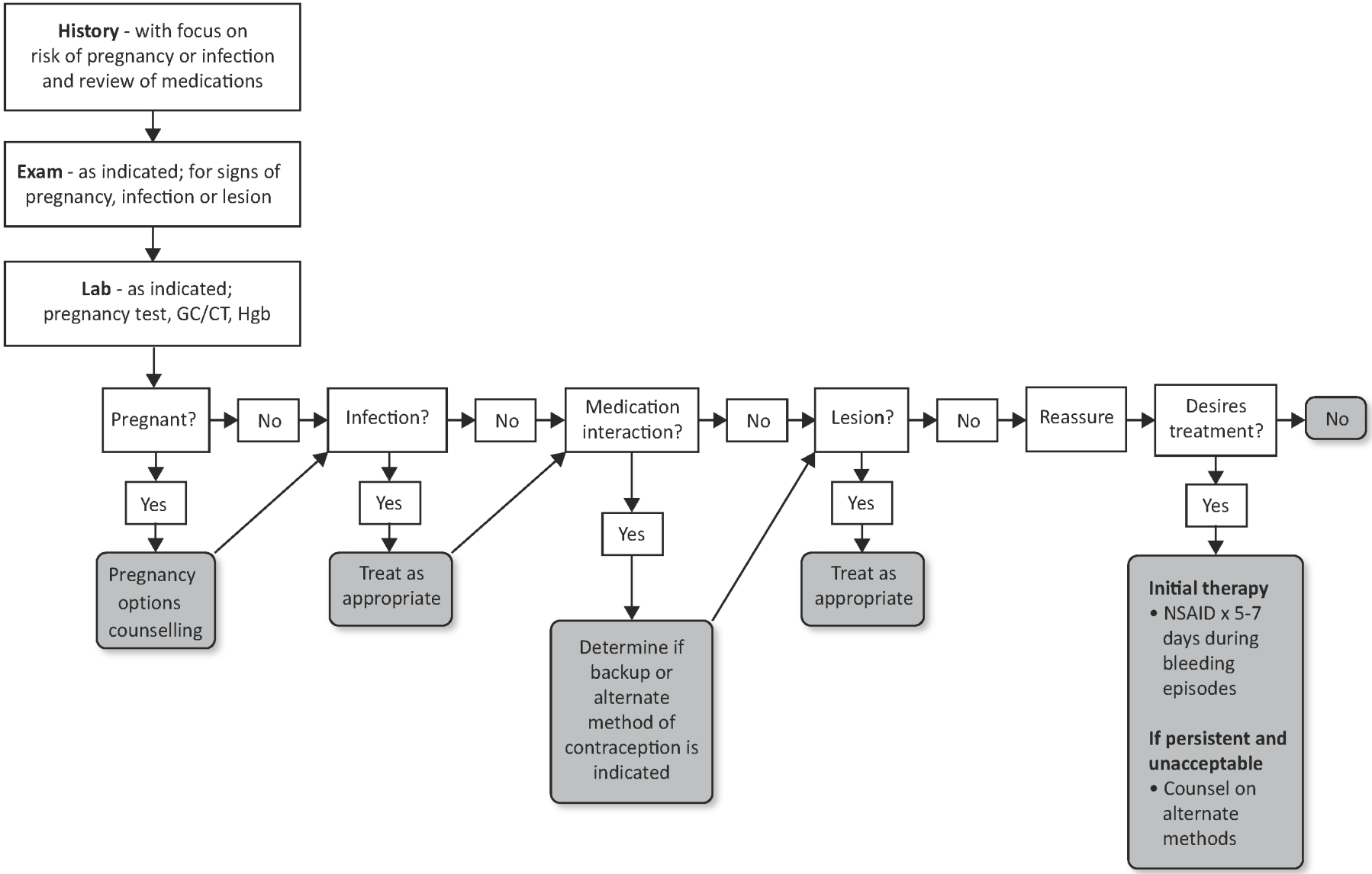
††May prescribe estrogen supplementation if not contraindicated. Recommended regimens include oral estrogen (CEE or esterified estrogen 0.3 or micronized estradiol 0.5 mg) and transdermal estradiol (14-50 µg)

✓ See Flow Diagram 6.3.g. Headache

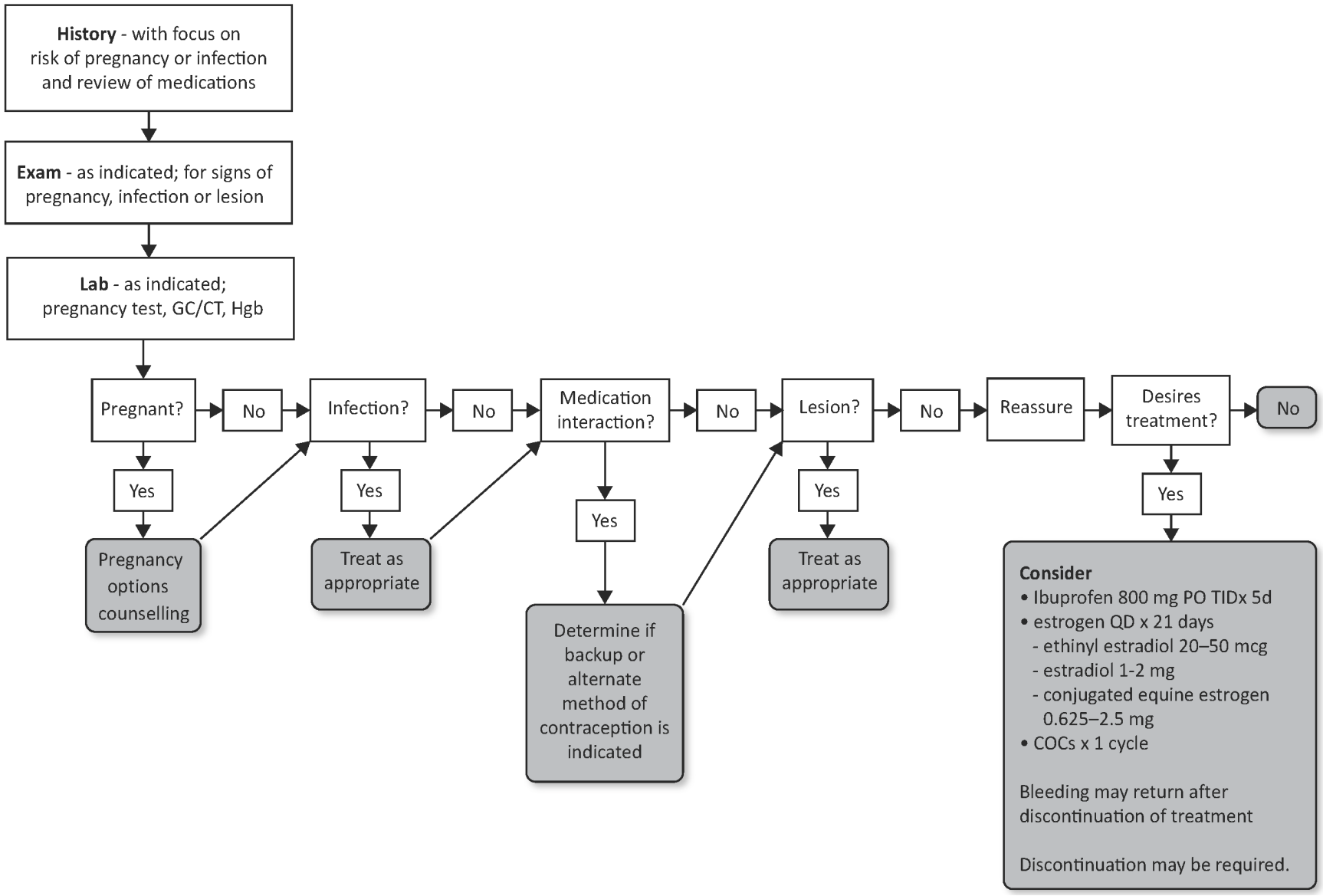
6.4.b. Flow Diagram: Sudden Amenorrhea – DMPA



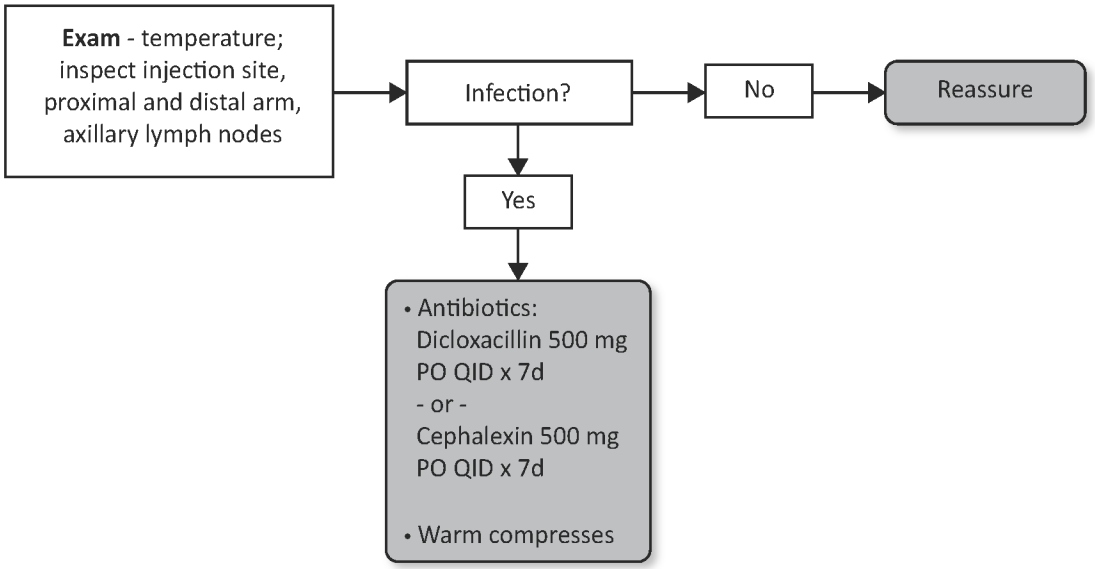
6.4.c. Flow Diagram: Unscheduled Light Bleeding or Spotting – DMPA



6.4.d. Flow Diagram: Heavy or Prolonged Bleeding – DMPA



6.4.e. Algorithm: Injection Site Complication – DMPA



6.5 INTRAUTERINE CONTRACEPTIVES (IUC)

6.5.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

6.5.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
CIIC Continued Use of IUC Beyond Recommended Removal Date			●	
CIIC IUC		●	At each insertion	
CIIC IUC Pregnancy			●	
CIIC IUC Removal – Missing String		●	●	
CIIC IUC Special Conditions*			At each insertion	

Document	Document #	**Must** sign	**Must** give	**Must** offer
CIIC Preparing Your Cervix with Misoprostol			●	
Package insert			At each insertion	
Product User Card			At each insertion	
Release When Test/Service/Consultation Will Not Be Obtained		once		
Request for Surgery or Special Procedure		●	At each insertion	
Written information on all available contraceptive methods			If starting an Rx method for the first time	To all others seeking a new method/change
*severe thrombocytopenia (CuIUC) systemic lupus erythematosus (SLE) — when antiphospholipid antibodies are positive or unknown (LNG IUC); undiagnosed breast mass (LNG IUC)				

6.5.2 Prescribing IUC

I. Prescription
   A. LngIUC 13.5 mg — can be used for up to three years
   B. LngIUC 52 mg — can be used for up to five years
   C. Cu IUC — can be used for up to 12 years

✓ FYI — IUC Failures

✓ When initiating or switching to an IUC, **must** follow Table 6.1.a. Choosing a Method

✓ See Table 6.9.a. Requirements for Initial Prescribing/Providing/Dispensing and Renewal

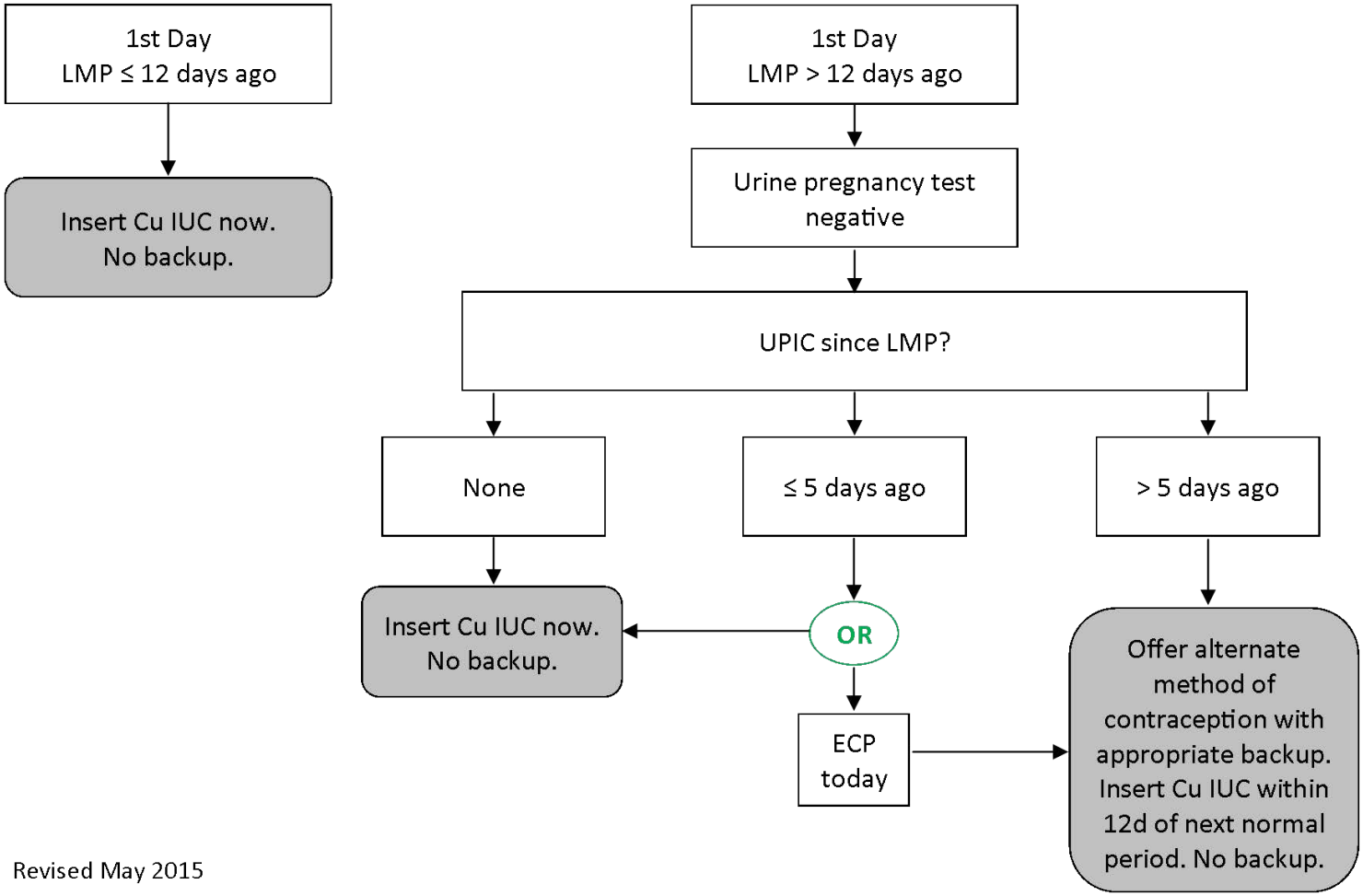
6.5.b. Table: Timing of Initiation - IUC

Current Method	Insert IUC	Backup
No effective contraception Barrier methods	Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history?	
	▪ For Cu IUC – see Algorithm 6.5.c.	
	○ ≤ 12 days (first 7 days of cycle + 5 day EC effect) since onset of menses	None

Current Method	Insert IUC	Backup
	○ > 12 days since onset of menses • May only insert Cu IUC in sexually active client, if a pregnancy test negative and first act UPIC in current cycle ≤ 5 days prior	None
	▪ For LNG IUC – see Algorithm 6.5.d.	
	○ If ≤ 7 days since onset of menses	None
	○ If >7 days since onset of menses	Backup for 7 days
Current correct use of hormonal contraception (HC) or IUC	Anytime in cycle ▪ If switching from HC to CU IUC ▪ If switching from HC to LNG IUC	None
	○ If ≤ 7 days since onset of menses	None
	○ If >7 days since onset of menses	Backup for 7 days or have client complete current cycle of HC
	If switching from DMPA that had been initiated >7 days after onset of menses, **must** perform urine pregnancy test before IUC may be inserted. If switching from CU IUC to LNG IUC, > 5 days since onset of menses and has had IC this cycle, consider EC at time of insertion	
Post-EC Pills	LNG IUC, insert immediately — same day as EC or the following day ▪ If >7 days since onset of menses, **must** perform pregnancy test before IUC may be inserted ▪ Advise client to repeat pregnancy test if no menses in 3 weeks.	Backup for 7 days after LNG EC or 14 days after UPA EC
Post-surgical procedure for elective or spontaneous abortion and post early pregnancy failure – no procedure	▪ ≤ 7 days post-procedure or passing pregnancy (when day known)	▪ None, if placed at time of procedure. ▪ Otherwise, backup for 7 days for LNG IUC.
	▪ > 7 days or unknown~~, see "no effective contraception" above.~~	See "no effective contraception" above

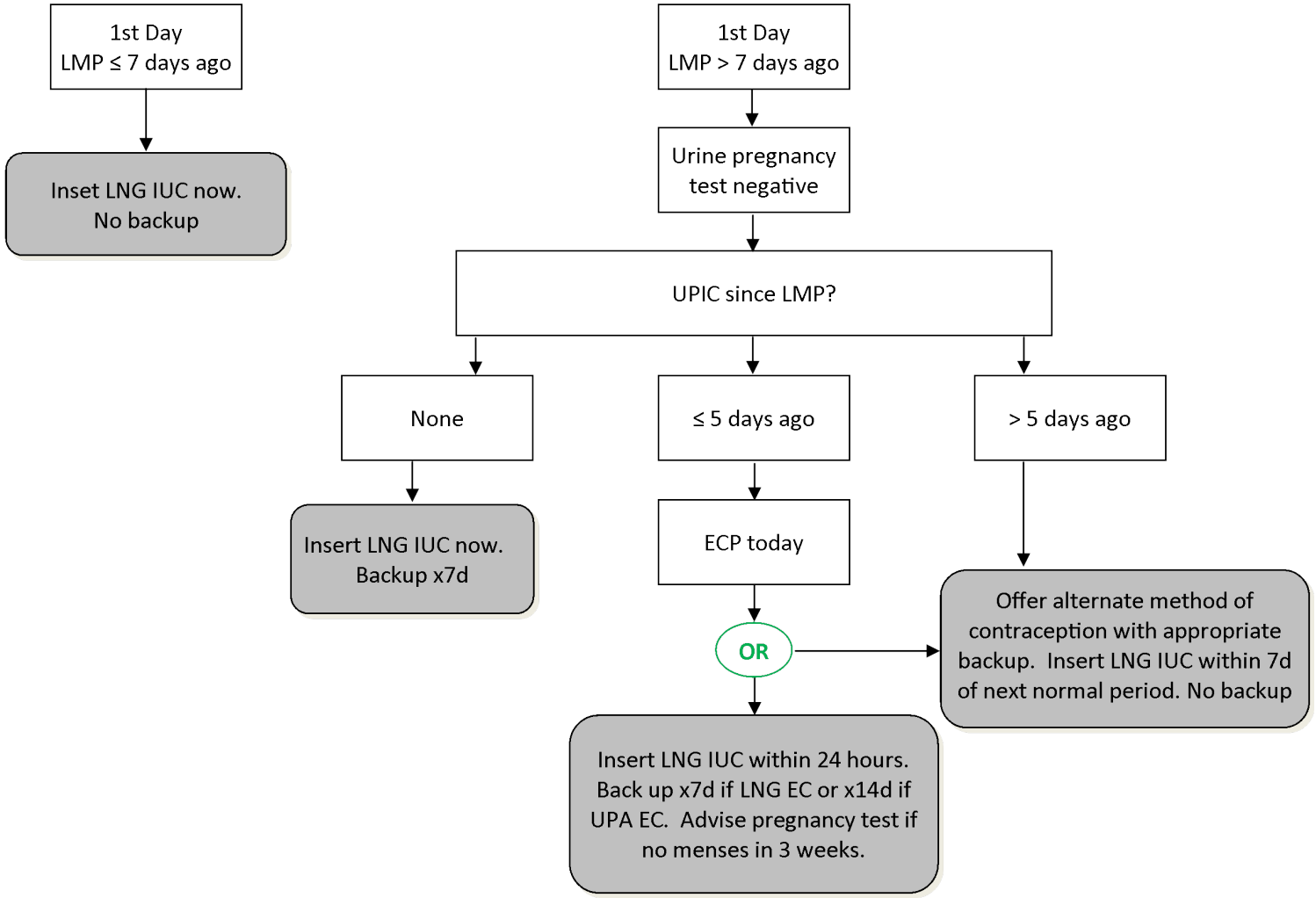
Current Method	Insert IUC	Backup
Post-medication abortion	At the earliest, once it is confirmed that client is no longer pregnant, See "No effective contraception," above	
Post-delivery — breastfeeding	Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history? ▪ CU IUC – see no effective contraception, above ▪ LNG IUC and menses has resumed – see no effective contraception, above	For LNG IUC: ▪ If < 21 days postpartum, none. ▪ If < 6 months postpartum, amenorrheic, and vast majority of feeds are breastfeeds, none. ▪ Otherwise if ≥ 21 days postpartum and menses has not resumed, backup for 7 days.
Post-delivery – not breastfeeding	Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history? ▪ CU IUC – see no effective contraception, above ▪ LNG IUC and menses has resumed – see no effective contraception, above	For LNG IUC: ▪ If < 21 days postpartum, none. ▪ If ≥ 21 days postpartum and menses has not resumed, backup for 7 days.

6.5.c. Algorithm: Quick Start Copper IUC



Revised May 2015

6.5.d. Algorithm: Quick Start LNG IUC



I. Insertion Procedures
   A. Misoprostol may be used to aid with cervical dilatation prior to insertion. Acceptable regimens include — misoprostol 400 mcg PO 8 to 12 hours prior to insertion or misoprostol 200 mcg PV 8 to 12 hours prior to insertion or 400 mcg sublingual 1 hour prior to insertion.

✓ FYI - Misoprostol for Cervical Ripening

   B. The use of a local anesthetic block may be offered.
   C. The insertion technique described in the IUC package should be followed.
   D. Instruct client on how to check for IUC string.

6.5.3 Follow-up

I. No routine IUC follow-up visit required.
II. IUC related medical visits
   A. Client should be queried about changes in personal history, possible side effects, and her menstrual cycle/bleeding pattern.
   B. Physical exam and laboratory testing **must** be performed, as indicated.
   C. Presence of string **must** be documented.

6.5.4 Management of Side Effects and Complications

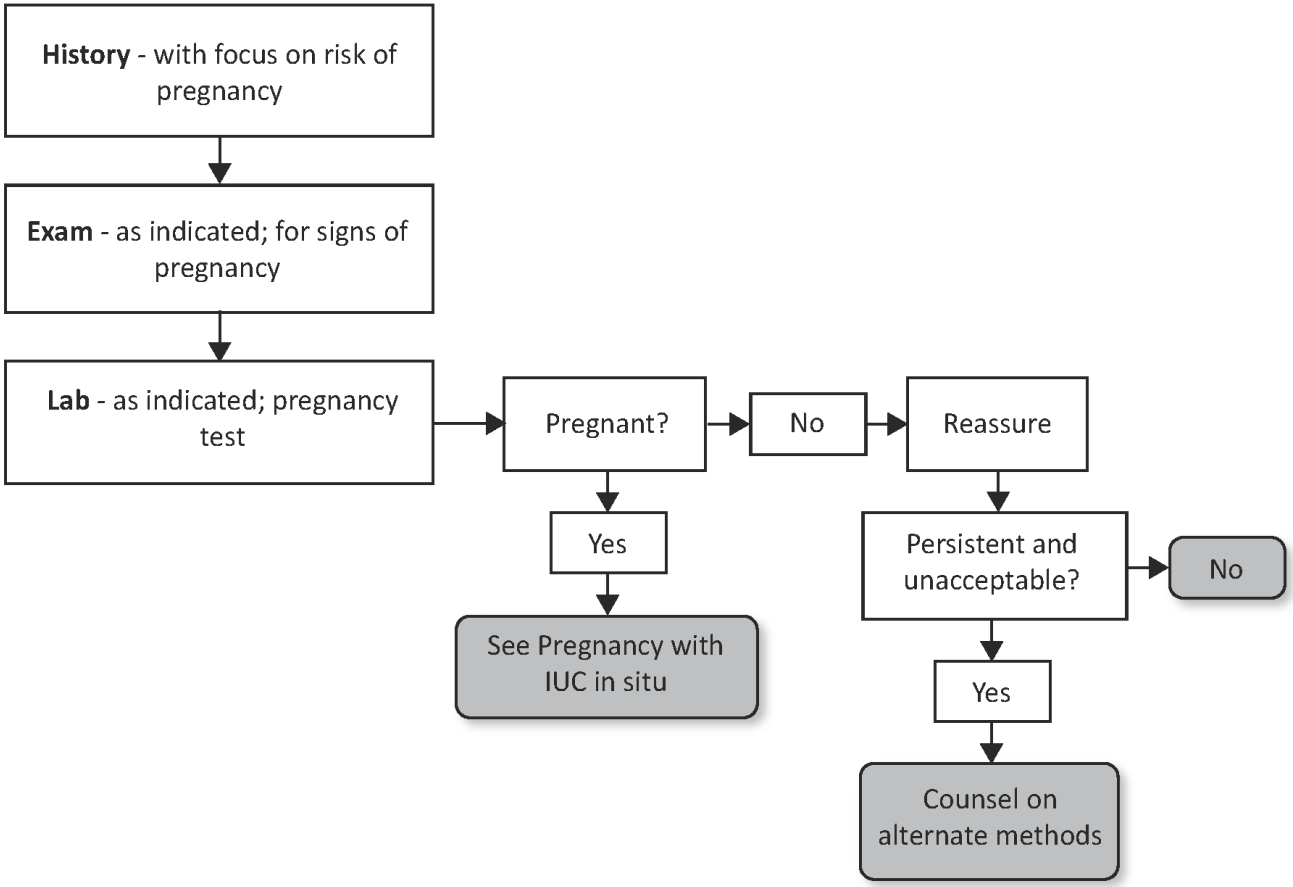
6.5.e. Table: Conditions/Signs/Symptoms That Develop with IUC Use

Legend	
A	Contraindications — **must** discontinue
B	Special Conditions Requiring Further Evaluation — Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral **must** be based on protocols approved by the medical director or in consultation with the medical director or affiliate physician. ***Must** give Special Conditions CIIC
C	Other considerations - condition should be considered in risk/benefit analysis when continuing the method

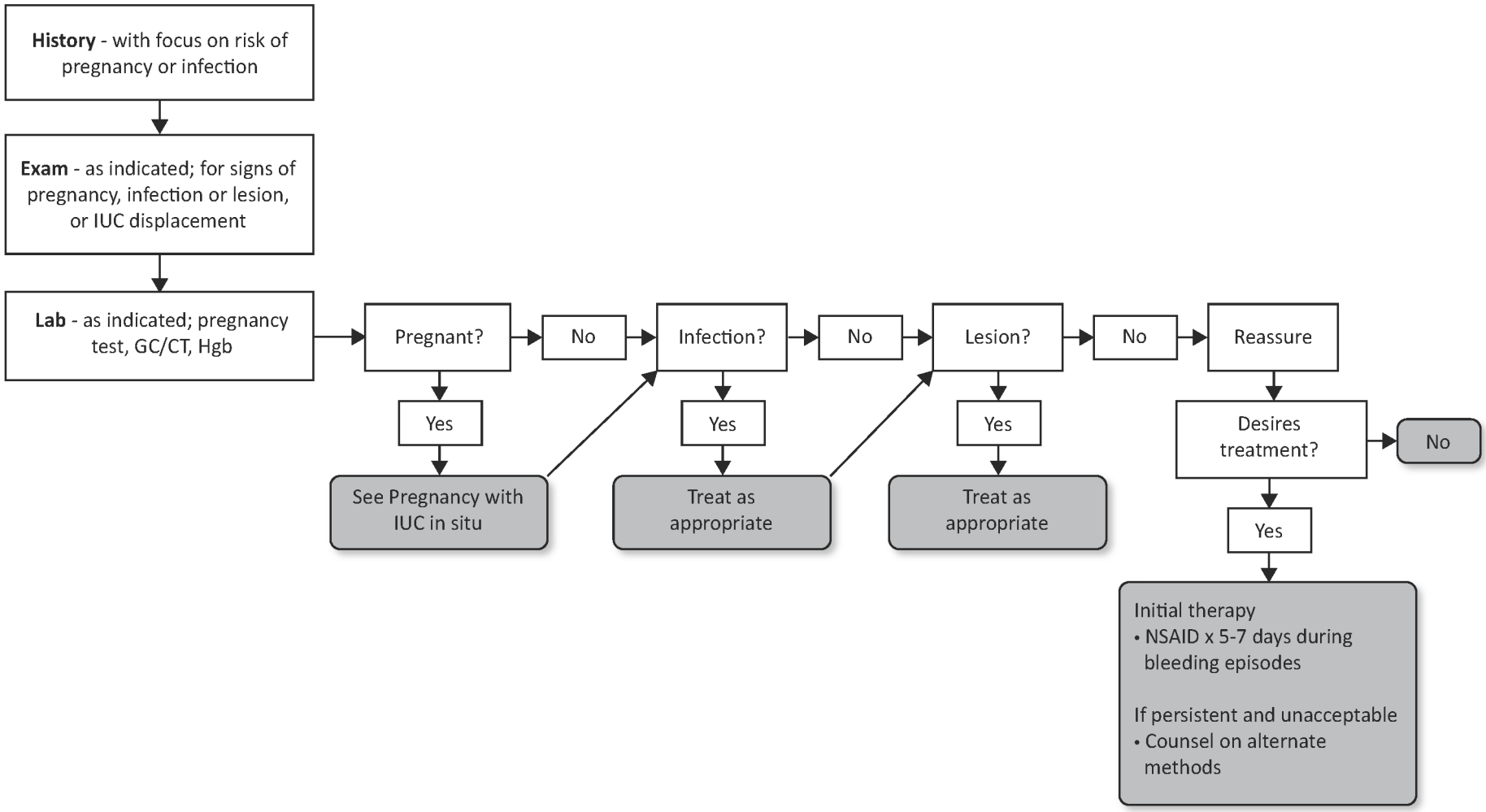
Condition/Signs/Symptoms	A	B	C
Actinomyces on Pap Test ✓ FYI — Actinomyces on Pap and It's Time to Replace the IUC ✓ FYI —Actinomyces			●*
Amenorrhea ✓ FYI - Bleeding and Amenorrhea			LNG IUC**
Bleeding irregularities ✓ FYI - Managing Unscheduled Bleeding in COC, DMPA, and IUC Users			●**
Breast cancer – histologically proven malignancy or strong evidence of malignancy (e.g. BI-RADS 5)	LngIUC		
Breast mass (undiagnosed) – may continue LngIUC. **Must** initiate evaluation as soon as possible.*		LngIUC	
Embedded IUC – refer to provider experienced in difficult removals		●	
Expulsion – partial – should be removed promptly ✓ FYI - IUC Expulsions	●		
Infection – vaginal and cervical (USMEC 2, continuation) – treat per MS&Gs			●
Ischemic heart disease (USMEC 3, continuation)		LngIUC	
Perforation†	●		
PID (USMEC 2, continuation)			●**
Pregnancy (USMEC 4)	●**		
String missing			●**
Tuberculosis – pelvic (USMEC, 3 continuation)		●	

*__Must__ give Special Conditions CIIC.
**See flow diagrams 6.5.f. to 6.5.k.
†See ARMS Emergency Manual

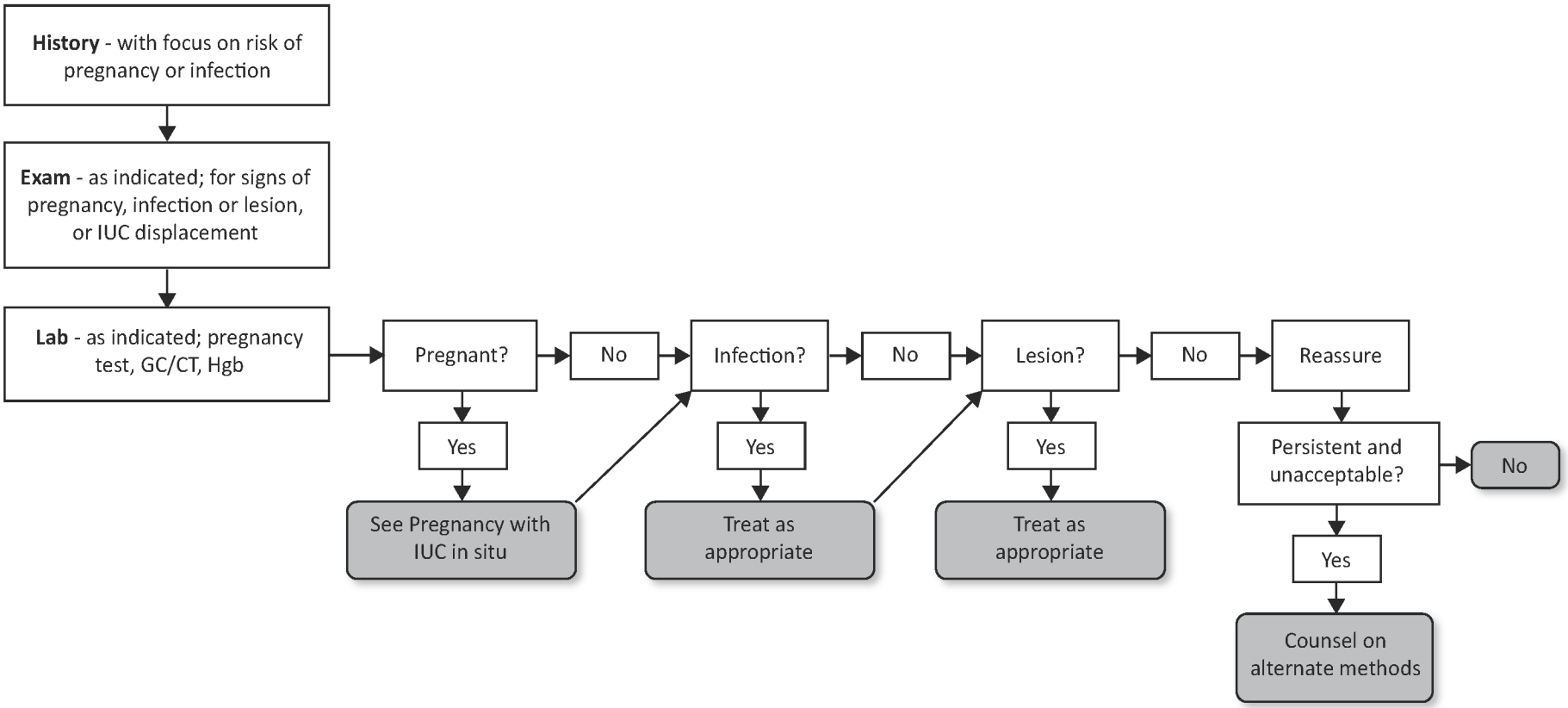
6.5.f. Flow Diagram: Amenorrhea with LNG IUC in Place



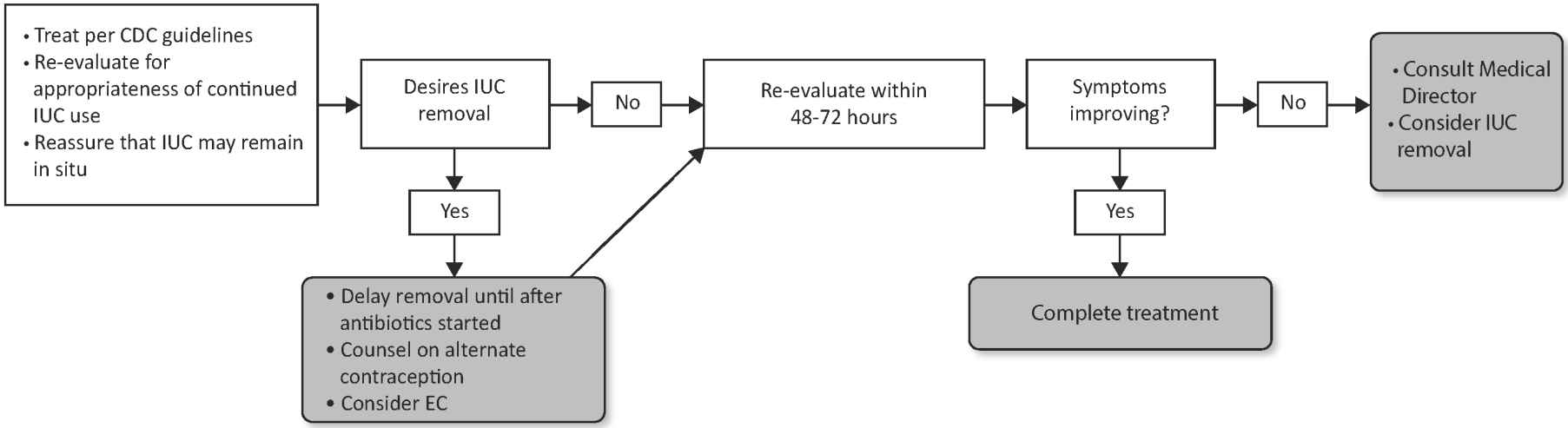
6.5.g. Flow Diagram: Cu IUC Bleeding Irregularities



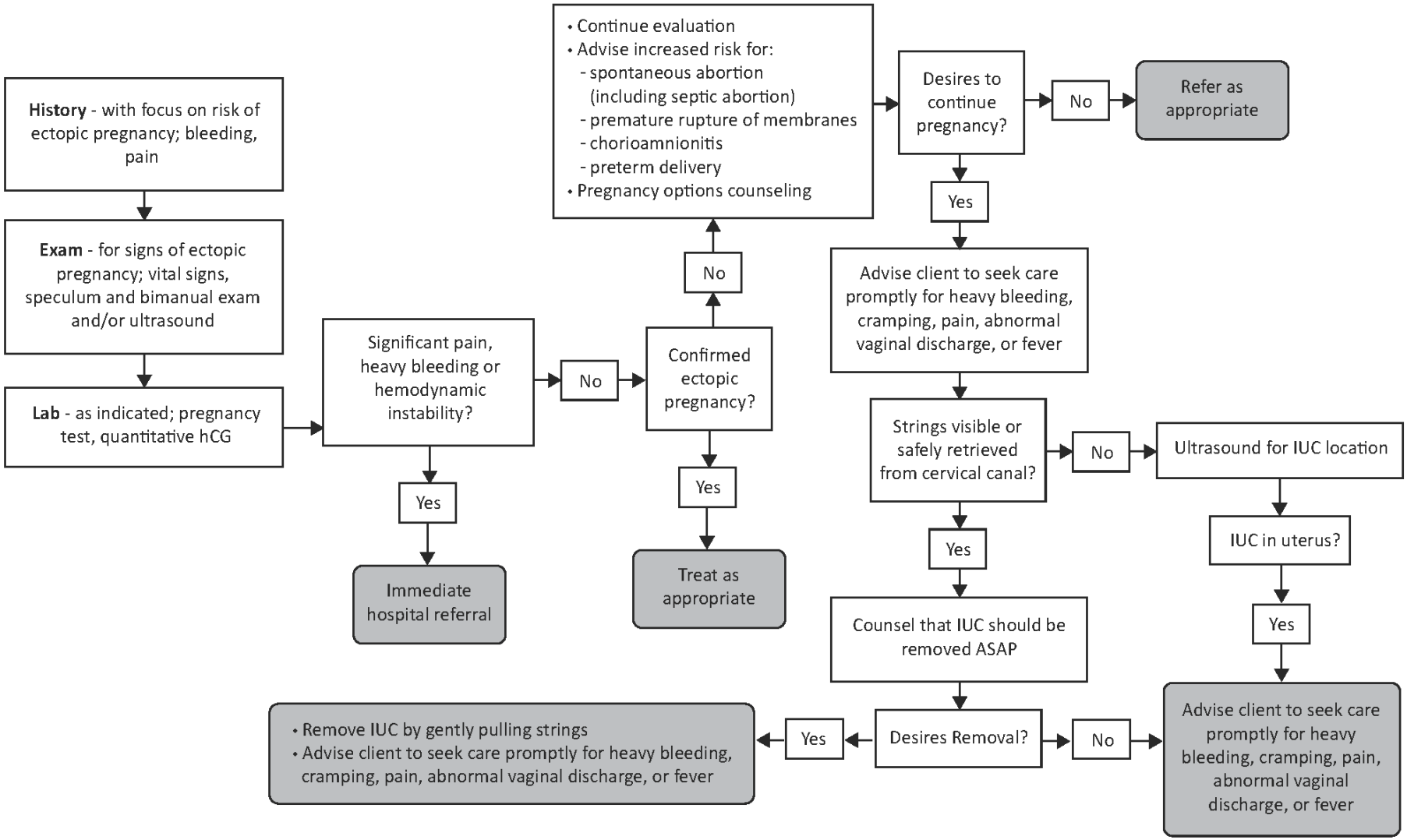
6.5.h. Flow Diagram: LNG IUC Bleeding Irregularities



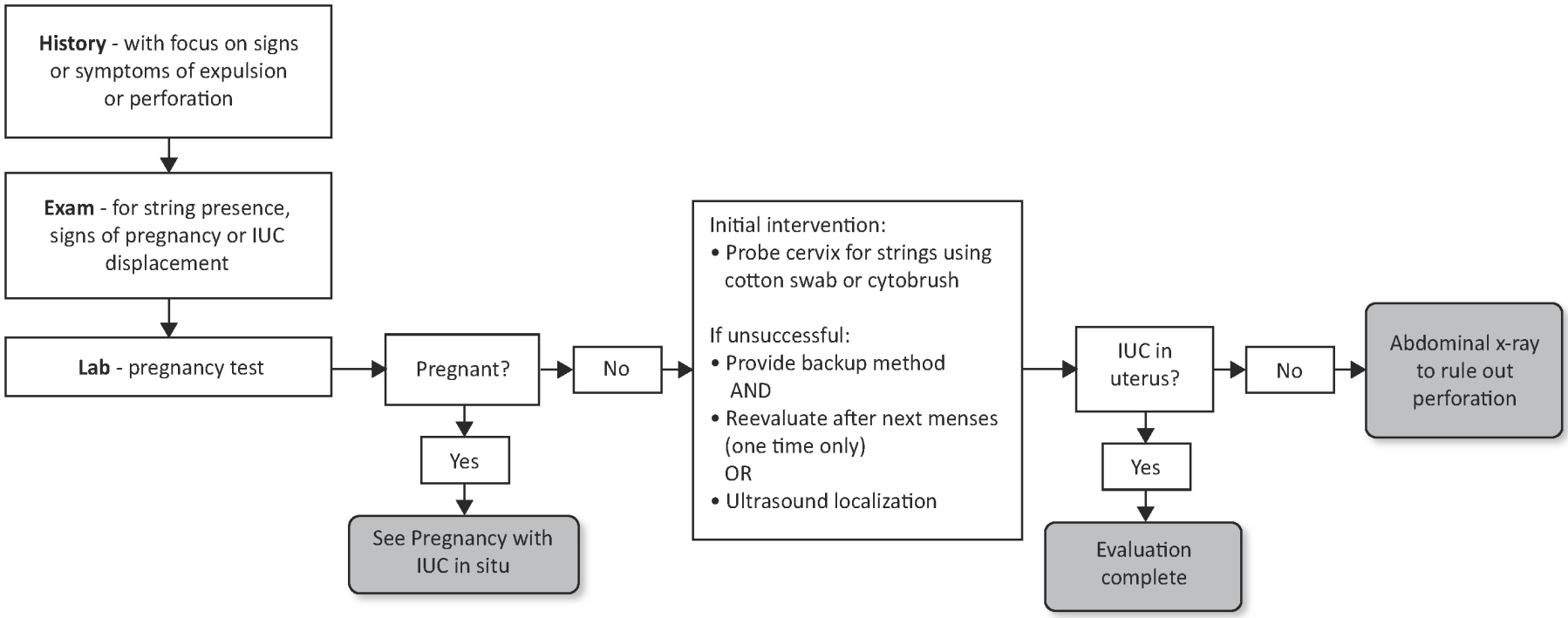
6.5.i. Flow Diagram: PID with IUC in Place



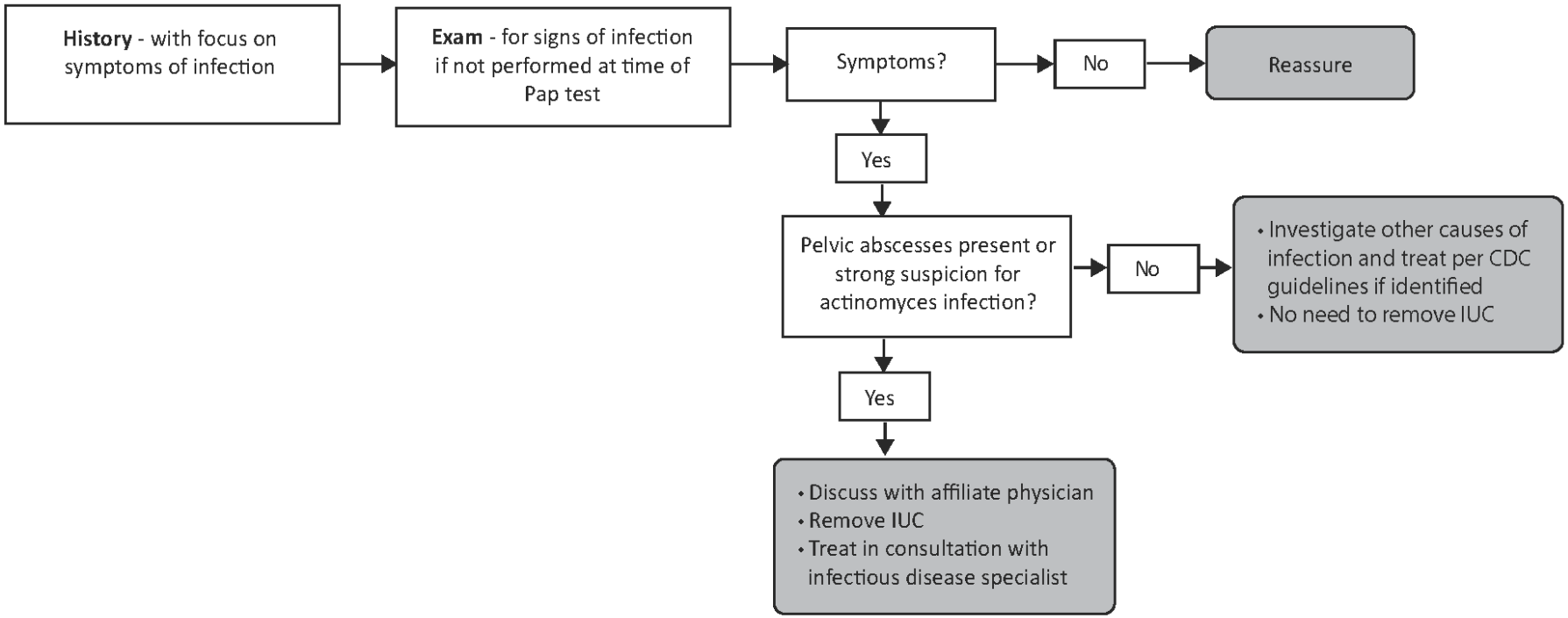
6.5.j. Flow Diagram: Pregnancy with IUC in place



6.5.k. Flow Diagram: Missing IUC String



6.5.I. Flow Diagram: Actinomyces on Pap Test – IUC



6.5.5 Removal

I. Removal Procedure
   A. Follow the removal guidelines in the product literature.
   B. If beyond the first 5 days of the cycle, should not remove the IUC until 5 days after last intercourse. There is a theoretical risk of pregnancy.
      1. If client wants removal despite risk of pregnancy, explain risk, give/offer EC, and document in medical record.
      2. If switching methods, see timing chart in appropriate contraceptive section.
   C. A client who refuses to have her IUC removed or replaced beyond the specified interval **must**
      1. Be given the Client Information for Informed Consent: Continued Use for an IUC Past Expiration Date
      2. Sign the Release When Tests/Services/ Consultation for Medical Follow-Up Will Not be Obtained as Advised

6.6 PRESCRIPTION BARRIERS

6.6.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

6.6.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
CI How to Use the Cervical Cap			At first RX	At each refitting
CI How to Use the Diaphragm			At first RX	At each refitting
CIIC Diaphragm and Cervical Cap			At first RX and with every update of CIIC	
Package insert			At first RX	At each refitting
Release When Test/Service/Consultation Will Not Be Obtained		once		
Written information on all available contraceptive methods			If starting an Rx method for the first time	To all others seeking a new method/change

6.6.2 Prescribing Barrier Methods

✓ When initiating or switching to a prescription barrier, **must** follow Table 6.1.a Choosing a Method

✓ See Table 6.9.a. Requirements for Initial Prescribing/Providing/Dispensing and Renewal

I. Fitting/insertion
   A. Fitting/Insertion technique described in the package should be followed.
   B. Offer check of self-insertion

✓ FYI – Determining Cap Size

6.6.3 Follow-up

I. Return Visits — in 2 to 6 weeks to check fit, evaluate placement skills, and to screen for possible problems and reactions

6.7 PROGESTIN ONLY PILL (POP)

6.7.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record

✓ See Administrative Chapter 4 Client Education and Informed Consent

6.7.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
CIIC HC Special Conditions*			At first RX and every renewal	
CIIC POPS			At first RX and with every update of CIIC	
Package insert			At first RX	annually
Release When Test/Service/Consultation Will Not Be Obtained		once		
Written information on all available contraceptive methods			If starting an Rx method for the first time	To all others seeking a new method/change
* systemic lupus erythematosus (SLE) — when antiphospholipid antibodies are positive or unknown; undiagnosed breast mass				

6.7.2 Prescribing POPs

I. Prescription — limited to 13 months supply before the next risk assessment. Clinician discretion may be used to prescribe additional cycles.

✓ When initiating or switching to POPs, **must** follow Table 6.1.a Choosing a Method

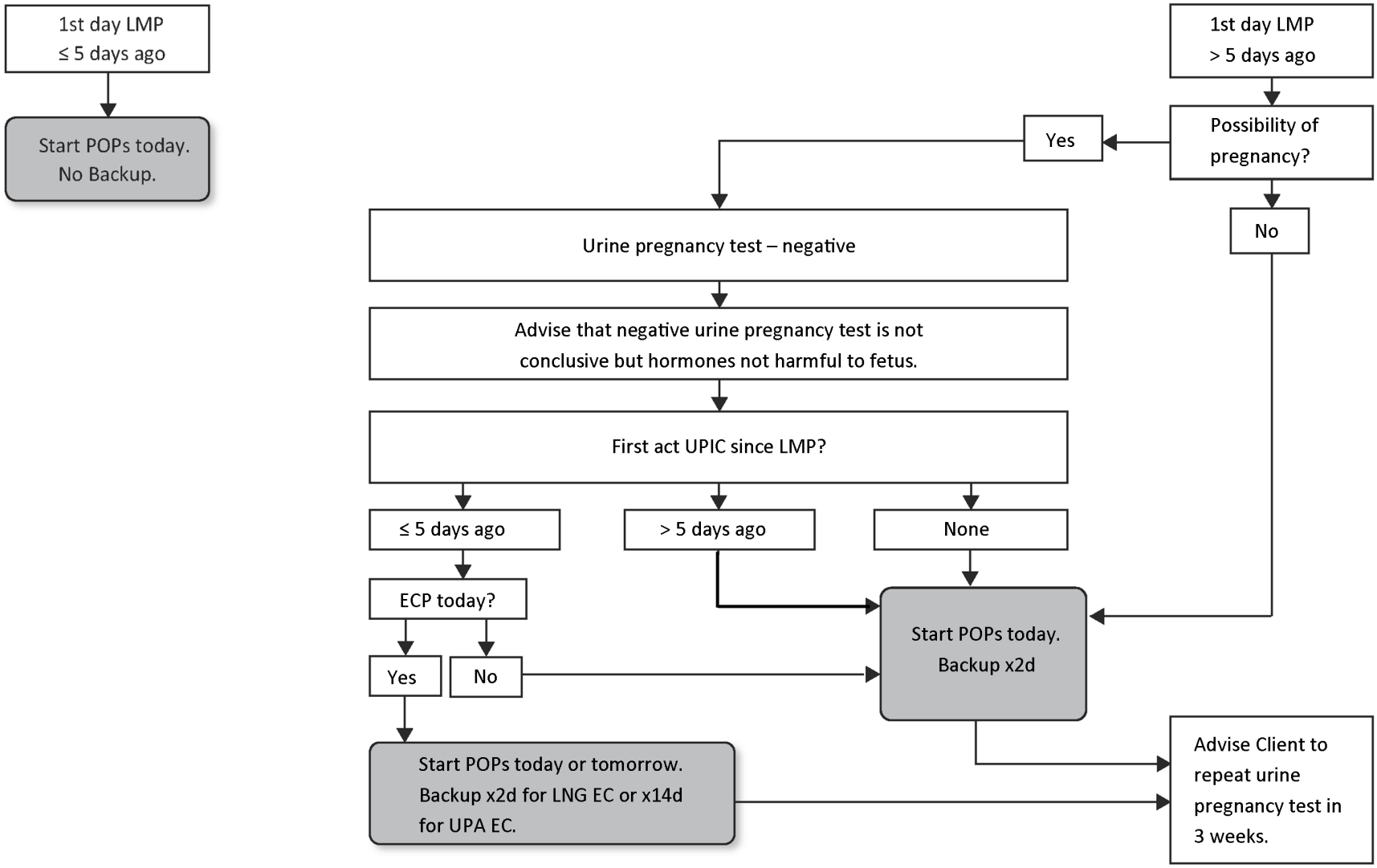
✓ See Table 6.9.a. Requirements for Initial Prescribing/Providing/Dispensing and Renewal

6.7.b. Table: Timing of Initiation – POPs

CURRENT METHOD	TAKE FIRST POP TABLET	BACKUP
No effective contraception Barrier methods	Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history? (See Algorithm 6.7.c.) If possibility of pregnancy is suspected, **must** perform a urine pregnancy test. If negative, initiate POPs and advise client to repeat urine test in 3 weeks.	▪ If ≤ 5 days since onset of menses, none. ▪ If > 5 days since onset of menses, backup for 2 days.
Current correct use of hormonal contraception (HC) (for LNG IUC see below)	Anytime in cycle (pills, patch, ring) or on day of implant removal or when DMPA injection due If switching from DMPA and it had been initiated > 7 days after onset of menses, **must** perform urine pregnancy test before prescribing POPS.	None
IUC	Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history?	
	▪ ≤ 5 days since onset of menses	None
	▪ > 5 days and no IC this cycle	Backup for 2 days
	▪ > 5 days since onset of menses and has had IC this cycle, ~~thre~~e options:	
	○ Start POPs and remove IUC ≥ 2 days later.	None
	○ ~~Abstain or use barrier for ≥ 2 days, remove IUC, start POPs~~	~~None~~
	○ Remove IUC, provide EC, start POPs.	~~Backup for 2 days~~

CURRENT METHOD	TAKE FIRST POP TABLET	BACKUP
Post-EC Pills	Immediately — same day as EC or the following day ▪ If > 5 days since onset of menses, perform urine pregnancy test prior to initiation of POPs. ▪ Advise client to repeat pregnancy test if no menses in 3 weeks.	Backup for 2 days after LNG EC or 14 days after UPA EC
Post-surgical procedure for spontaneous or elective abortion and post early pregnancy failure – no procedure	▪ ≤ 7 days post procedure or passing pregnancy (when day known)	▪ None, if initiated that day. ▪ Otherwise, backup for 2 days.
	▪ > 7 days or unknown~~, see "no effective contraception" above.~~	See "no effective contraception" above
Post-medication abortion	May initiate prior to confirmation of termination pregnancy	
	▪ Day of misoprostol up to 7 days after mifepristone	None
	▪ > 7 days after mifepristone and before resuming intercourse	Backup for 2 days
Post-delivery after 24 weeks – breastfeeding	Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history? If menses has resumed, see "no effective contraception" above.	▪ If <21 days postpartum, none. ▪ If < 6 months postpartum, amenorrheic, and vast majority of feeds are breastfeeds, none. Otherwise if ≥ 21 days postpartum and menses has not resumed, backup for 2 days.
Post-delivery after 24 weeks – not breastfeeding	Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history? If menses has resumed, see "no effective contraception" above.	▪ If <21 days postpartum, none. ▪ If ≥ 21 days postpartum and has not resumed menses, backup for 2 days.

6.7.c. Algorithm: Quick Start for POPs



6.7.3 Follow-up for POP-related Medical Visits

I. Client should be queried about changes in personal history, possible side effects, and her menstrual cycle/bleeding pattern.
   A. Physical exam and laboratory testing **must** be performed, as indicated.

6.7.4 Management of Side-Effects and Complications

6.7.d. Table: Conditions/Signs/Symptoms that Develop While on POPs

Legend	
A	Contraindications — **must** discontinue
B	Special Conditions Requiring Further Evaluation — Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral **must** be based on protocols approved by the medical director or in consultation with the medical director or affiliate physician. ***Must** give Special Conditions CIIC
C	Other considerations - condition should be considered in risk/benefit analysis when choosing the method

Condition/Signs/Symptoms	A	B	C
Breast cancer – histologically proven malignancy or strong evidence of malignancy (e.g. BI-RADS 5)	●		
Breast mass (undiagnosed) – may continue POPs. **Must** initiate evaluation as soon as possible.*		●	
Ischemic heart disease (USMEC 3, continuation)		●	
Stroke (US MEC 3, continuation)		●	
***Must** give CIIC Special Conditions.			

6.8 NON-PRESCRIPTION CONTRACEPTION METHODS / FERTILITY AWARENESS-BASED METHODS

✓ FYI — Non-prescription contraceptives

6.8.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

6.8.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer	Should give
CI Condoms and Female Condoms					first time dispensed
CI Fertility Awareness-Based Methods			first time used		
Instructions on Fertility Awareness-Based Method used*			first time used		
Release When Test/Service/Consultation Will Not Be Obtained		Once			
Written information on all available contraceptive methods			If starting contraception for the first time	To all others seeking a new method/change	
*Not supplied by PPFA					

- ✓ FYI - Key Points of Advice about Nonoxynol-9 (N-9)

6.8.2 Provision of Condoms/FAM

- ✓ When initiating or switching to condoms or FAM, **must** follow Table 6.1.a. Choosing a Method
- ✓ See Table 6.9.a. Requirements for Initial Prescribing/Providing/Dispensing and Renewal

6.8.b. Table: Timing of Initiation

Current Method	Initiate FAM	Backup
No effective contraception	Anytime in cycle if it is reasonably certain client is not pregnant. ✓ FYI — How can a provider be reasonably certain a woman is not pregnant — by her history?	Recommend condoms if client is unsure of her fertile days.
Current correct use of hormonal contraception	After client has resumed normal, predictable menstrual cycles. Until then, she may not be able to accurately predict her fertile days.	Use barrier methods or abstinence until normal menstrual cycles have resumed.

Current Method	Initiate FAM	Backup
IUC	Any time in cycle if client was using copper IUC. If client is transitioning from LNG-IUC to FAM, and had amenorrhea or irregular bleeding, she should wait until she resumes having normal, predictable menstrual cycles.	Use barrier methods or abstinence until normal menstrual cycles have resumed.
Post-abortion (elective or spontaneous; medical or surgical)	Wait until at least 1 normal menstrual cycle has occurred.	Use barrier methods or abstinence until normal menstrual cycles have resumed.
Post-delivery after 24 weeks – nursing or not nursing	Wait until at least 1 normal menstrual cycle has occurred.	Use barrier methods or abstinence until normal menstrual cycles have resumed.

6.8.3 Follow-up

I. Encourage client to return to affiliate if she has difficulty making FAM work for her.
II. Review client's satisfaction and success with FAM at well woman visits and PRN.

6.9 ADDITIONAL INFORMATION

6.9.a. Table: Contraception - Requirements for Initial Prescribing/Providing/Dispensing and Renewal

Requirement	CHC	DMPA	POPS	Implant	Cu IUC	LNG IUC	Rx Barriers	Condoms/ FAM
History — **must** perform within the past year and at each renewal or insertion								
Contraindications and special conditions ✓ See Table 6.1.a.	●	●	●	●	●	●	●	●
Evaluation of risks for sexually transmitted infections					●	●		
Possible pregnancy	●	●	●	●	●	●	●	
History of breast mass	●	●	●	●		●	●	
Post-delivery status	●				●	●	●	

Requirement	CHC	DMPA	POPS	Implant	Cu IUC	LNG IUC	Rx Barriers	Condoms/ FAM
Lactational status	●					●		
Physical Examination — **must** perform								
BP — within 3 months and at each renewal	●	○*						
CBE or mammogram in asymptomatic women, annually								
Speculum exam, with each insertion					●	●		
Bimanual exam, with each insertion/fitting					●**	●**	●	
Laboratory Testing — should perform, if indicated								
Gonorrhea and chlamydia tests					●	●		
Wet prep and tests for other STIs					●	●		

*Routine BP screening for DMPA initiation/continuation is not required. When there is a history of hypertension, **must** perform BP within 3 months of initiation and at each renewal.

****Must** determine uterine size and position. Limited ultrasound may be useful when palpation/confirmation of uterine position is difficult on bimanual exam.

6.9.b. Table: For Your Information

Section	Topic	Detail
6.1.1	Systemic antibiotics and hormonal contraception	There is no pharmacologic evidence that the acute or chronic use of systemic antibiotics (e.g., tetracycline, ampicillin) decreases the efficacy of low-dose CHCs in women who take them correctly.
6.1.1	Women with significant medical conditions	For women with conditions that make unintended pregnancy an unacceptable health risk, a long acting, highly effective method may be the best choice.
6.1.a.	Adverse Venous Thromboembolism (VTE) Risk Profile	There are many factors that may increase a woman's risk for VTE. They include BMI ≥ 30, age ≥ 35, chronic immobility, smoking, known thrombogenic mutations, family and personal history of VTE, pregnancy, postpartum status, and CHC use. For women in the postpartum period, additional risk factors include transfusion at delivery, postpartum hemorrhage, postcesarean section, and preeclampsia.
6.1.a.	Risk factors for osteoporosis (DMPA)[R1]	Other birth control methods should be considered in the risk/benefit analysis for the use of DMPA in women with osteoporosis risk factors — alcoholism, strong family history of osteoporosis, metabolic bone disease, anorexia nervosa, tobacco use, and chronic use of drugs that can reduce bone mass,

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td></td><td></td><td>such as anticonvulsants or corticosteroids.

In addition, there remains a concern that older women who reach menopause while still using DMPA may no longer have the opportunity to regain BMD before entering the period of bone loss normally associated with postmenopausal age.</td></tr>
<tr><td>6.1.a.</td><td>Systemic Lupus Erythematosus (SLE)</td><td>Severe thrombocytopenia is listed as a special condition for Cu IUC use, because women with this condition lack the ability to clot correctly. Use of the Cu IUC, which is associated with increased bleeding, may increase that risk.

Women with SLE who are not known to be negative for antiphospholipids are at increased risk for PE or DVT. Because use of a hormone containing IUC (LNG IUC) may add to this risk, it is listed as a special condition.</td></tr>
<tr><td>6.1.a.
6.5.e.</td><td>Actinomyces on Pap and it's Time to Replace the IUC</td><td>A group of experts considered whether it's contraindicated to replace a current IUC in a woman with asymptomatic actinomyces on Pap. They concluded that there is no evidence that would preclude replacing the IUC but the woman must be informed of potential risks.</td></tr>
<tr><td>6.1.a.</td><td>Assessing for Severity of Cirrhosis by Using the Child Pugh Scoring System</td><td>The Child Pugh score can be used to assess severity of cirrhosis or other liver disease. It employs five clinical measures. Each measure is scored one to three, with three indicating most severe derangement.
<table>
<tr><th>Measure</th><th>1 point</th><th>2 points</th><th>3 points</th></tr>
<tr><td>Total bilirubin, µmol/l (mg/dl)</td><td><34 (<2)</td><td>34-50 (2-3)</td><td>>50 (>3)</td></tr>
<tr><td>Serum albumin, g/l</td><td>>35</td><td>28-35</td><td><28</td></tr>
<tr><td>PT INR</td><td><1.7</td><td>1.71-2.30</td><td>> 2.30</td></tr>
<tr><td>Ascites</td><td>None</td><td>Mild</td><td>Moderate to Severe</td></tr>
<tr><td>Hepatic encephalopathy</td><td>None</td><td>Grade I-II (or suppressed with medication)</td><td>Grade III-IV (or refractory)</td></tr>
</table></td></tr>
</table>

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td></td><td></td><td>By adding the scores of the five clinical measures, severity of disease is then classified into Child-Pugh class A to C.
<table>
<tr><th>Points</th><th>Class</th><th>One year survival</th><th>Two year survival</th></tr>
<tr><td>5-6</td><td>A</td><td>100%</td><td>85%</td></tr>
<tr><td>7-9</td><td>B</td><td>81%</td><td>57%</td></tr>
<tr><td>10-15</td><td>C</td><td>45%</td><td>35%</td></tr>
</table></td></tr>
<tr><td>6.2.c
6.3.b.
6.4.b.
6.5.b.
6.7.b.
6.8.b.</td><td>How can a provider be reasonably certain a woman is not pregnant — by her history?</td><td>A provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:
Is ≤7 days after the start of normal menses
Has not had sexual intercourse since the start of last normal menses
Has been correctly and consistently using a reliable method of contraception
Is ≤7 days after spontaneous or induced abortion
Is within 4 weeks postpartum
Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds),* amenorrheic, and <6 months postpartum</td></tr>
<tr><td>6.1.2</td><td>Extended Use of the Patch and the Ring</td><td>In an interim vote in January 2007, the Primary Care Subcommittee of the National Medical Committee voted that there is not enough evidence to recommend or prohibit extended use of the Ortho Evra contraceptive patch. Upon subsequent published evidence, the question will be reconsidered. Whenever considering extended use, it is important to weigh the risks vs. benefits.

Extended use of the ring is permissible. As long as NuvaRing is changed within five weeks, back up contraception is not needed. An easy regimen for clients to remember is to change the ring on the first day of each month.</td></tr>
<tr><td>6.4.a.</td><td>Hormonal Contraception and Bone Health, 2007 (DMPA excerpts only)</td><td>Women using DMPA lose some bone density while they are using it. This happens to both adults and teenagers. The amount of bone lost is somewhere between 5-7% in the hip and spine. This change happens quite rapidly at first. The loss then becomes much slower over the course of 2 years. The good news is that when the DMPA is stopped, both adults and teenagers regain bone density over a short time period. In 2 years, their bone density is about the same as other women their age who did</td></tr>
</table>

Section	Topic	Detail
		not use DMPA. Although the bone recovers its density after stopping the progestin-only injectable, two groups of women may need special attention: those women who enter menopause while using it, and those who are teenagers while they are using it. The reason is that women who are teenagers are still making bone in a way that adult women do not. Therefore, researchers wonder whether this will affect the maximum level of bone density they will reach normally. If there is a negative effect, this may lead to weaker bones and an increased risk of fracture later in life, as an elderly person. We will not know the answer to this question until women using these contraceptives age. But since we know that the bone density almost completely 'recovers' after stopping the progestin-only injectable, the chance is small that this will increase the risk of facture much later on in life. With regard to bone density and hormonal contraception, the World Health Organization recommends ▪ Women aged 18-45 should be able to use DMPA (and other progestin-only injectables) without any limits. ▪ A teenager or a woman over 45 may use DMPA (and other progestin-only injectables) if she and her health care provider decide that it is the best method for her, even if it may decrease her bone density. For the full document, go to ✓ http://www.who.int/reproductive-health/publications/providerbriefs/bonehealth.pdf
6.2.e. 6.4.a. 6.5.e.	Managing Unscheduled Bleeding in COC, DMPA, and IUC Users[R2, R3]	**For COC Users - Changing formulation** No research indicates that any specific COC is best at eliminating unscheduled spotting or bleeding. However, following guidance based on the timing of the woman's bleeding and spotting in her pill pack may be helpful. ▪ Bleeding before completing active pills – try increasing the progestin content of the pills, either by changing to a different monophasic formulation or by switching to a triphasic formulation that increases progestin levels in the last active pills. ▪ Bleeding following scheduled bleeding – consider increasing the estrogen content in the first pills in the pack or decreasing the progestin content of those first pills by switching to another formulation.

Section	Topic	Detail
		▪ Mid-cycle spotting or bleeding – try switching to triphasic formulations that increase both estrogen and progestin in the middle pills. Some experts recommend switching from COC to CVR, which has more constant hormone levels. **For DMPA and IUC Users – Treating with medication** Experts recommend the following regimens for women desiring treatment ▪ DMPA users - Mefenamic acid 500 mg twice per day for five days ▪ IUC users - ibuprofen 400 mg, naproxen 250 mg, or mefenamic acid 500 mg three times per day for five to seven days
6.3.d.	Expected Bleeding Patterns	The majority of Implanon users will experience an alteration of bleeding patterns during the first year of use. Infrequent bleeding, defined as less than three bleeding episodes in 90 days, is the most common variation, occurring in 50% of women in the first 3 months of Implanon use, declining to 30% after 6 months. Prolonged bleeding is defined as at least one episode in 90 days that lasts at least 14 days. Prolonged bleeding is also more common in the first 3 months (approximately 20%) declining to about 10% with time. Frequent bleeding, defined as >5 bleeding episodes in 90 days, occurs less than 10% of the time. Less than 1% of clients had low hemoglobin levels. Bleeding patterns will vary with time and will not necessarily show a trend or remain consistent throughout the duration of use of Implanon. About 20% of the time, while using Implanon, the client can expect to experience amenorrhea. The absolute risk of pregnancy while using Implanon is low. (Rate of 0.00–0.09 per 100 woman-years compared to 43.07 per 100 woman-years for a non-contraceptor.) No ectopic pregnancies were reported in the clinical trials.
6.3.2.	Misoprostol for Cervical Ripening	Misoprostol may cause birth defects. Although this information is included in the Client Information for Informed Consent, it's important to stress with clients.

Section	Topic	Detail	
6.5.2.	IUC Failure Rates	LNG IUC pregnancy failure rates ▪ Perfect use in first year — 0.1 percent ▪ Typical use in first year — 0.1 percent ▪ Cumulative five-year — 0.7 percent	Cu IUC pregnancy failure rates ▪ Perfect use in first year — 0.6 percent ▪ Typical use in first year — 0.8 percent ▪ Cumulative 12-year — 1.9 percent
6.1.a. 6.5.e.	Actinomyces	Actinomyces are anaerobic bacteria capable of causing a rare, but severe, pelvic infection (pelvic actinomycosis) generally occurring in women over 35 years old with long-term IUC use, especially if they have been malnourished. A large majority of IUC wearers with Actinomyces on Pap test have asymptomatic colonization (not infection) that does not require antibiotic therapy or IUC removal. Identification of Actinomyces on a Pap test is not diagnostic of any disease and is not predictive of disease. Symptoms of actinomycotic PID include deep-thrust dyspareunia, intermenstrual bleeding or spotting, or pelvic or abdominal pain.	
6.5.e.	Bleeding and Amenorrhea	▪ In Cu IUC users bleeding between menstrual periods may occur during the first 3 to 6 months post-insertion. (US SPR, 2013) Menstrual periods may be longer and heavier than usual. ▪ In LNG IUC users there may be an increased number of days of bleeding and spotting, especially during the first 3 to 6 months of use. The bleeding pattern usually stabilizes after initial 3 to 6 months, but may remain irregular. Amenorrhea develops in about 50 percent of LNG IUC users by one year. ▪ NSAIDs reduce bleeding in both asymptomatic IUC users and users with heavy blood loss.	
6.5.e.	IUC Expulsions	▪ Partial expulsions outnumber complete expulsions by more than a factor of three. ▪ Most partial expulsions are silent and delayed beyond the first month of use. ▪ Signs and symptoms include acute onset of bleeding and cramping. ▪ Confirmation of diagnosis may be made when o Strings appear to have greatly lengthened. o Device is felt in the endocervical canal with a uterine sound. o Device is visualized in canal with endocervical speculum. o Plastic tip is palpated by bimanual exam.	

Section	Topic	Detail
6.6.2.	Determining Cap Size	Determination of FemCap size is based on client's obstetrical history ▪ 22 mm (small) — never pregnant. ▪ 26 mm (medium) — no vaginal births. ▪ 30 mm (large) — history of vaginal delivery. A different size device than is determined by using obstetrical history may be needed. The FemCap may be considered correctly in place when the ▪ Device is comfortable for the client ▪ Cervix is covered ▪ Device is in the uppermost part of the vagina
6.8	Non-Prescription Contraceptives[R4,R5]	▪ Non-prescription barrier contraceptives are an important contraceptive option because of their wide availability, relative ease of use, and efficacy when used correctly. ▪ While the contraceptive efficacies of the various over-the-counter methods, when used alone, are comparable to each other, the combined use of barriers and spermicides increases their effectiveness significantly. ▪ When used consistently and correctly, lubricated latex condoms (without nonoxynol-9) and female condoms provide a high degree of protection against the acquisition and transmission of a number of sexually transmitted pathogens, including gonorrhea, chlamydia, syphilis, hepatitis B virus, HSV, and HIV. ▪ Although condom use will not prevent transmission of HPV to or from uncovered areas, recent studies suggest that consistent condom use significantly reduces the risk of genital HPV infection among newly sexually active young women, and that regression of HPV lesions in women and men is accelerated by condom use. ▪ Many experts believe that the value of ongoing condom use to prevent transmission of HPV within mutually monogamous relationships is limited, because it is likely that exposure of the partner has already occurred. However, if an infected person has a new sex partner, use of condoms should be recommended to decrease the risk of transmission to a previously uninfected person. ▪ Non-prescription contraceptives include o Latex, polyurethane, and animal membrane condoms

Section	Topic	Detail
		○ Polyurethane and nitrile female condoms ○ Spermicide creams, films, foams, jellies, and suppositories ○ Contraceptive sponges
6.8.a.	Key Points of Advice about Nonoxynol-9 (N-9)	▪ N-9 is a spermicide used in lubricants and vaginal contraceptives. ▪ N-9 does reduce the risk of pregnancy. ▪ N-9 does not reduce the risk of sexually transmitted infection. ▪ N-9 may irritate the penis, vagina, vulva, and, especially, the anus and rectum — *increasing* the risk of STI, including HIV. ▪ N-9 should not be used ○ By women and men at risk for HIV infection ○ By women who have frequent vaginal intercourse (more than several times daily) ○ For anal intercourse ○ To prevent infection ○ By women and men who have allergies to spermicide The latex condom is the best way for sexually active men and women to reduce the risk of infection.

6.9.c. Table: References

Section	R#	Reference
Throughout		Centers for Disease Control and Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2013. June 21, 2013. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm?s_cid=rr6205a1_w (accessed May 10, 2014)
6.1.a.		Centers for Disease Control and Prevention. Update to CDC's U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: Revised Recommendations for the Use of Contraceptive Methods During the Postpartum Period. July 8, 2011. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6026a3.htm?s_cid=mm6026a3_w (accessed May 10, 2014)
Throughout		Centers for Disease Control and Prevention. U.S. Medical Eligibility Criteria for Contraceptive Use. May 28, 2010. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr59e0528a1.htm?s_cid=rr59e0528a1_e (accessed June 2, 2010).
6.9.b.	R3	Edelman A. Kaneshiro B. Management of unscheduled bleeding in women using contraception. In: UpToDate, Zieman M (Ed), UpToDate, Waltham, MA (Accessed May 10, 2014)

Section	R#	Reference
6.9.b.	R2	Hatcher R et al. Contraceptive technology. (20th ed.) New York: Ardent Media, Inc. 2011.
6.9.b.	R5	Maaike CG et al. Condom use promotes regression of cervical intraepithlial neoplasia and clearance of human papilliomavirus: A randomized clinical trial. Condom use promotes regression of human papillomavirus-associated penile lesions in male sexual partners of women with cervical intraepithelial neoplasia. International Journal of Cancer, 107, 811–816 & 804–810
Throughout		RHEDI. Quick Start Algorithm. 2005. http://rhedi.org/contraception/quick_start_algorithm.php (accessed May 2010).
6.9.b.	R4	Winer R.L. et al. (July 2005). The effect of consistent condom use on the risk of genital HPV infection among new sexually active young women. Poster presented at the 16th meeting of the International Society for Sexually Transmitted Diseases Research, Amsterdam, the Netherlands.
6.9.b.	R1	World Health Organization. Provider brief: Hormonal contraception and bone health. Geneva: WHO; 2007. Available at: http://www.who.int/reproductive-health/publications/providerbriefs/bonehealth.pdf. Accessed December 2008.

6.9.d. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIICs	CI After Insertion of the Implant CI After Taking Out the Implant CI Condoms and Female Condoms CI Fertility Awareness-Based Methods CI How To Use the Cervical Cap CI How To Use the Diaphragm CI How To Use the Patch CI How To Use the Pill CI How To Use the Ring CI IUC Pregnancy CIIC Diaphragm and Cervical Cap CIIC DMPA	Part 3, Chapter 02_06

Type	Resource	Location
	CIIC HC Special Conditions CIIC Implant CIIC IUC CIIC IUC Continued Use Beyond Recommended Removal Date CIIC IUC Removal – Missing String CIIC IUC Special Conditions CIIC Pill Patch and Ring CIIC Preparing Your Cervix with Misoprostol CIIC POPs CIIC Taking Out the Implant	
Client Education	Contraceptive Effectiveness Chart	Part 3, Chapter 02_06

6.9.e. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ CDC US Medical Eligibility Criteria (US MEC) for Contraceptive Use, Summary Chart, and Mobile App ✓ CDC US Selected Practice Recommendations (US SPR) for Contraceptive Use ✓ CDC Providing Quality Family Planning Services (QFP)	
Training	**CAL Courses** Emergency Contraception Series Intrauterine Contraception (IUC): Selection, Insertion, and Simulation Long Acting Reversible Contraceptives (LARC) Orientation to Family Planning	
	2014 VOICE Introduction to US SPR	To be posted on the CAL

[1] Checking hemoglobin or hematocrit prior to insertion of IUC is not required.

[2] Evidence exists that hemoglobin levels and red blood cell survival increase and painful sickle crises decrease with DMPA use.

[3] Risk is multifactorial. Risk factors for cardiovascular disease include: age ≥ 35, tobacco use, high cholesterol levels, diabetes, chronic hypertension, family history of premature coronary heart disease (CHD) in a male first degree relative < 55 years, CHD in a female first degree relative < 65 years). (CHC contraindicated in smokers ≥ 35.) The larger the number of risk factors, as well as the greater severity of each risk factor, the greater the risk of myocardial infarction. As a consequence, as cardiovascular risk factors increase in number or severity, a woman becomes a less appropriate CHC or DMPA candidate.

[4] Risk factors for recurrent DVT/PE: h/o estrogen-associated DVT/PE, pregnancy associated DVT/PE, idiopathic DVT/PE, known thrombophilia(including antiphospholipid syndrome), active cancer excluding non-melanoma skin cancer (metastatic, on therapy, or within 6 months after clinical remission), h/o recurrent DVT/PE

[5] H/o superficial thrombophlebitis is not a contraindication to CHC (USMEC 2).

[6] Known thrombogenic mutations include: factor V leiden, prothrombin mutation; protein S, protein C and antithrombin deficiencies

[7] The following are NOT contraindications for CHC: negative antiphospholipid antibodies (USMEC 2), thrombocytopenia (USMEC 2), immunosuppressive treatment (USMEC 2)

[8] The following are NOT special conditions for DMPA: negative antiphospholipid antibodies (USMEC 2), mild/no thrombocytopenia

[9] The following are NOT special conditions for the implant, POPs, LngIUC: negative antiphospholipid antibodies (USMEC 2), thrombocytopenia (USMEC 2) immunosuppressive treatment (USMEC 2)

[10] The following are NOT special conditions for CuIUC: antiphospholipid antibodies, mild/no thrombocytopenia, immunosuppressive treatment.

[11] history of diagnosis of anorexia nervosa defined as (DSM IV criteria) body weight more than 15% below normal weight for age, or a body mass index (BMI) below 17.5 or distortion of body image and intense fear of gaining weight or becoming fat even though underweight; in postmenarcheal females, history of prolonged amenorrhea (> six months) due to hypoestrogenic conditions such as super athlete or significant eating disorder; not breastfeeding; long-term oral glucocorticoid therapy (or plans for long-term use) defined as prednisone equivalent of ≥ 5 mg/day for ≥ three months (ACR 2001)

[12] Definitions: A.) Osteoporosis— bone density T-score ≤ 2.5 at the lumbar spine or hip. (WHO) Although the WHO system was designed for postmenopausal women, it is sometimes applied to premenopausal women who have strong risk factors for bone loss or fracture at an early age, e.g., anorexia nervosa, rheumatoid arthritis, chronic glucocorticoid therapy. B.) Known fragility fracture(s) — fracture caused by an injury that would be insufficient to fracture normal bone: the result of reduced compressive and/or torsional strength of bone. (WHO; NMC 2010)

[13] Use the following tool to screen for migraine aura when client is unsure of her history.

Do you ever have visual disturbances that

□ Start before the headache?

□ Last up to one hour?

□ Resolve before the headache begins?

Ask the woman for a description of her visual disturbance if any of the above questions are answered positively. Watch her hands as she describes her symptoms. If her hand moves up in a wavy circular area beside her head, aura is more likely than if she leaves her hand down. Ask the woman to draw her visual symptom — women with aura commonly draw a jagged crescent or indicate a scintillating letter "C" with a dark spot within it. (MacGregor & Mishell 2005)

[14] Evidence exists that grand mal seizure activity decreases with DMPA use. (Hatcher 2007)

[15] LNG IUC may be used as treatment to control bleeding (not for contraception) in women with uterine abnormalities even if correct placement is not possible. There is no published data on the rate of expulsion or pregnancy in IUC users with myomata.

[16] Small uterine cavity with sounding less than 6.0 cm is not a special condition for the smaller LNG IUC — 13.5 mg.

[17] Once chlamydia, gonorrhea and/or mucopurulent cervicitis has been treated – defined as 7 days after a 1-dose treatment or after completion of a 7 day treatment regimen – there is no contraindication to IUC.

[18] If a woman has a very high individual likelihood of exposure to gonorrhea or chlamydial infection, the condition is a USMEC 3. IUC insertion and continuation is USMEC 2 for women with HIV/AIDS with stable immune systems on antiretroviral therapy.

[19] Risk factors for endometrial cancer include personal or family history of ovarian, breast, colon or endometrial cancer, tamoxifen use, chronic anovulation, obesity, unopposed estrogen therapy, and prior endometrial hyperplasia

[20] Mild IBD and with no other risk factor for VTE is not a special condition. (USMEC 2)

[21] The following are NOT contraindications to CHC: mild (compensated) cirrhosis (USMEC 1), chronic viral hepatitis (USMEC 1), hepatitis carrier (USMEC 1). A workup is not necessary.

[22] The following are NOT special conditions for DMPA, POP, Implant, or LNG IUC: mild (compensated cirrhosis) and viral hepatitis (acute, carrier, chronic) (USMEC 1). A workup is not necessary.

[23] Focal nodular hyperplasia is not a special condition for DMPA, Implant, POP, or LNG IUC

[24] Uncomplicated solid organ transplantation is not a contraindication (USMEC 2)

CHAPTER 7: EMERGENCY CONTRACEPTION

Revised June 2014

Chapter 7 Table of Contents

CHAPTER 7: EMERGENCY CONTRACEPTION

Revised June 2014

7.1 CLIENT EDUCATION AND INFORMED CONSENT

I. Informed consent **must** be obtained. All written materials given to client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

7.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** give	**Must** offer
CIIC Emergency Contraception		At first Rx and every renewal, if applicable	
Package insert		At first Rx	With each new Rx, but no more frequently than annually
See Chapter 6.5 Intrauterine Contraceptives			

7.2 EC PRODUCTS

7.2.1 Copper Intrauterine Contraceptive (Cu IUC)

I. Cu IUC – Insert within 5 days following unprotected intercourse for EC and may continue as an ongoing method of contraception. (See Chapter 6.5 Intrauterine Contraceptives)

7.2.2 Oral EC regimens

The remainder of this chapter relates to oral EC regimens only.

I. Prescription
   A. Dedicated Products
      1. Ulipristal acetate (UPA) — 1 tablet (30 mg) taken orally as soon as possible within 120 hours after intercourse
      2. Levonorgestrel Regimens (LNG EC) —1.5 mg taken orally as soon as possible within 72 hours after intercourse

✓ FYI – 2 dose regimens

   B. Combined Oral Contraceptives (COCs) — for a list of oral contraceptives that can be used as EC, go to The Emergency Contraception website, linked below.

✓ Oral contraceptives that can be used for emergency contraception in the United States

II. Contraindications and Special Conditions for RX EC Pills - Table 7.2.a. **must** be followed when making decisions about client selection.

7.2.a. Table: Contraindications and Special Conditions for RX EC Pills

LEGEND	
A	Contraindications — EC Pills may not be provided
B	Special Conditions Requiring Further Evaluation — These conditions require affiliate protocols for management or consultation with the provider performing the procedure.

CONDITION	A	B
Breast Feeding – client should be instructed to pump and discard her breast milk for 36 hours		UPA only

III. Requirements for prescribing for immediate use
   A. A targeted history including the following components should be obtained
      1. Time since last unprotected intercourse
      2. Calculation of BMI
      3. Lactational status

✓ FYI – Effectiveness of EC regimens

IV. Repeated Use — may advise repeated use of EC within the same cycle.
   A. Should counsel to use most effective method available starting with Cu IUC.
   B. EC pills do not need to be taken more than once every 24 hours.
   C. If a woman has used LNG EC, repeat use of any oral EC regimen is acceptable.
   D. If a woman has used UPA
      1. There is limited evidence on safety or effectiveness of repeated use of UPA.
      2. There is some evidence that taking LNG EC after UPA may not be effective.

V. Initiation of Contraception Post-EC – see Table 7.2.b., below.

VI. Advanced prescription is encouraged.

7.2.b. Table: Timing of Initiation of Contraception Post–EC

Timing of Initiation of Contraception Post-EC	
Barrier Methods	Start using immediately.
Hormonal methods ▪ CHC ▪ POPs ▪ Implant ▪ DMPA ▪ LNG IUC	▪ For all hormonal methods, start using immediately — same day as EC, or the following day. ○ Advise back-up method for 7 days (2 days for POPs) after LNG EC or 14 days after UPA. ○ For COCs • If a regimen of monophasic COCs was used as EC, the client may continue to take 1 pill per day from the same pack. Advise client to skip placebo pills. For ongoing contraception, prescribe as per Chapter 6. ○ For implant and LNG IUC • Perform a highly sensitive urine pregnancy test prior to initiation, unless first day LNMP within past 7 days. • Advise client to repeat pregnancy test in 3 weeks. ○ For DMPA • Perform a highly sensitive urine pregnancy test prior to initiation, unless first day LNMP within past 7 days. • Advise client to repeat pregnancy test in 3 weeks. • A urine pregnancy test **must** be performed before the subsequent (next) DMPA injection. ▪ Alternatively, start after the next menstrual period. Advise use of a barrier method in the interim.
Cu IUC	▪ Use the Cu IUC only as both EC method and for ongoing contraception. For EC, insert within 5 days of unprotected intercourse. See Chapter 6.5 Intrauterine Contraceptives
Fertility Awareness Methods	Initiate after the first normal menstrual period following EC use. Advise use of a barrier method until the first normal period.
Sterilization	Perform the procedure after the start of the menstrual period following EC use. Use a back-up method until the sterilization is completed.

VII. Management of Side Effects

A. Nausea and Vomiting

1. If vomiting occurs within 3 hours after taking EC (any formulation), dose should be repeated as soon as possible.
2. An antiemetic should be considered. Antiemetics should be taken 1 hour prior to taking EC.
3. If vomiting continues, a repeat dose can be given vaginally.

✓ FYI – Side Effects

7.3 ADDITIONAL INFORMATION

7.3.a. Table: For Your Information

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>7.2.2</td><td>2-Dose EC Regimens</td><td>2-dose LNG EC regimens may be labeled with instructions to take each dose 12 hours apart. However, available evidence has not demonstrated any advantage to this option as compared to taking both doses simultaneously.</td></tr>
<tr><td>7.2.2</td><td>Effectiveness of EC Regimens[R1]</td><td>Three variables have been found to influence risk of pregnancy after using EC: BMI, conception probability based on day of cycle, and further intercourse after EC.
<table>
<tr><th>Regimen</th><th>% Effectiveness</th><th>Notes</th></tr>
<tr><td>Cu IUC</td><td>>99</td><td>Most effective</td></tr>
<tr><td>UPA</td><td>85</td><td>Maintains effectiveness through 120 hours.
Less effective in women with BMI 30-35
Not effective in women with BMI >35</td></tr>
<tr><td>LNG EC</td><td>75-89</td><td>Less effective in women with BMI 25.0-29.9.
Less effective beyond 72 hours.
Not effective in women with BMI ≥30</td></tr>
</table></td></tr>
<tr><td>7.2.2</td><td>Side Effects</td><td>Nausea and Vomiting
▪ Combined EC — About 50 percent of women experience nausea and 20 percent vomit.
▪ LNG EC — 13 percent experience nausea and 6 percent vomit.
▪ UPA —11 percent experienced nausea in clinical trials.

Bleeding Patterns
▪ UPA
○ Menses may occur earlier or later than expected by a few days.
• In clinical trials, 7 percent reported menses occurring more than 7 days earlier than expected and 19 percent reported a delay of more than 7 days.
○ Subsequent menstrual flow likely to be prolonged.
▪ Single dose LNG EC regimen
○ Shortens the treatment cycle, hastening the onset of the subsequent menstrual period.
○ Increases the chance that the subsequent menstrual flow will be prolonged.
○ Rarely causes intermenstrual bleeding.</td></tr>
</table>

7.3.b. Table: References

Section	Ref#	Reference
7.3.a.	R1	Glasier A, Cameron ST, Blithe D, Scherrer B, Mathe H, Levy D, Gainer E, Ulmann A. Can we identify women at risk of pregnancy despite using emergency contraception? Data from randomized trials of ulipristal acetate and levonorgestrel. Contraception. 2011;84:363 – 7.
Throughout		International Consortium for Emergency Contraception. Emergency Contraceptive Pills: Medical and Service Delivery Guidelines. Third edition 2012. http://www.cecinfo.org/custom-content/uploads/2014/01/ICEC_Medical-and-Service-Delivery-Guildelines-English_June-2013.pdf Accessed May 31, 2014.

7.3.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIICs	CIIC Emergency Contraception	Part 3, Chapter 02_07

7.3.d. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ EC4U Toolkit	
	BMI Table	Part 3, Chapter 02_21
Training	**CAL Courses** Emergency Contraception Series	
	PPFA 2013 VOICE Updates in Emergency Contraception	Accessed through the CAL

CHAPTER 8: GYNECOLOGICAL CONDITIONS

Revised June 2014

Chapter 8 Table of Contents

8.1 ABNORMAL UTERINE BLEEDING, AMENORRHEA, POLYCYSTIC OVARIAN SYNDROME AND STRUCTURAL LESIONS OF THE UTERUS

8.1.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

8.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
CIIC Endometrial Biopsy		●	●	
Information on any medication dispensed (package insert may be used)			●	
Release When Test/Service/Consultation Will Not Be Obtained		Once		
Request for Surgery or Special Procedure		●		●
Written information as appropriate			●	

8.1.2 Abnormal Uterine Bleeding

I. Evaluation

✓ FYI – The PALM-COEIN System

8.1.b. Table: Evaluation of AUB

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Should include ▪ Age of menarche and menopause ▪ Pregnancy symptoms, if applicable ▪ Menstrual bleeding patterns ▪ Severity of bleeding (presence of clots) ▪ Pain (severity and treatment) ▪ Medical conditions ▪ Surgical history	Should include ▪ Weight and BMI ▪ Pulse and blood pressure ▪ Orthostatic changes if symptomatic (dizziness, light-headed) ▪ Thyroid palpation ▪ Inspection of skin for ○ Signs of PCOS (acne, hirsutism)	Lab tests should include ▪ Pregnancy test ▪ CBC ▪ TSH ▪ Chlamydia test, if indicated ▪ Pap test, if indicated ▪ Platelets, PT/PTT**

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
▪ Current or recent use of medications or herbal remedies ✓ FYI – Medications and Herbs Associated with AUB ▪ Signs or symptoms of anemia ▪ Personal or family history of blood dyscrasias ▪ History or symptoms suggestive of underlying disorder of hemostasis ✓ See Important Information — Clinical Screening for an Underlying Disorder of Hemostasis	○ Signs of insulin resistance (acanthosis nigricans) ○ Signs of bleeding disorder (petechiae, ecchymoses, skin pallor, swollen joints) ▪ Pelvic exam*, including ○ Inspection for bleeding from vulva, vagina, cervix, urethra or anus ○ Presence of mass, ulcerations, vaginal discharge, foreign body ○ Size, contour, and tenderness of uterus ○ Adnexal masses/tenderness	▪ Other testing may include ▪ Endometrial biopsy ✓ See Important Information – Indications for Endometrial Biopsy Diagnostic imaging (when indicated) may include ▪ Transvaginal (or transabdominal) ultrasound
*Speculum exam is not indicated for adolescents **Must perform for all adolescents with heavy menstrual bleeding and adult clients with a positive personal or family history of a bleeding disorder		

Important Information – Indications for Endometrial Biopsy[R1]

Endometrial biopsy is an important component of the evaluation of AUB. Endometrial biopsy should be performed in clients

- Age ≥ 45
- Age < 45 with history of
  - Unopposed estrogen exposure
  - Failed medical management
  - Persistent AUB

Endometrial biopsy **must** be performed in clients age ≥ 45 with

- Personal or family history of ovarian, breast, colon or endometrial cancer
- Tamoxifen use
- Chronic anovulation
- Obesity
- Unopposed estrogen exposure
- Prior endometrial hyperplasia

In addition, endometrial biopsy **must** be performed in all clients experiencing postmenopausal bleeding unless TVUTZ shows endometrial thickness of 4 mm or less.

Important Information — Clinical Screening for an Underlying Disorder of Hemostasis

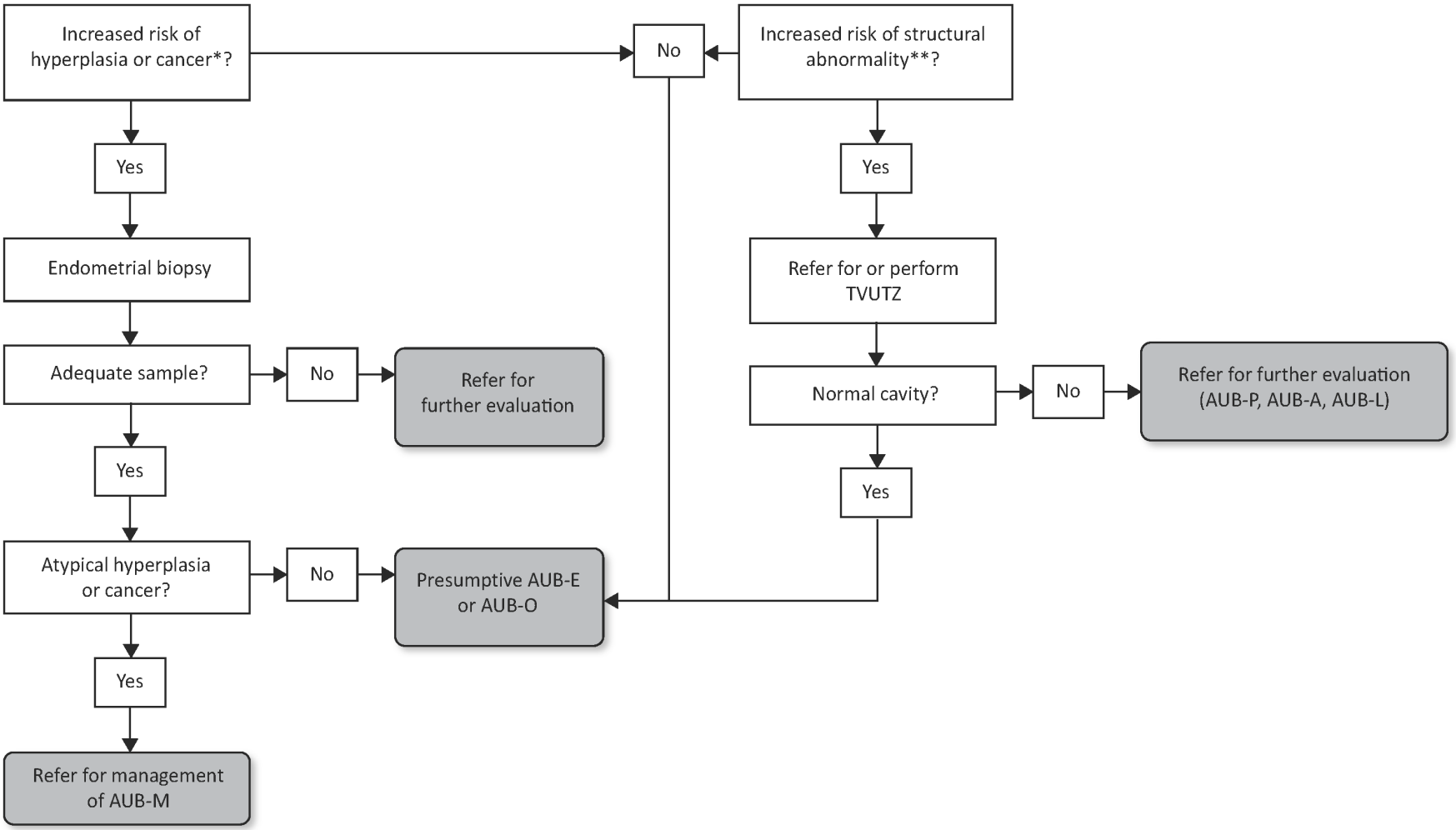
Consider further evaluation for an underlying bleeding disorder in any client who screens positive by the criteria below:

- Heavy menstrual bleeding since menarche
- One of the following
  - Postpartum hemorrhage
  - Surgery-related bleeding
  - Bleeding associated with dental work
- Two or more of the following
  - Bruising 1 to 2 times per month
  - Epistaxis 1 to 2 times per month
  - Frequent gum bleeding
  - Family history of bleeding symptoms

Initial tests **must** include a CBC with platelets, PT and PTT. Further evaluation, if indicated, should consist of consultation with a hematologist and testing of von Willebrand factor and ristocetin cofactor.

8.1.c. Algorithm: Uterine Evaluation in AUB

There are 2 questions that **must** be asked "Is there an increased risk of hyperplasia or cancer?" and "Is there an increased risk of structural abnormality?"



✓ * See Important Information – Indications for Endometrial Biopsy

**previous medical therapy unsuccessful

✓ FYI – Age-based Differential Diagnosis of AUB

I. Management

A. General Principles

1. Therapy should be tailored to client's individual therapeutic goals, desire for contraception, underlying medical conditions and tolerance of side effects.
2. If identified during evaluation, the following conditions should be managed according to the protocol within their specific section
   a. Pregnancy-related bleeding – See Chapter 13 Pregnancy Evaluation and Management of Complications
   b. Infectious conditions – See Chapter 9 Infections
   c. Abnormal bleeding related to use of a hormonal contraceptive – See Chapter 6.2 Combined Hormonal Contraceptives
3. If identified during evaluation, hypothyroidism must be referred (in or out of affiliate).
4. In clients at increased risk of hyperplasia or cancer (age >45, anovulation associated with unopposed estrogen) must complete uterine evaluation before initiating therapy.
5. Clients who experience persistent bleeding despite a trial of therapy and/or previous benign endometrial pathology are at increased risk of structural abnormalities and uterine evaluation is warranted per Algorithm 8.1.c. Uterine Evaluation.
6. Intervention is not always required if bleeding is mild and is tolerable to the client.
7. Clinically stable clients with mild to moderate anemia should be given iron supplementation while their bleeding is being treated.
8. Clients without increased risk of hyperplasia or cancer or structural abnormalities may start a trial of empiric therapy prior to any uterine evaluation (See management of presumed AUB-E or AUB-O, below).

8.1.d. Table: Management of AUB and Related Conditions

Classification (suspected or confirmed)	Suggested by	Management
AUB-P	▪ Abnormal appearing cavity on ultrasound ▪ Failure of initial trial of medical therapy	**Must** refer
AUB-A	▪ Dysmenorrhea ▪ Deep dyspareunia ▪ Enlarged, globular uterus ▪ Pelvic tenderness (especially just before and during menses)	▪ Empirical trial of medical therapy ▪ **Must** refer if symptoms not controlled or worsening
AUB-L	▪ Palpable mass on abdominal exam ▪ Ultrasound findings	▪ **Must** be evaluated by affiliate physician ▪ If minimal symptoms, manage with iron and analgesics as needed

Classification (suspected or confirmed)	Suggested by	Management
		▪ If abnormal bleeding ✓ See Important Information – Indications for Endometrial Biopsy ○ Supplement with iron as needed ○ Contraceptive steroids • Oral contraceptives may control bleeding symptoms without stimulating further leiomyoma growth • Progestin therapy (+/- GnRH agonists) demonstrated mixed results • If initiated, monitor closely for changes in uterine or leiomyoma size ○ LNG IUS may be beneficial however clients may have a higher rate of expulsion and vaginal spotting **Must** refer for evaluation by a gynecologist if: ▪ Uterine size ≥ 14 weeks (client can return to affiliate if expectant management per gynecologist) ▪ Rapidly enlarging uterus ▪ Inability to distinguish site of origin of pelvic mass (i.e., uterine vs. ovarian) ▪ Severe menorrhagia or significant anemia
AUB-M	Hyperplasia or malignancy on endometrial biopsy	**Must** refer
AUB-C	Positive screening/evaluation for coagulopathy	**Must** refer
AUB-O	AUB ranging from amenorrhea, through extremely light and infrequent bleeding, to episodes of unpredictable and extreme HMB requiring medical or surgical intervention	▪ Medical therapies are first line treatment ▪ Surgical therapy rarely indicated unless medical therapy fails, is contraindicated, is not tolerated, or in a client

Classification (suspected or confirmed)	Suggested by	Management
		with concomitant significant intracavitary lesions - see Table 8.1.e ▪ Weight loss and increased exercise are strongly advised in overweight anovulatory women
AUB-E	AUB in the context of predictable and cyclic menstrual bleeding, typical of ovulatory cycles, with no other definable causes identified	▪ Medical therapies are first line treatment ▪ Surgical therapy rarely indicated unless medical therapy fails, is contraindicated, is not tolerated, or in a client with concomitant significant intracavitary lesions - see Table 8.1.e
AUB-I	Client using IUC or pharmacologic agents that directly impact endometrium, interfere with coagulation or influence systemic control of ovulation	Manage as appropriate

8.1.e. Table: Medications for the Empirical Therapy of AUB

Treatment	Dose/Regimen	Contraindications	Adverse Effects	Efficacy/Benefits	Contraception?
Hormonal					
CHC	Cyclic, continuous or extended regimen	See Chapter 6.2 Combined Hormonal Contraceptives	▪ Breast tenderness ▪ Headache ▪ Nausea ▪ Unscheduled bleeding	▪ Menstrual regularity ▪ 20-50% reduction in mean blood loss (MBL) ▪ Reduction in dysmenorrhea ▪ Treatment of PMS	Yes

Treatment	Dose/Regimen	Contraindications	Adverse Effects	Efficacy/Benefits	Contraception?
LNG-IUS*		See Chapter 6.5 Intrauterine Contraceptives	▪ Irregular bleeding first 3 to 6 months ▪ Breast tenderness ▪ Cramping ▪ Pain at insertion	▪ Amenorrhea in up to 80% at 1 year ▪ 70-97% reduction in MBL ▪ Reduced dysmenorrhea	Yes
Cyclic oral progestin	Medroxyprogesterone acetate (MPA) 5-10 mg PO for 10-12 days q month Norethindrone acetate (NET) 5-10 mg PO for 10-12 days q month Micronized progesterone 200 mg PO daily for 10 days q month	▪ Pregnancy ▪ Breast cancer ▪ Liver disease - see Chapter 6.9 FYI — Assessing for Severity of Cirrhosis by Using the Child Pugh Scoring System	▪ Breast tenderness ▪ Mood changes ▪ Bloating ▪ Acne ▪ Headache ▪ Weight gain	Bleeding reduced by up to 87%	No
Injected progestin	DMPA 150 mg IM q 10-15 weeks DMPA 104 mg SQ q 10-15 weeks	See Chapter 6.4 DMPA	▪ Irregular bleeding ▪ Breast tenderness ▪ Weight gain ▪ Mood changes ▪ Headache ▪ Nausea ▪ Decreased BMD (reversible)	▪ 60 % amenorrhea at 12 months ▪ 68% amenorrhea at 24 months	Yes

Treatment	Dose/Regimen	Contraindications	Adverse Effects	Efficacy/Benefits	Contraception?
Non-Hormonal					
NSAIDS	Naprosyn 500 mg at onset of menses, 3-5 hours later, then 250-500 mg BID Ibuprofen 600 mg QD Mefanamic acid 500 mg TID	▪ Allergy ▪ Renal disease ▪ Untreated HTN ▪ Platelet or coagulation disorders ▪ Active gastritis or peptic ulcers	▪ Indigestion ▪ Worsening/ exacerbation of asthma, gastritis or peptic ulcers	▪ 20-50% reduction in MBL ▪ Reduction of dysmenorrhea in 70% of women	No
Antifibrinolytics	Tranexamic acid 1300 mg TID during menses for maximum of 5 days	Past history of VTE	▪ Indigestion ▪ Diarrhea ▪ Headache ▪ Leg cramps	40-59% reduction in MBL	No
*LNG-IUS should be considered for clients of all age groups					

II. Referral – **must** refer clients who
   A. Are hemodynamically unstable — requires immediate referral to the ER
   B. Have active bleeding with severe anemia — requires urgent referral
   C. Have suspected ectopic pregnancy — requires urgent referral
   D. Require hospitalization or surgical management
   E. Have known or suspected malignancy
   F. Have a workup suggestive of hematologic disorders
   G. Require management of systemic diseases (i.e., severe renal or liver disease)
   H. Have heavy bleeding not responding to medical therapies

8.1.3 Adenomyosis

I. Adenomyosis is a diagnosis of exclusion that can only be definitively diagnosed by a pathologist after hysterectomy. Clients with suspected adenomyosis may be managed by affiliates with an initial trial of empiric therapy. Clients experiencing AUB should be managed per 8.1 Abnormal Uterine Bleeding. Clients with suspected adenomyosis who are experiencing dysmenorrhea should be managed per 8.3 Dysmenorrhea**.**

8.1.4 Amenorrhea

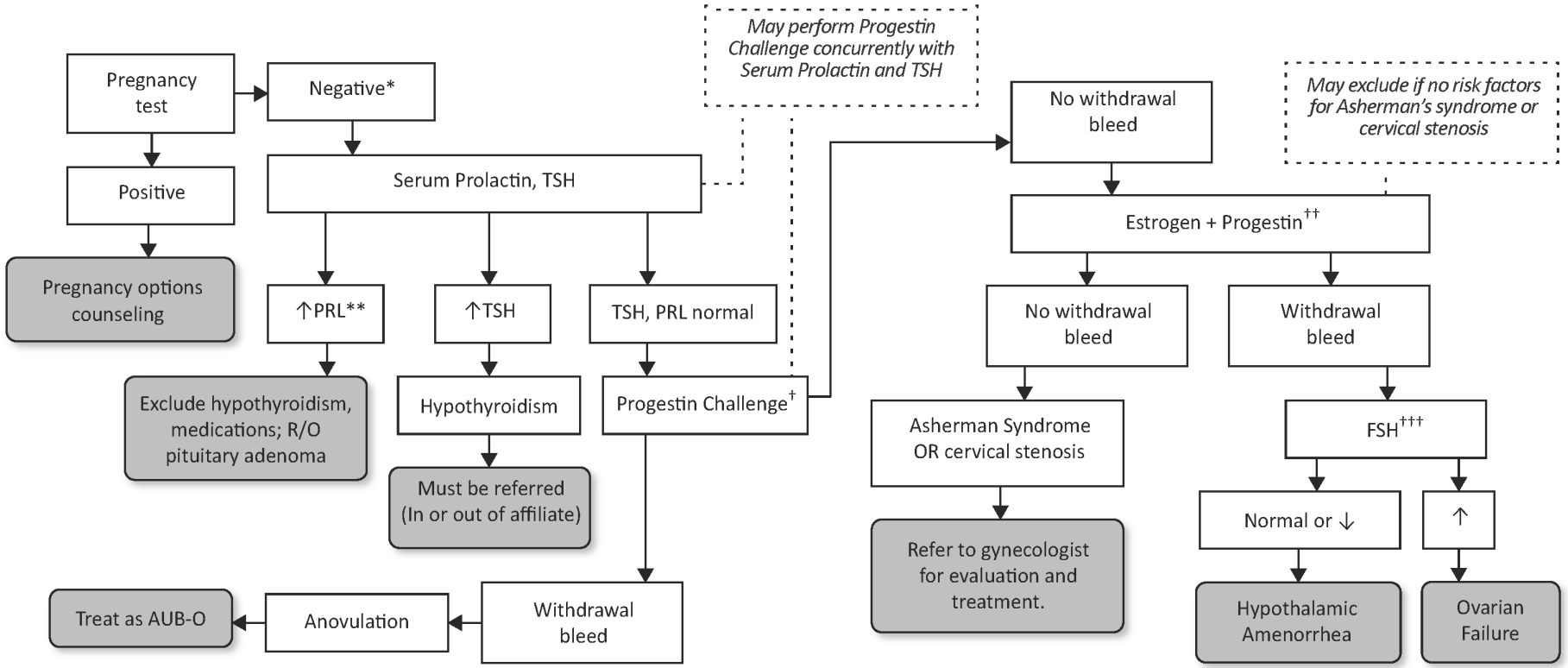
I. Evaluation and Management

✓ FYI – Etiology of Amenorrhea

8.1.f. Table: Evaluation of Amenorrhea

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Should include ▪ LMP ▪ Pregnancy symptoms ▪ Breastfeeding* ▪ Menstrual history, including presence of cyclic premenstrual symptoms ▪ Contraceptive history, including recent discontinuation** ▪ Surgical history† ▪ Presence of ○ Galactorrhea ○ Headache ○ Hirsutism ○ Hot flashes ○ Vaginal dryness ○ Visual changes ▪ Weight loss ✓ FYI – Causes of Amenorrhea by History	Should include ▪ Height and weight ▪ Skin examination for ○ Hirsutism ○ Acne ▪ Breast examination ○ To assess development ○ For presence of galactorrhea ▪ Pelvic examination with particular attention to ○ Clitoral size ○ Pubertal hair development ○ Hymen ○ Depth of vagina ○ Presence of cervix, uterus, and ovaries	**Must** include ▪ Pregnancy test ▪ TSH and PRL if pregnancy test negative ○ Progesterone challenge may be initiated at time of TSH and prolactin testing, or after results have been received. See Algorithm 8.1.g., below Additional tests may be indicated, such as ▪ Gonadotropins (LH and FSH) See Algorithm 8.1.g. Evaluation and Management of Amenorrhea
*Evaluation of secondary amenorrhea in lactating women is not necessary, except to exclude pregnancy. **Clients experiencing amenorrhea after the discontinuation of hormonal contraception should be managed in the same manner as non-hormonal users. Evaluation should not begin until 6 months after stopping hormonal contraception, except to exclude pregnancy. †If abortion or D&C preceded onset of amenorrhea, see Algorithm 8.1.h., below		

8.1.g. Algorithm: Evaluation and Management of Amenorrhea



*Consider retest in 2 weeks

**Increased PRL

- Mild (< 50 ng/ml)
  - Obtain AM fasting specimen (before exam) within six months.
  - If still elevated but < 50 ng/ml, without obvious explanation, **must** discuss with affiliate physician.
- High (≥ 50 ng/ml)
  - Refer out or order MRI of hypothalamus / pituitary; coned-down view of sella is an alternative.
    - Clients with abnormal imaging (e.g., pituitary adenoma) **must** be referred to appropriate specialist for management.
    - If imaging normal, **must** consult with affiliate physician or refer to specialist for management.

[†]Progestin challenge procedure

- Medroxyprogesterone acetate (Provera) 10 mg PO daily for five days.
  - Schedule follow-up in two weeks after completion.
  - Any bleeding within 14 days after completion of progestin is positive result.

[††]Estrogen+progestin procedure

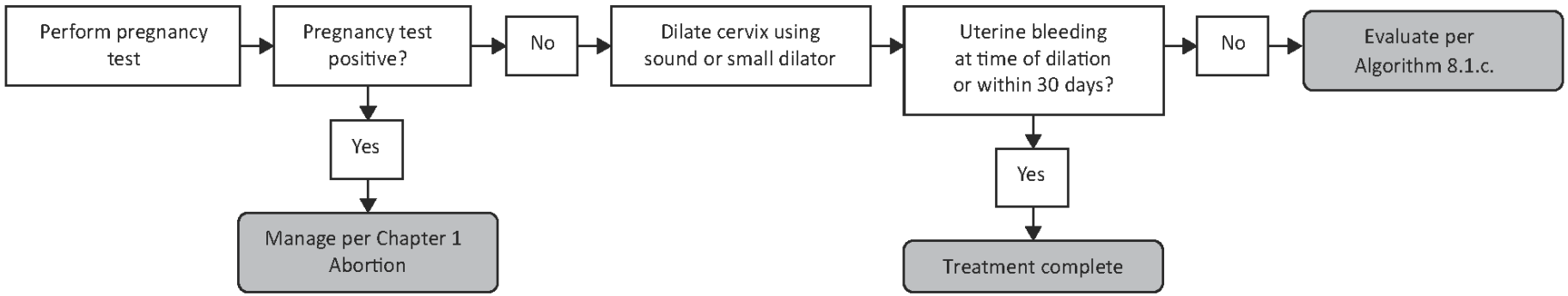
- Conjugated estrogens (Premarin) 2.5 mg PO daily for 21 days; add Provera 10 mg PO daily for last five days of estrogen.
- Schedule follow-up in two weeks after completion.
- Any bleeding within the 14 days after completion of the progestin is positive result

[†††]FSH

Draw FSH at least four weeks after last hormone exposure to rule out central or ovarian failure.

- If FSH >30 mIU/ml, diagnosis is ovarian failure (menopause.)
  - If ≥ 40 years old, manage per menopause protocol.
  - If < 30 years old, refer out for management.
  - If 30-40 years old, consult with medical director or refer out for management.
- If FSH normal or low and other tests are normal, diagnosis is hypothalamic amenorrhea — management depends on client's wishes for fertility.
  - If pregnancy desired, refer to reproductive endocrinologist.
  - Otherwise, treat with CHC or Estrogen + Progestin to prevent osteoporosis
  - Consider MRI of hypothalamus / pituitary or coned-down view of the sella or refer to outside specialist.

8.1.h. Algorithm: Evaluation and Management of Amenorrhea After Surgical Abortion or D&C



II. Referral – **must** refer clients with
   A. Primary amenorrhea
   B. Ovarian failure if < 30 years old
   C. Asherman syndrome or outlet obstruction not responding to dilation
   D. Abnormal MRI or coned-down view of sella
   E. Hypothyroidism (may be managed in or out of affiliate)

8.1.5 Leiomyoma

I. Evaluation

8.1.i. Table: Evaluation of Leiomyoma

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Should include ▪ Menstrual history ▪ Presence of pain, pelvic pressure, or dyspareunia ▪ Change in bowel or bladder habits (urinary frequency, difficulty voiding, constipation) ▪ Signs of anemia (headache, lightheadedness	**Must** include ▪ Abdominal exam ▪ Bimanual exam with evaluation of ○ Uterine size (compared to pregnancy in weeks) ○ Uterine breadth ○ Uterine consistency	Laboratory tests may include ▪ Pregnancy test ▪ Hgb, Hct, or CBC ▪ Endometrial biopsy, if indicated ✓ See Important Information – Indications for Endometrial Biopsy Diagnostic imaging may include ▪ Pelvic ultrasound

II. Management – See Table 8.1.d.
III. Referral – **must** refer clients with
   A. Uterine size ≥ 14 weeks
   B. Rapidly enlarging uterus
   C. Unknown origin of pelvic mass (i.e., uterine vs. ovarian)
   D. Severe menorrhagia or significant anemia

8.1.6 Polycystic Ovarian Syndrome (PCOS)

I. Evaluation

8.1.j. Table: Evaluation of Clients with Suspected PCOS

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Should include ▪ Menstrual history ▪ Symptoms of hyperandrogenism, including ○ Hirsutism ○ Acne ○ Male pattern balding ○ Virilization (deepening of voice, clitoromegaly, increased muscle mass) ▪ Infertility ▪ Galactorrhea ▪ Weight gain ▪ Systemic illnesss (especially diabetes or dyslipidemia) ▪ Family history of Type 2 diabetes, dyslipidemia, menstrual irregularity, insulin resistance, hyperandrogenism or metabolic syndrome ▪ Medications, in particular ○ Contraceptives ○ Valproic acid	Should include ▪ Vital signs ○ BP ○ BMI ○ Waist circumference ▪ Examination of skin ○ Signs of hyperandrogenism (hirsutism, acne, striae) ○ Signs of hyperinsulinemia (acanthosis nigricans) ○ Body hair distribution ▪ Thyroid palpation ▪ Breast exam to evaluate for galactorrhea ▪ Abdominal and pelvic examination with attention to presence of adnexal masses, clitoromegaly, body habitus — pear vs. apple	Initial laboratory testing should include ▪ Pregnancy test ▪ If clinical signs of hyperandrogenism, total testosterone and sex-hormone binding globulin or bioavailable and free testosterone ▪ PRL ▪ 17-hydroxyprogesterone Other tests to consider based on history or physical findings ▪ Evaluation for metabolic abnormalities ▪ 2 hour GTT ▪ Fasting lipid profile ▪ Amenorrhea workup, if indicated - see 8.1.4 Amenorrhea ▪ 24-hour urinary free-cortisol excretion test or low-dose dexamethasone suppression test Diagnostic imaging, when indicated, may include ▪ Ultrasound

II. Diagnosis and Management

A. Diagnosis — the goal of diagnosing PCOS is to exclude other causes of anovulation and hyperandrogenism.

✓ FYI - Differential Diagnosis of PCOS

✓ FYI - Clinical Characteristics and Sequelae of PCOS

B. Management— the goal in treatment of PCOS is to address both the symptoms that are bothersome to the client, as well as prevent sequelae.

8.1.k. Table: Treatment Options for PCOS

Goal of Therapy	Treatment
Treatment of anovulation/amenorrhea	▪ If not desiring pregnancy, treat as AUB-O - see Table 8.1.d. ▪ If seeking fertility, refer to reproductive endocrinologist.
Prevention of metabolic sequelae	▪ Encourage weight reduction, exercise and healthy diet. ▪ Consider screening for the development of dyslipidemia, impaired glucose tolerance, and hypertension.
Treatment of androgen excess	▪ CHCs are the preferred treatment in clients not currently seeking pregnancy and without contraindications, as they are the most effective means of androgen suppression.
Treatment of hirsutism	▪ Treat per 8.4.3 Hirsutism

III. Referral – **must** refer clients with

A. Signs/symptoms of virilization

B. Hyperandrogenemia suggestive of adrenal tumor

C. Dyslipidemia, impaired glucose tolerance, hypertension, if screened (may be in or out of affiliate)

D. Desire for fertility

8.2 BARTHOLIN GLAND ABNORMALITIES AND PELVIC MASSES

8.2.1 Bartholin Gland Abnormalities

I. Client Education and Informed Consent

A. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

8.2.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
CIIC Treatment of Bartholin's Duct Cyst or Abscess		●	●	
Information on any medication dispensed (package insert may be used)			●	
Release When Test/Service/Consultation Will Not Be Obtained		Once		
Request for Surgery or Special Procedure		●		●
Written information as appropriate			●	

II. Evaluation and Management

8.2.b. Evaluation of Bartholin Gland Conditions

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Should include ▪ Current medical conditions, especially those that might cause immune compromise (chronic corticosteroid use, diabetes, or HIV infection) ▪ Sexual risk assessment ▪ Drug allergies ▪ Past episodes of Bartholin conditions, including when and how treated ▪ Possibility of pregnancy ▪ Recent symptoms, including interference with physical activity or sexual intercourse, rate of growth, and systemic symptoms (chills or fever)	Should include ▪ Temperature, if Bartholin's duct infection suspected or diagnosed ▪ Evaluation for consistency, determination of cellulitis or abscess, location, size, and tenderness of affected area	Should include ▪ If cellulitis present, culture ▪ CT/GC testing as indicated

8.2.c. Table: Diagnosis and Management of Bartholin Gland Conditions

Condition	Presentation	Diagnosis and Management
Bartholin's Cyst	▪ Usually unilateral and asymptomatic ▪ Soft, painless mass in lower medial labia majora or lower vestibular area	No intervention necessary
Bartholin's Abscess	▪ Severe pain and swelling ▪ Fluctuant mass in lower medial labia majora or lower vestibular area ▪ May be accompanied by cellulitis and edema	▪ Abscesses that point and rupture spontaneously may be treated with analgesics and warm compresses or with Sitz baths ▪ Unruptured abscess should be drained and marsupialize or place word catheter (Level II GYN or Level III only) ▪ Antibiotic treatment is indicated for clients with ○ Recurrent infection ○ Extensive surrounding cellulitis ○ Immunosuppression ○ Risk for MRSA ○ Known or suspected gonorrhea or chlamydia infection ▪ Suggested antibiotic regimens ○ Amoxicillin-clavulanate 875 mg orally 2 times a day for 1 week plus clindamycin 300 mg orally 4 times per day for 1 week ○ Treat STIs according to CDC guidelines ✓ CDC STD Treatment Guidelines ▪ Infective endocarditis (IE) prophylaxis - follow the American Heart Association (AHA) guidelines. ✓ AHA Guidelines: Prevention of Infective Endocarditis

III. Referral - **must** refer clients with
   A. Cysts with solid component
   B. Cysts of such size or location that marsupialization cannot be performed safely under local anesthesia at the affiliate unless affiliate provides Level III GYN.
   C. Evidence of sepsis, including fever of 39°C (102.2°F) or greater

D. Severe immune compromise that could affect response to treatment
E. Any suspicion of necrotizing fasciitis

8.2.2 Pelvic Masses

I. Client Education and Informed Consent
A. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

8.2.d. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
Information on any medication dispensed (package insert may be used)			●	
Release When Test/Service/Consultation Will Not Be Obtained		Once		
Written information as appropriate			●	

II. Evaluation and Management

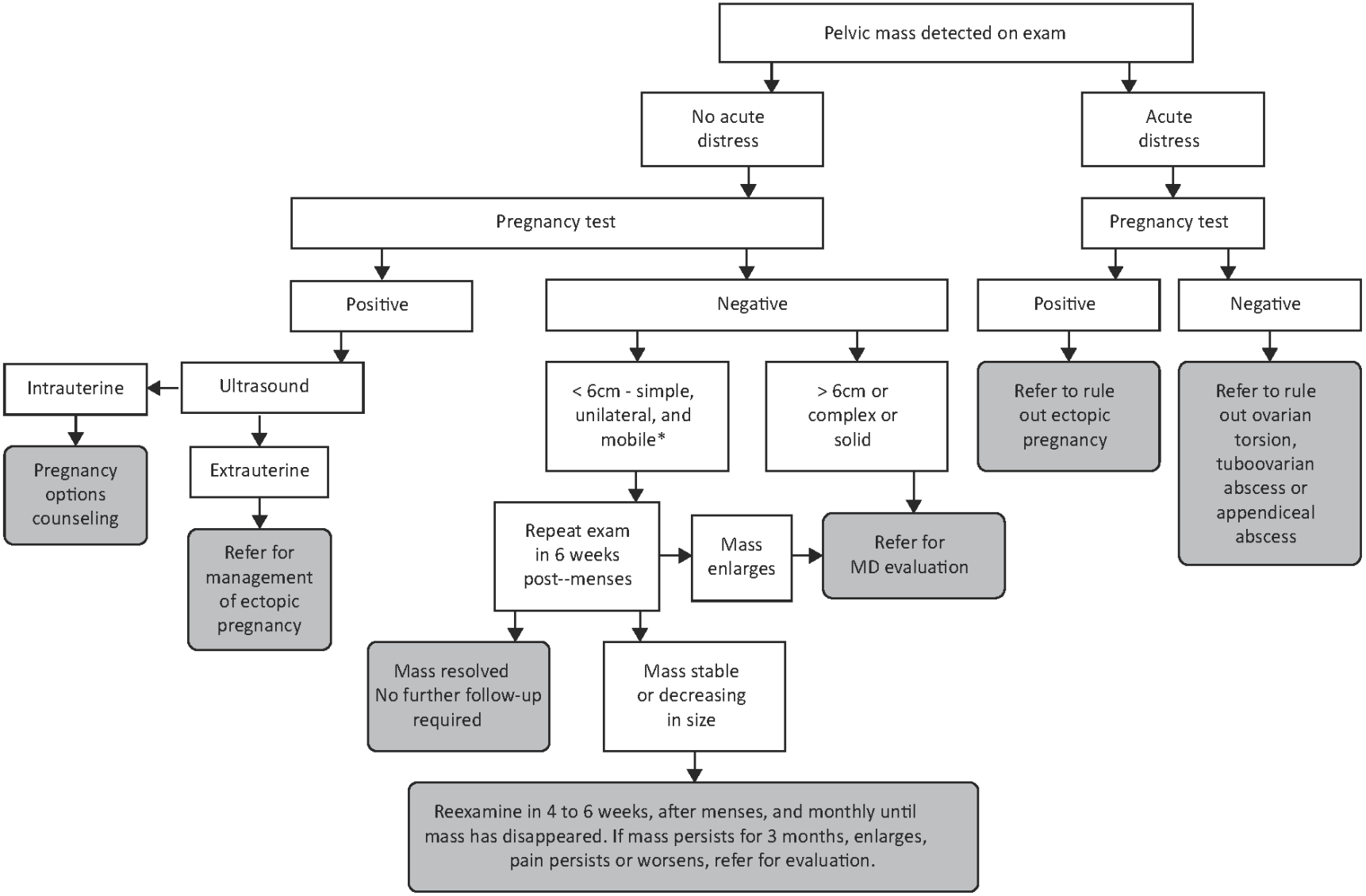
8.2.e. Table: Evaluation of Clients with a Pelvic Mass

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Should include ▪ LMP ▪ Pregnancy symptoms ▪ Nature, progression and duration of presenting symptoms, if any ▪ Presence of ○ Pain, pelvic or abdominal ○ Change in bowel or bladder habits ○ Changes in abdominal size ○ Bloating ○ Difficulty eating or feeling full	**Must** include ▪ Abdominal palpation with close attention to presence/absence of tenderness and/or ascites ▪ Pelvic examination including size, location, bilaterality, consistency, mobility, tenderness of the mass(es). ▪ Rectal examination as indicated	May include ▪ Pregnancy test ▪ Hgb, Hct or CBC ▪ Other tests as indicated Diagnostic imaging, when indicated, may include ▪ Ultrasound

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
○ Weight change ○ New onset hirsutism ▪ Menstrual history ▪ Medications, including contraceptive use ▪ History of previous adnexal mass ▪ Personal or family history of neoplasia (breast, gastric, pancreas, endometrium, ovarian, colon) ▪ Family or personal history of endometriosis		

✓ FYI – Differential Diagnosis of Pelvic Masses

8.2.f. Algorithm: Evaluation and Management of Adnexal Masses in Reproductive-Aged Women



*Symptomatic functional cysts or fibroids may be treated conservatively with oral pain medication.

III. Referral – Clients with the following conditions **must** be referred to a specialist:

A. Malignancy is known or suspected:

1. Postmenopausal pelvic mass or pelvic mass in women > 50
2. Enlarging or persistent mass
3. Mass is bilateral, fixed, solid, or complex (by ultrasound)
4. Mass is symptomatic (see exception above)
5. Other symptoms suggestive of malignancy (ascites, nodules in abdomen or cul-de-sac)
6. Mass > 6 cm

B. Premenarchal mass

8.3 DYSMENORRHEA, ENDOMETRIOSIS, AND PELVIC PAIN

8.3.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

8.3.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
Information on any medication dispensed (package insert may be used)			●	
Release When Test/Service/Consultation Will Not Be Obtained		Once		
Written information as appropriate			●	

8.3.2 Dysmenorrhea

I. Evaluation and Management

8.3.b. Table: Evaluation of Dysmenorrhea

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Should include ▪ Menstrual history ▪ Characteristics of dysmenorrhea (e.g., severity, location, onset, duration, progression of symptoms) ▪ Presence of associated symptoms: nausea, vomiting, diarrhea, back pain, dizziness, or headache during menstruation ▪ Impact of dysmenorrhea on daily activities, such as attendance at school or work ▪ Presence of pelvic pain unrelated to menses (e.g. dyspareunia)	Should include ▪ Abdominal examination ▪ Pelvic examination* ▪ Rectal examination as indicated	May include ▪ CT/GC ▪ Wet mount ▪ Other tests as indicated Diagnostic imaging, when indicated, may include ▪ Ultrasound

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
▪ Sexual history including history of infection ▪ Medications ▪ Contraceptive history ▪ Previous pelvic surgery or cervical treatment such as LEEP or cone		
* Bimanual evaluation may be deferred in initial evaluation of young, non-sexually active adolescents with mild-moderate cyclical cramps.		

8.3.c. Table: Management of Dysmenorrhea

Primary Dysmenorrhea	
Conservative therapy	▪ Heat ▪ Stress reduction ▪ Regular aerobic exercise
Prostaglandin inhibitors*	▪ Initiate just prior to onset of menses and continue until no longer needed ▪ Commonly used regimens include o Ibuprofen 400-800 mg every 6 hours o Naproxen 250-500 mg every 6-8 hours o Naproxen sodium 275-550 mg every 6-8 hours o Mefenamic acid 250 mg every 6 hours
Endometrial thinning*	Commonly used regimens include ▪ CHC (cyclic or continuous) ▪ DMPA ▪ LNG-IUS
Analgesics	May be prescribed when desired effect not achieved by NSAIDs and/or hormonal contraception.
Herbals and nutritional therapies	There have been several clinical trials, but to date, only vitamin B_1 (100 mg daily) has been shown to be more effective than placebo.
Acupuncture, acupressure and transcutaneous nerve stimulation	Clinical trials have shown these modalities are superior to placebo in the treatment of primary dysmenorrhea. Consider referral.

Secondary Dysmenorrhea
Can be caused by gynecologic as well as non-gynecologic conditions. Major causes are shown in the FYI – Major Causes of Secondary Dysmenorrhea. Therapy should be aimed at the underlying cause and may require referral to appropriate specialist. ✓ FYI – Major Causes of Secondary Dysmenorrhea
*NSAIDs and hormonal therapies to induce endometrial thinning can take a minimum of 3 to 4 months before results are seen. Therapies such as DMPA and the LNG-IUS may take longer to become effective.

II. Referral - Clients with the following conditions **must** be referred to a specialist:
   A. Structural abnormalities or a history suggestive of a physical source for their pain
   B. Symptoms not responsive to above therapies

8.3.3 Endometriosis

I. Evaluation

8.3.d. Table: Evaluation for Endometriosis

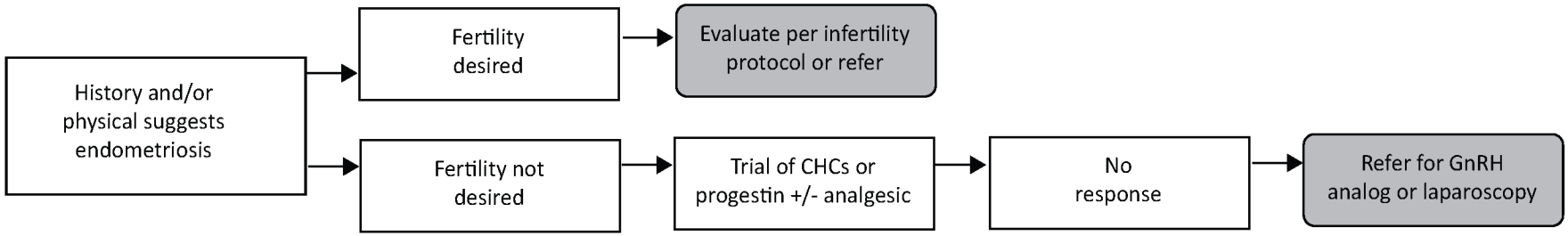
History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Should include ▪ Dysmenorrhea ▪ Dyspareunia ▪ Pelvic pain ▪ Ovulation pain ▪ Dyclical or perimenstrual symptoms, such as bowel or bladder pain, with or without abnormal bleeding ▪ Infertility ▪ Dyschezia ▪ Dysuria	Pelvic exam **must** include ▪ Speculum exam ▪ Bimanual exam ▪ Rectovaginal exam, if indicated	Diagnostic Imaging may include ▪ Transvaginal ultrasound (if adnexal mass suspected)

✓ FYI – Physical Exam Finding Suggestive of Endometriosis

II. Diagnosis and Management

A. Diagnosis - Definitive diagnosis of endometriosis requires direct visualization of disease (via laparoscopy or laparotomy) combined with histologic confirmation. However, pain symptoms suggestive of the disease can be treated empirically without a definitive diagnosis.

8.3.e. Algorithm: Management of Endometriosis



8.3.f. Table: Treatment of Endometriosis

Therapy	Regimen
First line	▪ Continuous CHC - See Chapter 6.2 Combined Hormonal Contraceptives ▪ DMPA (SC or IM) – See Chapter 6.4 DMPA ▪ Progestin therapy ○ Medroxyprogesterone acetate (Provera) 30-100 mg PO QD ○ Norethindrone acetate 5-20 mg daily
Second line	LNG IUS
NSAIDs	Although the use of NSAIDs for pain relief seems logical, their effectiveness has not been studied well or compared with other treatments. For empiric medical therapy, CHCs and medroxyprogesterone acetate have apparent therapeutic equivalence and should be used as first-line therapies.

III. Referral - **Must** refer clients with

A. Infertility, seeking pregnancy

B. Suspected endometrioma

C. Symptoms not responsive to trial of therapy
D. Worsening symptoms

8.3.4 Pelvic Pain

I. Evaluation

✓ FYI – Classification and Evaluation of Pelvic Pain

8.3.g. Table: Evaluation of Pelvic Pain

✓ FYI – Historical Factors That Increase the Risk of Chronic Pelvic Pain (CPP)

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Should include ▪ Characteristics of pain — When did pain begin? How has it changed? ✓ FYI — PQRST approach to evaluation of pain ✓ FYI — Character of Pain and Potential Cause ▪ Menstrual history and relationship of pain to the menstrual cycle ▪ Contraceptive history ▪ History of pelvic surgery ▪ Associated symptoms (nausea, vomiting, diarrhea, constipation, blood in stool/urine, change in vaginal discharge, vaginal bleeding) ▪ Review of bowel and bladder symptoms ✓ FYI – Rome Criteria for Diagnosis of Irritable Bowel Syndrome (IBS) ✓ FYI – Interstitial Cystitis (IC) ▪ Weight loss or gain ▪ Psychosocial history: unusual stressors at time of onset; significant life changes ▪ What has been effective treatment, what has not? ▪ What does the client believe is causing the pain? ▪ How does the client's family respond to the pain? ▪ How has the pain altered the client's lifestyle?	Should include ▪ Vital signs ▪ Abdominal and pelvic exam ▪ When examining pelvic floor, check for tender points on each side using a single digit both externally and intravaginally. ▪ Examine bladder and urethra. (With a single digit, palpate the urethra, the trigone and the area of each ureteral insertion.) ▪ Rectal examination with palpation of cul-de-sac and uterosacral ligaments. ▪ For clients with CPP, a musculoskeletal exam should be considered.	Laboratory testing may include: ▪ Pregnancy test ▪ Wet mount, CT/GC ▪ Urinalysis and/or culture ▪ CBC with differential ▪ C-reactive protein ▪ Stool testing for occult blood Diagnostic imaging may include ▪ Pelvic ultrasound

II. Management - Management is based on the suspected source of pelvic pain. A list of possible conditions causing pelvic pain and their required management is included in Table 8.3.h.

8.3.h. Conditions Associated with Pelvic Pain and Required Management

Condition	Required Management
Adenomyosis, suspected	✓ Manage per 8.1.3 Adenomyosis protocol
Endometriosis, suspected	✓ Manage per 8.3.3 Endometriosis protocol
Gastrointestinal	Refer
Interstitial Cystitis	Refer
Leiomyoma	✓ Manage per 8.1.5 Leiomyoma protocol
Musculoskeletal	Refer
Pelvic mass	✓ Manage per 8.2.2 Pelvic Mass protocol
PID	✓ Manage per Chapter 9.2. Evaluation and Management of the Client with Positive Screening Test Results or Symptoms
PID, requiring inpatient therapy	Refer for hospitalization
UTI	✓ Manage per Chapter 9.2. Evaluation and Management of the Client with Positive Screening Test Results or Symptoms
Vulvodynia	✓ Manage per Table 8.7.d. Diagnosis and Management of Vulvar Skin Conditions/VAIN
Vulvovaginitis	✓ Manage per Chapter 9.2. Evaluation and Management of the Client with Positive Screening Test Results or Symptoms

III. Referral – clients with any of the following **must** be referred
- A. Any acute, life-threatening condition
- B. Adnexal torsion
- C. Appendicitis
- D. Ectopic pregnancy
- E. Hemodynamic instability
- F. All suspected non-gynecologic causes
- G. If surgical intervention is needed

H. If no source of pain can be identified
I. If symptoms worsen, recur after treatment, or persist

8.4 GALACTORRHEA AND HIRSUTISM

8.4.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

8.4.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
Information on any medication dispensed (package insert may be used)			●	
Release When Test/Service/Consultation Will Not Be Obtained		Once		
Written information as appropriate			●	

8.4.2 Galactorrhea

I. Evaluation and Management

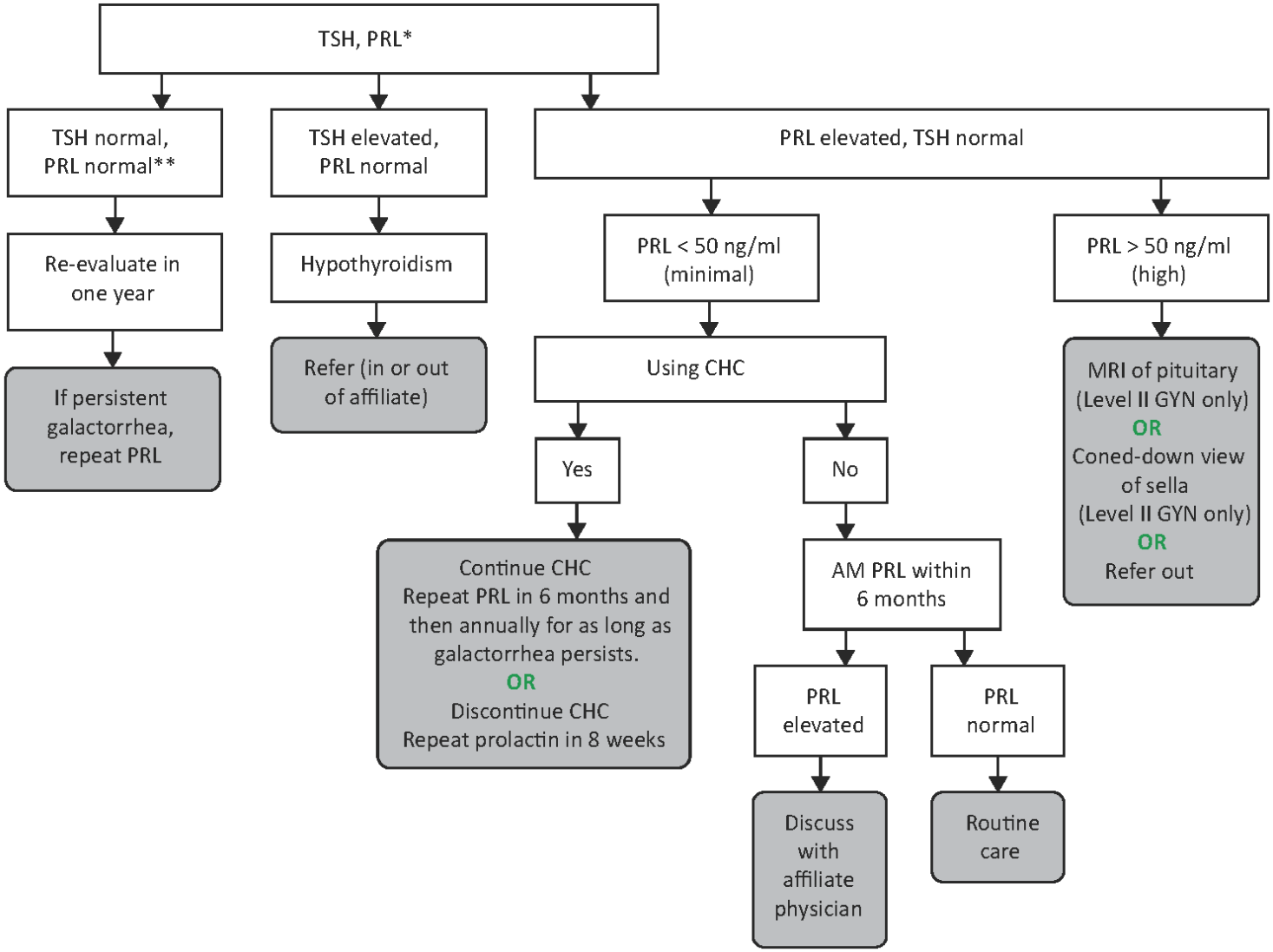
✓ FYI - Galactorrhea

8.4.b. Table: Evaluation of Galactorrhea

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Should include ▪ Duration of galactorrhea ▪ Uni/bilaterality ▪ Whether it occurs only with nipple stimulation or spontaneously ▪ Color of the discharge (bloody, white, clear), and whether the color has changed over time	**Must** include ▪ Thyroid palpation ▪ Breast examination* – See Chapter 3 Breast Services ▪ Ask client to massage breasts to express milk. ○ If no galactorrhea, attempt to express	Laboratory tests **must** include ▪ Pregnancy test, as indicated ▪ PRL (fasting and before exam) ▪ TSH ▪ If present, refer to 8.1.4 Amenorrhea and 8.4.3 Hirsutism protocols for other tests as indicated

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
▪ Menstrual history, including amenorrhea ▪ Medications/herbs ✓ FYI – Medications and Herbs Associated with Galactorrhea ▪ Other symptoms of hyperprolactinemia (infertility, acne, hirsutism) ▪ Symptoms of hypothyroidism ▪ Symptoms of intracranial mass (vision changes, headache) ▪ History of renal disease	— start at base of breast and massage toward nipple. ○ If material expressed, note amount, color, bilaterality and whether it comes from one duct or many ducts.	Diagnostic imaging may include (Level II or Level III GYN only) ▪ MRI ▪ Coned-down view of sella
*Women found to have nipple discharge inconsistent with galactorrhea **must** be managed according to Chapter 3 Breast Services		

8.4.c. Algorithm: Evaluation and Management of Galactorrhea



*Counsel client to avoid excessive breast stimulation, including repeated self-examinations and/or excessive nipple manipulation during sexual activity.

** Reassure. If bothersome to the client, consult with prescribing clinician about possible change in prescription.

II. Referral – **must** refer clients with
   A. Galactorrhea combined with any of the following
      1. Headaches or a visual field defect
      2. Infertility
      3. Hypothyroidism or abnormal TSH
      4. Abnormal imaging studies
   B. Any single duct or bloody nipple discharge - **see Chapter 3 Breast Services**
   C. Palpable breast mass - **see Chapter 3 Breast Services**
   D. Galactorrhea bothersome enough for the client to request treatment to stop it
   E. Known or suspected malignancy

8.4.3 Hirsutism

I. Evaluation

✓ FYI - Hirsutism

8.4.d. Table: Evaluation of Hirsutism

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Should include ▪ Characteristics of hirsutism* ○ Age of onset ○ Rate of progression ○ Changes with weight fluctuations or prior treatment ▪ Symptoms or signs of virilization (e.g., frontal balding, acne, clitoromegaly, increased muscle mass, deepening of the voice) ▪ Detailed menstrual history ▪ Associated skin changes (i.e., acne, striae), location of hair	May include ▪ Height and weight ▪ BP ▪ Examination of breasts for galactorrhea ▪ Examination of the skin for ○ Hirsutism — increased coarse hair on lip, chin, chest abdomen, and back ○ Acne ○ Temporal balding ○ Acanthosis nigricans ○ Abdominal striae ○ Easy bruising	**Must** include ▪ Serum total testosterone ▪ Other tests as indicated ○ TSH/PRL if galactorrhea present (see 8.4.2 Galactorrhea) ○ 17-hydroxyprogesterone if PCOS suspected (see 8.1.6 PCOS)

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
▪ History of infertility ▪ Weight gain ▪ Medications, supplements ✓ FYI – Medications and Hirsutism ▪ Contraceptive history ▪ Family history of hirsutism or hyperandrogenism, diabetes, infertility ▪ Use of hair removal methods	○ Moon facies ○ "Buffalo hump" ▪ Abdominal and pelvic examinations ○ Masses ○ Clitoromegaly	
*Onset during teenage years or in early 20s with slow progression suggests PCOS while late onset, abrupt onset, or rapid progression of symptoms suggests adrenal or ovarian tumor.		

II. Management
  A. May prescribe the following
    1. CHCs (Will diminish future hair growth but won't treat hair that is already present.) See Chapter 6 Contraception – Reversible.
    2. Spironolactone 50 mg daily
    3. Eflornithine hydrochloride [Vaniqua] — apply to affected area on face and chin only, leave on for 4 hours, repeat twice a day at least 8 hours apart.
  B. Advise clients that hirsutism will likely not improve for 6 months or more.
  C. Refer for mechanical and cosmetic measures (e.g., shaving, waxing, depilatories, bleaching, electrolysis (don't start until after 6 months of CHC) or laser treatment).
  D. In obese women, weight loss can reduce androgen production and slow hair growth.
  E. If inadequate response, refer for anti-androgen therapy.

III. Follow-up
  A. In 3 to 6 months, if treatment initiated
  B. If hirsutism progresses despite above treatments

IV. Referral - must refer client if
  A. Serum total testosterone ≥200 ng/dl or rapid virilization
  B. Rapidly progressive hirsutism and/or significant virilization
  C. Suspicious abdominal or pelvic mass on ultrasound

D. Elevated serum 17-hydroxprogesterone
E. Severe endocrine abnormality known or suspected (e.g., acromegaly, congenital adrenal hyperplasia, Cushing Syndrome, insulin-resistant acanthosis nigricans syndromes)

8.5 MENOPAUSE

8.5.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

8.5.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	Should give	**Must** offer
CI Getting Enough Calcium and Vitamin D				●	
CI Hot Flashes				●	
CI Menopause and Perimenopause				●	
CI Preventing CVD				●	
CI Problems Sleeping				●	
CIIC Endometrial Biopsy		●	●		
CIIC Menopausal Hormone Therapy (MHT), when MHT is prescribed*			●		
Release When Test/Service/Consultation Will Not Be Obtained As Recommended		Once			
Request for Surgery or Special Procedure		●			●
Written information about any medication dispensed (package insert may be used)			At first Rx		annually
* Not required when intravaginal estrogen only is prescribed.					

8.5.2 Vasomotor Symptoms

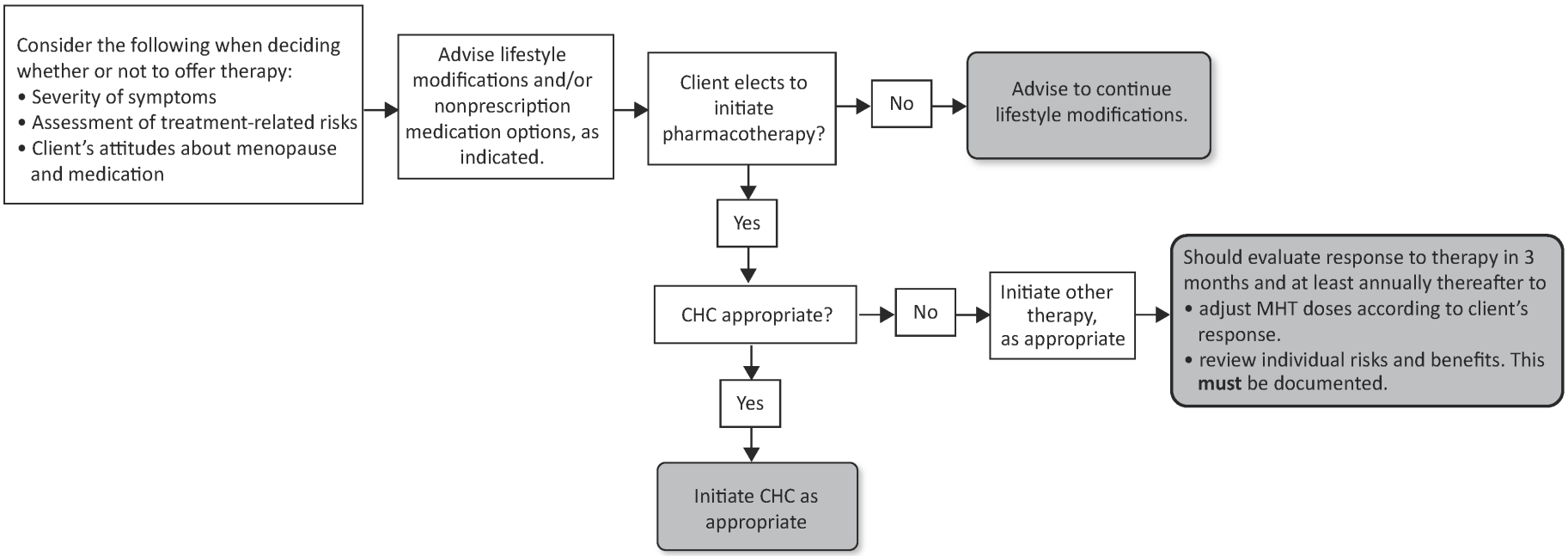
I. Evaluation and Management

✓ FYI - Menopause

8.5.b. Table: Evaluation of Vasomotor Symptoms

History	Physical Examination
Should include the following regarding hot flashes: ▪ Frequency ▪ Severity ▪ Effects on activities of daily living (See Chapter 21 Well-Woman Care)	As indicated

8.5.c. Algorithm: Management of Vasomotor Symptoms



8.5.d. Table: Nonprescription Options for Treatment of Vasomotor Symptoms

The following therapies have limited available data regarding efficacy and safety.

Therapy	Efficacy	Side Effects/Safety Data
Isoflavones (Found in soy and red clover)	▪ May have small benefit in short term (12 weeks) ▪ No evidence for long term (6 to 12 month) effects ▪ Products with high equol production capacity (the isoflavone daidzein is converted by gut flora into equol) are more effective than usual mixture of soy isoflavones	▪ No harmful effect on breast or endometrium ▪ Safe with history of breast cancer
Black Cohosh	▪ Results are mixed ▪ Most early trials with Remifemin which now has changed	▪ Side effects: GI discomfort, nausea, vomiting, dizziness, headache, bradycardia

Therapy	Efficacy	Side Effects/Safety Data
	formulation and strength and therefore may not be effective	▪ May be associated in rare cases with liver failure — avoid in clients with liver disease
Dong Quai	▪ Efficacy when used as monotherapy has not been proven in RCTs	▪ Side effects: photosensitivity, anticoagulation ▪ Can trigger heavy uterine bleeding ▪ Contraindicated in women with fibroids, coagulations disorders or those using anticoagulants
Evening Primrose Oil	▪ No proven benefit	▪ Side effects include inflammation, thrombosis, immunosuppression, nausea, diarrhea ▪ May increase seizures in clients taking antipsychotics for schizophrenia ▪ Should not be used with phenothiazines
Ginseng	▪ No proven benefit	▪ May increase risk of bleeding ▪ Avoid in clients on antihypertensives and stimulants

8.5.e. Table: Menopausal Hormone Therapy (MHT) – includes Estrogen Therapy (ET)/Estrogen-Progestogen Therapy (EPT)

Legend	
A	Contraindications — **must** not use
B	Special Conditions Requiring Further Evaluation — Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral **must** be based on protocols approved by the medical director or program director or in consultation with the medical director or affiliate physician.

Condition/Signs/Symptoms	A	B
Active liver disease	●	
Antiepileptic medication – current use		●
Breast biopsy with atypia		●
Cancer		
▪ Breast or other estrogen-related cancer	●	
▪ Documented Stage I, Grade I endometrial cancer treated with hysterectomy		●

Condition/Signs/Symptoms	A	B
▪ Meningioma, current treatment – **must** consult with oncologist or neurosurgeon		●
▪ Non-gynecologic cancer – **must** consult with affiliate medical director		●
Cardiovascular disease, known or suspected	●	
Deep vein thrombosis (DVT)	●	
Endometriosis		●
Gallbladder disease without cholecystectomy		●
Headaches, migraine		●
Hepatitis		
▪ Chronic – with elevated liver function tests	●	
▪ Chronic – with normal liver function tests - Use clinical judgment in monitoring liver function. One option is to check LFTs at 3 months after starting non-oral MHT and then at clinician discretion. (See Prescribe MHT according to the following principles, below)		●
Osteoporosis, premenopausal – known or suspected		●
Pregnancy	●	
Thromboembolic event	●	
Vaginal bleeding, undiagnosed	●	

II. Prescribe MHT according to the following principles

A. Tailor therapy to individual client's needs.

B. Only FDA-approved preparations may be provided.

✓ Approved Prescription Products for Menopausal Symptoms

C. Compounded therapies must not be used.

D. Start with the lowest recommended estrogen/progestin dose needed.

E. Transdermal is the preferred route of estrogen delivery.

F. Therapy should be limited to the shortest duration possible to attain treatment goals.

G. Clients without a uterus should generally not be prescribed a progestin with systemic ET, although exceptions (e.g. history of extensive endometriosis) may exist.
H. Clients with an intact uterus
    1. Should be prescribed combination therapy (MHT). This may be a continuous estrogen/progestin regimen or estrogen with sequential progestin.
    2. If client refuses or cannot tolerate oral or injectable progestins, she may either be
        a. Monitored with endometrial biopsies annually (a normal biopsy before initiating ET and normal biopsy results annually are required.)
        b. Offered a levonorgestrel-releasing IUC

8.5.f. Table: Initiation of Pharmacotherapy for Vasomotor Symptoms

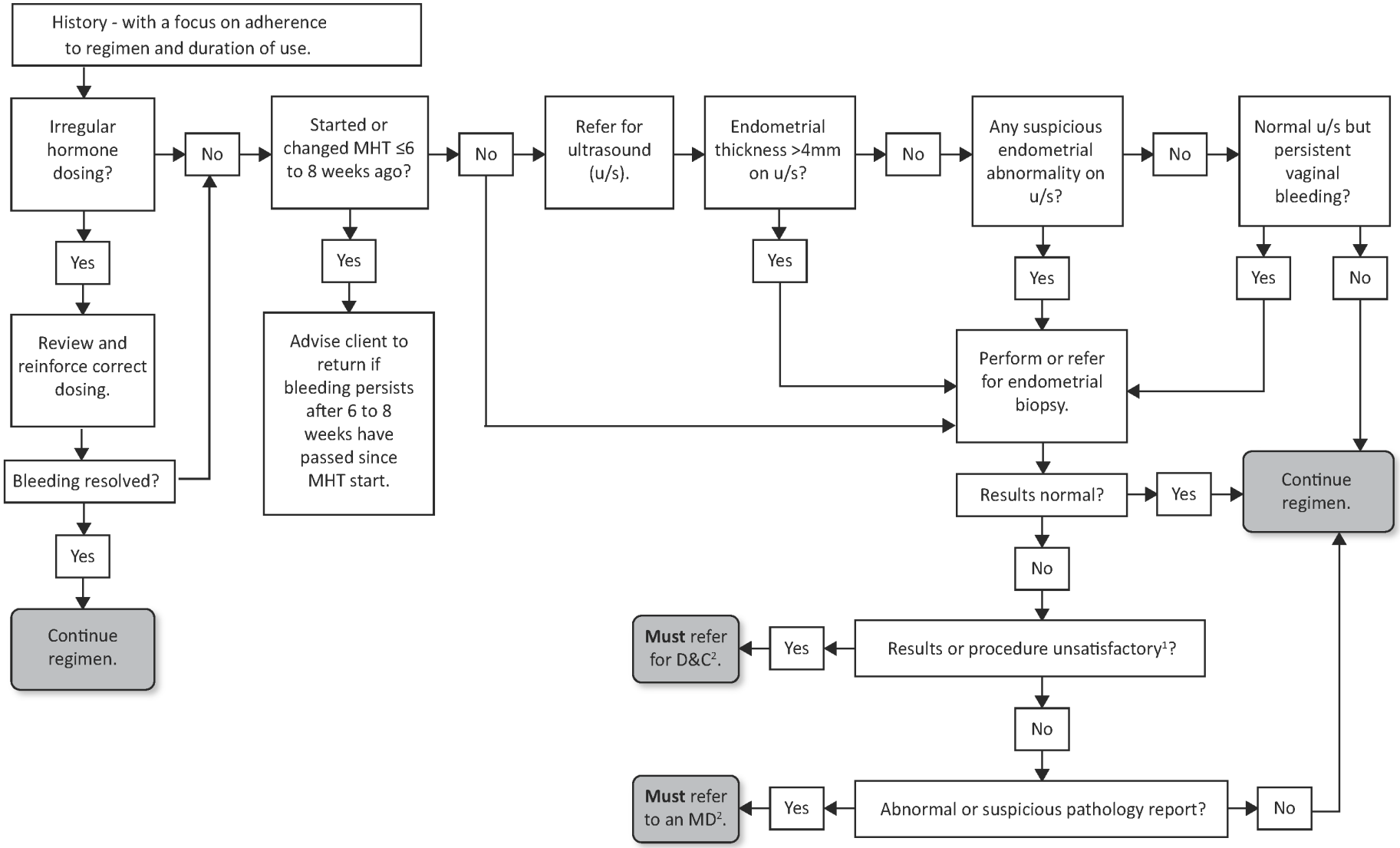
- ✓ FYI – Progestin Therapy
- ✓ FYI – Transitioning from DMPA to MHT

Requirements for Initiation	
Mammography/CBE	For women 40 and older, both an annual clinical breast exam (CBE) and a screening mammogram **must** be recommended. However, clients who obtain either an annual CBE or an annual screening mammogram may be prescribed MHT: ▪ The client's self-report (of previous normal CBE or mammogram) is adequate proof and **must** be documented in the chart. ▪ A limit of 3 months of MHT may be prescribed in advance of this requirement being met.
Lipid Assessment	▪ Fasting or non-fasting total cholesterol and HDL **must** be recommended unless documented results within the past 5 years are available. ▪ Fasting Lipid Profile **must** be obtained if total cholesterol > 240 mg/dl or total cholesterol 200–239 mg/dl with HDL < 35 mg/dl.

8.5.g. Table: Non-hormonal Therapies for Vasomotor Symptoms

Drug Class	Dosage	Considerations
SSRIs and/or NRI	▪ Paroxetine 12.5-25 mg/d ▪ Venlaxafine 37.5-75 mg/d	▪ Paroxetine or venlaxafine may benefit women who also have mood symptoms; while hot flash relief will be rapid, depression relief may take 6 to 8 weeks. ▪ Start with the lowest possible dose and increase if client exhibits no response after 1 to 2 weeks. ▪ Side effect profile o Nausea is dose-related and generally subsides within 2 weeks of initiation. o Advise clients with drowsiness to use the medication at night. ▪ Taper over 1 to 2 weeks when discontinuing depending upon dosage used. ▪ Avoid in women using tamoxifen, as they may decrease serum levels.
Eszopiclone	▪ Start at 1 mg PO qhs ▪ Maximum dose of 3 mg PO qhs	▪ Effective for treatment of nighttime (but not daytime) hot flashes. ▪ Additional benefits include reducing depression and anxiety and improving overall wellbeing. ▪ Beyond 3 months, the client **must** be referred to a primary care or other provider.
Gabapentin	▪ 300 mg/d, gradually increased to BID, then TID at 3 to 4 day intervals. ▪ Start at 100 mg/d in women >65 years old.	▪ Take at night to reduce initial side effects of dizziness and sedation; often subsides by 2 to 4 weeks post initiation of treatment. ▪ Take at least 2 hours after antacid use. ▪ May cause weight gain. ▪ Taper when discontinuing.

8.5.h. Algorithm: Management of Unscheduled Bleeding on MHT



[1]Examples include stenotic os or insufficient sample. [2]Referral may be internal or external to affiliate.

8.5.3 Sleep Disturbances

I. Screening and Evaluation - Assess sleep quality in all women during perimenopause and beyond. Evaluation should also include screening for
   A. IPV
   B. Substance abuse
   C. Other psychosocial risk factors

✓ FYI - Sleep Disorders May Not be Related to Vasomotor Symptoms

II. General principles of Managing Sleep Disorders
   A. Decisions on whether to use behavioral therapies, medication, or both should be made based upon the type of sleep disturbance (acute or chronic, primary or secondary to other conditions), the context of the problem (high vasomotor symptoms or life strain) and the severity of daytime consequences.
   B. Before initiating prescription therapy, consider
      1. Management of untreated perimenopausal symptoms (especially night sweats) or optimizing current management with MHT
      2. Sleep hygiene education
      3. OTC sleep aid products

8.5.i. Table: Management of Sleep Disorders

Therapy	Management
Nonprescription therapies	▪ Valerian ○ Recommended dosages • Extract – 50 to 100 mg 2 to 3x/d • Root – 2,000 to 4,000 mg daily ○ May take 5 to 7 days to be effective ○ Few side effects with short term use ○ Long-term use may be associated with headache, restlessness, sleeplessness and cardiac disorders. ▪ OTC sleep aids ✓ FYI – Melatonin

Therapy	Management
Prescription medications	▪ Short acting nonbenzodiazepine hypnotic sleeping aids o Acceptable agents include zaleplon [Sonata], zolpidem tartrate [Ambien], eszopiclone [Lunesta]. o Indicated for transient insomnia or other disturbed sleep patterns. o Short-term therapy is limited to 1 to 3 months. o Beyond 3 months, the client **must** be referred to a primary care or other provider. ▪ Ramelteon [Rozerem] — melatonin receptor agonist; indicated for clients who have difficulty falling asleep ▪ Tricyclic Antidepressants —trazadone 25 to 50 mg qhs — safe, cheap, well tolerated, non-addictive, effective
Refer as needed — consider sleep studies to rule out sleep apnea, periodic limb movements, restless leg syndrome	

8.5.4 Urogenital Atrophy

I. Evaluation and Management

8.5.j. Table: Evaluation for Urogenital Atrophy – Perform when suspected based on client symptoms

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Should elicit symptoms consistent with vaginitis, UTI and/or sexual dysfunction	Should include ▪ External perineal exam ▪ Speculum exam	May include ▪ Microscopic saline/KOH wet prep ▪ Vaginal pH ▪ Urinalysis

8.5.k. Management of Urogenital Atrophy

Therapy	Management
Non-hormonal therapies	Advise clients to consider the following ▪ Regular sexual activity ▪ Use of water-based lubricants as needed for sexual intercourse ▪ Regular use of vaginal moisturizers

Therapy	Management
Hormonal therapies	▪ In women without vasomotor symptoms or other indications for systemic MHT, offer prescription vaginal estrogen cream, tablet or ring. ▪ Acceptable regimens include o Estring 7.5 mcg estradiol/d o Vagifem 25 mcg tablet intravaginally QHS x 2 weeks, then 2x/week o Premarin vaginal cream 0.5 g intravaginally 2 to 3x/week ▪ May prescribe topical estrogen without restriction in clients with a history of breast cancer or cardiovascular disease. ▪ For management of pelvic floor disorders, including use of vaginal estrogen with pessaries, protocols are available through PPFA. ▪ May receive therapy with intravaginal estrogen preparations in doses to treat urogenital atrophy without routine endometrial monitoring.

8.5.5 Osteoporosis Prevention and Management

I. Evaluation

8.5.I. Table: Evaluation

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Must include ▪ Risk factors for osteoporosis and fracture such as low body weight, prior low-trauma fracture, or high risk medication ▪ Potential secondary causes of osteoporosis and fragility fracture	**Must** include ▪ Height, weight, BMI ▪ Evaluation of signs of osteoporosis and potential secondary causes	**Must** include ▪ Baseline bone mineral density (BMD) testing in the following women using Dual Energy X-ray Absorptiometry (DEXA): o Age ≥65 o Younger postmenopausal women and women in perimenopause age 50 to 69 with clinical risk factors for fracture o With a history of fracture after age 50 o With a condition or taking a medication associated with low bone mass or bone loss NOTE: Additional testing modalities such as CT absorptiometry, peripheral

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
		DEXA, and quantitative ultrasound densitometry may be used, but individual abnormalities should be confirmed by DEXA prior to initiating therapy. Vertebral imaging should be performed in the following clients: ▪ Following BMD testing in ○ All women ≥70 years old if BMD T-score at the spine, total hip, or femoral neck is ≤-1.0 ○ Women age 65 to 69 if BMD T-score at the spine, total hip, or femoral neck is ≤-1.5 ▪ All postmenopausal women with specific risk factors, independent of BMD results: ○ Low trauma fracture during adulthood ○ Historical height loss of 1.5 inches or more ○ Prospective height loss of 0.8 inches or more ○ Recent or ongoing long term glucocorticoid treatment If BMD testing is not available, vertebral imaging may be considered based on age alone.

II. Diagnosis - established by
   A. Measurement of BMD

✓ FYI - Defining Osteoporosis by BMD

OR

   B. Occurrence of adulthood hip or vertebral fracture in the absence of major trauma

III. Management
   A. Advise lifestyle modifications to include
      1. Adequate intake of calcium and vitamin D
      2. Regular weight-bearing, muscle strengthening exercise
      3. Balance training

4. Fall prevention measures
5. Avoidance of tobacco and excessive alcohol

B. Treat vitamin D deficiency as follows
   1. 50,000IU vitamin D2 or vitamin D3 once a week or the equivalent daily dose (6,000IU vitamin D2 or vitamin D3) for 8 to 12 weeks to achieve a 25(OH)D blood level of approximately 30 ng/ml
   2. Advise maintenance therapy of 1,500 to 2,000 IU/day

C. Consider possibility of secondary causes of osteoporosis and refer as appropriate.

✓ FYI - Causes of Osteoporosis

D. Consider referral for physical and/or occupational therapy evaluation.

E. Consider pharmacotherapy for postmenopausal women ≥ age 50 presenting with the following
   1. Hip or vertebral (clinical or morphometric) fracture
   2. T-score ≤ -2.5 at the femoral neck, total hip or lumbar spine after appropriate evaluation to exclude secondary causes
   3. Low bone mass (T-score between -1.0 and -2.5 at the femoral neck or spine) and a 10-year probability of a hip fracture ≥ 3% or a 10-year probability of a major osteoporosis-related fracture ≥ 20% based on the US-adapted WHO algorithm (FRAX)

✓ FYI – FRAX

8.5.m. Table: Pharmacotherapy for Management of Osteoporosis

Class	Considerations	Side Effects
Bisphosphonates	▪ Because of the risk of esophageal ulcers, take alendronate, risedronate, and ibandronate first thing in the morning with a full glass of water, on an empty stomach, remaining upright at least 30 minutes after ingesting. ○ For ibandronate, wait at least 60 minutes before eating, drinking or taking other medication and remain upright during this time. ▪ Routine dental care should be encouraged in all clients.	▪ GI symptoms such as difficulty swallowing, inflammation of the esophagus and stomach. Consider alternative treatment route of administration or therapy in these clients, or those with ▪ Bone pain (less than 1%) ▪ Osteonecrosis of the jaw (dry socket) can occur ○ Rarely seen associated with standard therapy for osteoporosis

Class	Considerations	Side Effects
MHT See Table 8.5.e.	▪ The risks of osteoporosis should be weighed against the risks of MHT. ▪ The dose of estrogen needed to support bone health is significantly less than needed for the control of vasomotor symptoms. ▪ Fracture risk reduction with MHT decreases when MHT is discontinued. For maximal fracture risk reduction, HT/ET should be continued indefinitely. However, breast cancer risk with long-term use of HT/ET **must** be considered.	
Estrogen Agonists/Antagonists	▪ Formerly known as Selective Estrogen Receptor Modulators (SERMs) ▪ Raloxifene (Evista) only drug in class appropriate for osteoporosis prevention and treatment in women. Dose is 60 mg/day.	▪ May increase hot flashes ▪ Leg cramps
Cacitonin (Miacalcin)	▪ FDA approved for women who have been postmenopausal for at least 5 years ▪ Single daily intranasal 200IU spray ▪ Available in subcutaneous injection	▪ Rhinitis ▪ Epistaxis (rare)
Parathyroid Hormone (Forteo)	▪ FDA approved for women at high risk of fracture ▪ Daily 20mcg sub q injection ▪ May be used for a maximum of 2 years ▪ Common practice is to follow treatment with a bisphosphonate	▪ Leg cramps ▪ Nausea ▪ Dizziness

IV. Follow-up

A. In all clients,

1. Measure height yearly. Any loss of ≥2 cm should have repeat vertebral imaging.
2. Review lifestyle modification and risk reduction strategies.
3. Perform comprehensive risk assessment every 3 to 5 years, which should include

a. Updated fracture history
b. New chronic diseases and medications
c. Any height loss during the treatment period

B. Clients not requiring pharmacologic therapy at initial evaluation should be clinically re-evaluated when medically appropriate.
C. In clients taking pharmacotherapy,
1. Re-evaluate bone density every 2 years, using central DEXA.
2. Advise more frequent follow-up as appropriate (consult with affiliate medical director).
3. Perform medication adherence counseling. See Administrative Chapter 2 Client Centered Communications
4. Individualize duration of therapy.
5. After 3 to 5 years of therapy with bisphosphonates, consider discontinuation in clients who appear to be at modest risk of fracture after the initial treatment period. Consider continuation of bisphosphonate or an alternative therapy for clients at high risk for fracture.

8.6 PREMENSTRUAL DISORDERS (PMS/PMDD)

8.6.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

8.6.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
Release When Test/Service/Consultation Will Not Be Obtained As Recommended		Once		
Written information about any medication dispensed (package insert may be used)			●	
Written information as appropriate			●	

8.6.2 Evaluation and Management

I. Evaluation

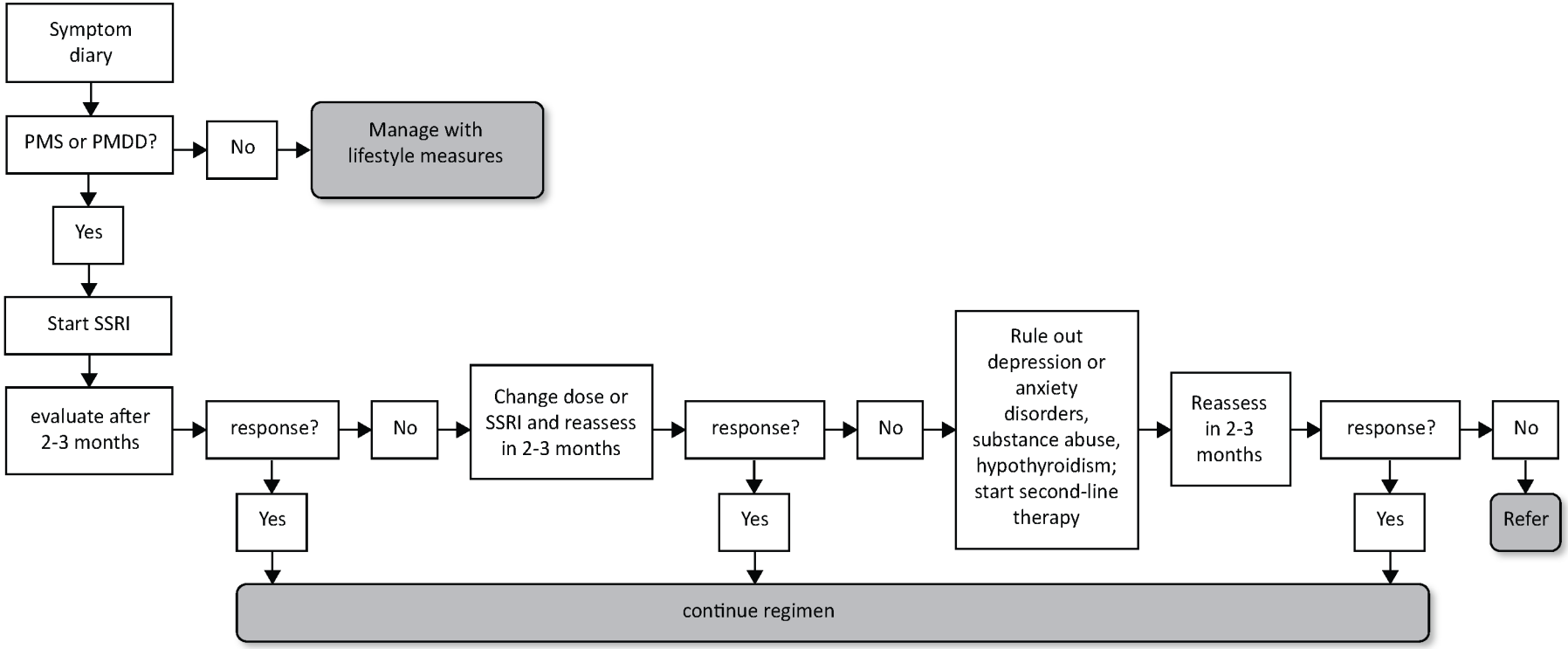
8.6.b. Table: Evaluation of Premenstrual Disorders

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Should include ▪ Menstrual history ▪ Characteristics (timing, type) of premenstrual symptoms — document prospectively using symptom inventory for at least 2 months* ▪ History of psychiatric disorders or substance abuse ▪ History suggestive of hypothyroidism ▪ Screening for depression ▪ Medications	Should include ▪ Thyroid palpation ▪ Other examination as indicated	Should include ▪ TSH, if indicated ▪ Other tests, as indicated
✓ *Suggest using the Daily Record of Severity of Problems (DRSP) or similar form.		

✓ FYI – Premenstrual Disorders

II. Diagnosis — Because the etiology of PMS/PMDD is still unknown, diagnosis is based on client history. Lab testing may be useful in some cases to rule out hypothyroidism or other endocrinopathies. When reviewing the history, there are 4 key elements needed to make a diagnosis of PMS:
   A. Symptoms consistent with the diagnosis
   B. Restriction of symptoms to luteal phase, resolving with onset of menses (assessed prospectively)
   C. Impairment of quality of life
   D. Exclusion of other potential diagnoses

8.6.c. Algorithm: Evaluation and Management of PMS or PMDD



III. Management – while premenstrual disorders, by definition, interfere with some part of the client's normal daily function, there are usually no medical sequelae if they are not treated. Thus, the decision to treat should be based upon the client's desire.

8.6.d. Table: Management of Premenstrual Disorders

Symptom Severity	Management
Mild (not causing distress or socioeconomic dysfunction)	Lifestyle measures ▪ Regular aerobic exercise (20-30 minutes/day 3 times per week) ▪ Adequate sleep ▪ Relaxation/stress-reduction techniques ▪ Provide emotional support, education and reassurance ▪ Encourage discussion of disorder with family members ▪ Consider referral for counseling
Moderate (meet criteria for PMS or PMDD) ✓ FYI - UCSD Criteria for Premenstrual Syndrome ✓ FYI - A Criteria for Premenstrual Dysphoric Disorder (DSM-V)	▪ Rule out depression or anxiety disorders, substance abuse, hypothyroidism ▪ Begin pharmacologic therapy (see table 8.6.e. below)

8.6.e. Table: Pharmacotherapy for Premenstrual Disorders

First-line Therapies	
Selective Serotonin Reuptake Inhibitors (SSRIs) ✓ FYI – Black Box Warning ✓ FYI – Intermittent vs. Continuous SSRI	▪ Regimen may be continuous or intermittent (luteal phase only, starting 7 to 14 days before onset of menses). o Suggested drugs • Fluoxetine • Sertraline • Paroxetine • Citalopram ▪ Effective dose may be less than used in treatment of depression. ▪ May take several cycles to become effective. ▪ Potential side effects include headaches, GI disturbances, jitteriness, insomnia, decreased libido.
Second-line Therapies	
CHCs	▪ Good option for clients who also desire contraception ▪ Select continuous regimen or one with shortened pill-free interval ▪ Select pill containing drospirenone or continuous regimen with levonorgestrel

Alprazolam	▪ Add to SSRI regimen ▪ 0.25 mg 2-3x/d on most symptomatic days only

IV. Referral — the following clients **must** be referred, those with
   A. Untreated major psychiatric conditions
   B. Worsening or persistent symptoms

8.7 VULVAR SKIN DISORDERS AND VAIN

8.7.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

8.7.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
CIIC Vulvar Biopsy		●	●	
Information on any medication dispensed (package insert may be used)			●	
Release When Test/Service/Consultation Will Not Be Obtained		Once		
Request for Surgery or Special Procedure		●		●
Written information as appropriate			●	

8.7.2 Evaluation and Management

I. Evaluation

8.7.b. Table: Evaluation of Vulvar Skin Disorders

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Must include ▪ Onset, duration, location and nature of symptoms (itching, burning, discharge,	**Must** include ▪ Location, number, color and character of lesions (raised, flat, atrophic, hypertrophic,	**Must** include ▪ Testing for infectious etiologies, as indicated ▪ Vulvar biopsy – see Table 8.7.c.

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
bleeding) ▪ Precipitating factors ▪ Previous treatments ▪ History of infectious, allergic, or systemic diseases (diabetes, Crohns) ▪ History of Behcet's syndrome ▪ History of or current dermatoses elsewhere on the body (psoriasis)	ulcerative, painful) ▪ Palpation of inguinal nodes ▪ Inspection of perineum and perianal area May include, as indicated ▪ Inspection of skin and oral cavity	○ If client is immunocompromised ○ If diagnosis is uncertain ○ If neoplasia is suspected ✓ FYI – Vulvar Lesions Suspicious for Neoplasia and Vulvar Biopsy ▪ Colposcopy, as indicated – see Table 8.7.d.

II. Management

8.7.c. Table: Vulvar Biopsy Technique and Follow-up

Anesthesia	▪ Local anesthesia **must** be used ▪ Consider anesthetic cream application prior to the injection of local anesthetic ○ Combination lidocaine and prilocaine cream 4% (onset 60 minutes) ○ Liposomal lidocaine cream (onset 30 minutes) ▪ Buffering lidocaine injection can minimize discomfort
Choice of instrument	▪ Punch biopsy is preferred for most lesions
Biopsy site selection	▪ Biopsy should **not** be taken from the center or the ulcerated area of a lesion.
Management of bleeding and infection	▪ Bleeding from biopsy site can be managed with pressure, silver nitrate, or Monsel's solution. A suture is rarely needed. ▪ Infection at biopsy site is very rare. If infection does occur, **must** prescribe coverage for Staphylococcus. Suggested regimens include ○ TMP-SMX (Bactrim DS; Septra DS) 1 double strength tablet BID PO x7 days ○ Dicloxacillin 250 mg QID x 7 days.
Follow-up	▪ Instruct client to return for follow-up visit if biopsy site does not heal as expected. ▪ Follow-up, treatment, and/or referrals **must** be individualized depending on results (see Table 8.7.d., below)

8.7.d. Table: Diagnosis and Management of Vulvar Skin Conditions/VAIN

Condition	Suggested by	Diagnosis	Management
Contact dermatitis	▪ Exam revealing poorly demarcated, erythematous rash and client reports itching	▪ Clinical ▪ Based on symptoms, personal or family history of atopy, or personal history of vulvar exposure to medications, perfumes, or other chemicals. ▪ Exclude infectious causes such as candida and HSV ▪ In difficult cases, patch testing and/or biopsy may be necessary	▪ Discuss vulvar care measures and avoidance of common vulvar irritants and allergens ✓ FYI – Vulvar Care Measures ✓ FYI – Common Vulvar Irritants ▪ To control nighttime itching, prescribe sedating antipruritic agent such as doxepin or hydroxyzine ▪ For mild symptoms ○ Suggested drugs include 1% hydrocortisone, 0.05% desonide and 0.1% triamcinolone (or other low-potency steroid) ○ Use daily for 2 to 4 weeks, then twice per week ○ May continue indefinitely, at the minimum frequency necessary to control symptoms ▪ For moderate to severe symptoms ○ Suggested drugs include clobetasol propionate or betamethasone dipropionate 0.05% ointment (or other high-potency steroid) ○ Use nightly for 30 days and reevaluate
Lichen planus	▪ White, reticulate, lacy or fernlike striae ▪ Pruritic, dusty pink papules	▪ Can be diagnosed clinically ▪ Biopsy is helpful to confirm diagnosis	▪ Clobetasol propionate 0.05% ointment (or other high-potency steroid) QHS, reevaluate in 1 to 2 months

Condition	Suggested by	Diagnosis	Management
			○ If improvement, reduce to 1 to 3 times weekly for a total of 12 weeks ○ If no improvement, continue QHS application and reevaluate ▪ Maintenance with 2 to 3 applications a week indefinitely may be necessary
Lichen sclerosis	▪ History of pruritus, followed by irritation, burning, dyspareunia and tearing ▪ White, thin-appearing tissue (cigarette paper) often in "keyhole" or figure-eight pattern around vulva and anus ▪ May see fissures and ulcers secondary to scratching; stenosis, labial agglutination, and loss of vulvar architecture may occur in later stages.	▪ Vulvar biopsy **must** be performed to confirm diagnosis prior to initiation of therapy.	▪ Goal is symptomatic relief – asymptomatic clients do not need treatment ▪ Clobetasol proprionate 0.05% ointment (or other high-potency steroid) ○ QHS, for 4 weeks ○ Then every other HS for 4 weeks ○ Then 2x/week for 4 weeks ▪ Maintenance with 1 to 2 applications a week indefinitely may be necessary to sustain symptomatic relief. ▪ Changing to moderate strength steroid ointment for maintenance treatment is another option. ▪ Ointments are preferred over creams or gels for all vulvar therapies. ▪ Follow-up at 3 and 6 months while treatment continues
Vaginal intraepithelial neoplasia (VAIN)	▪ Normal-appearing cervix in client having colposcopy because of abnormal cytology ▪ Abnormal cytology when no cervix is present ▪ Immunosuppressed woman	**Must** perform vaginal colposcopy ▪ Apply acetic acid to vagina ▪ Assess for acetowhite lesions ▪ Biopsy abnormal areas suspicious for VAIN or worse ▪ Lugol's staining should be used as an	VAIN 1 ▪ Not premalignant lesion ▪ Revaluate in 6 months ▪ If lesion persists, should perform colposcopy ▪ If clinical appearance consistent with warts,

Condition	Suggested by	Diagnosis	Management
	with premalignant disease of cervix or vulva ▪ Suspicious vaginal lesion	adjunct. ▪ Pretreatment with vaginal estrogen vaginal therapy prior to colposcopy in clients with severe atrophy may be beneficial.	standard treatment for vaginal warts is appropriate. See Chapter 9.2 Evaluation and Management of the Client with Positive Screening Test Results or Symptoms ▪ Biopsy if lesions do not respond to therapy. VAIN 2,3 ▪ Treatment may only be provided by those affiliates approved for Level III GYN ▪ There are 3 options o Excision o Laser vaporization o 5-FU therapy ▪ Follow-up **must** include colposcopy (and application of Lugol's) at 4 to 6 month intervals, until condition is resolved. ▪ Pregnant or immunocompromised women with VAIN 2,3 **must** be referred to an outside specialist
Vulvar atrophy		▪ Elevated vaginal pH ▪ Parabasal or intermediate cells on microscopy	✓ See 8.5.4 Urogenital Atrophy
Vulvar intraepithelial neoplasia (VIN) ✓ FYI – VAIN and VIN	▪ Lesions may be white or pigmented (red, grey, or brown), often with raised tissue ▪ If symptomatic, itching is most common; many women are asymptomatic	▪ Visual assessment and biopsy	▪ Treatment may only be provided by those affiliates approved for Level III GYN ▪ There are 3 options o Excision o Laser vaporization o Topical imiquimod ▪ Follow-up

Condition	Suggested by	Diagnosis	Management
			○ Medical therapy requires follow up at 4 to 6 week intervals with colposcopy until resolution ○ If the lesion(s) resolved, client **must** be monitored at 6 and 12 months and then annually thereafter ○ If the lesion does not resolve within 3 to 5 months, surgical management is required ▪ Pregnant or immunocompromised women with VIN **must** be referred to an outside specialist
Vulvodynia	▪ Burning, stinging irritation or a sense of rawness of the vulva ▪ Pain is present but vulva appears normal (other than erythema)	▪ Diagnosis of exclusion ▪ Cotton swab testing is used to localize and grade (mild, moderate, severe) painful areas. ▪ Perform wet prep, vaginal pH, cultures, or biopsies, as indicated, to rule out other etiologies.	▪ No high-quality evidence-based therapy with high degree of success. ▪ Emotional and psychological support can be helpful ▪ Multidisciplinary approach to management is encouraged ▪ Combined treatment approaches may be more successful than a single regimen ▪ Discuss vulvar care measures and avoidance of common vulvar irritants and allergens ✓ FYI – Vulvar Care Measures ✓ FYI – Common Vulvar Irritants ▪ Options for pharmacologic therapy include ○ Creams • Five percent local anesthetics (before intercourse or extended

Condition	Suggested by	Diagnosis	Management
			use) • Compounded tricyclic antidepressant o Tricyclic antidepressants o Anticonvulsants (Gabapentin, pregabalin) ▪ Therapies not showing benefit include topical steroid creams, topical testosterone, antifungal agents, or low-oxalate diets. ▪ Biofeedback and physical therapy may benefit some women. ▪ Eliminating known bladder irritants from the diet (tomatoes, alcohol, foods with citric acid, chocolate, caffeine, artificial sweeteners, spices) may be effective in women who report urinary symptoms as part of their pain ▪ Treatment often takes weeks to months before results are seen - give regimen a minimum of 3 months to assess effect

III. Referral - if any of the following, **must** refer

A. VAIN 2,3 and VIN

1. In affiliates not approved for Level II or Level III GYN
2. If client is pregnant or immunocompromised

B. Any condition which worsens or does not respond to therapy

8.8 ADDITIONAL INFORMATION

8.8.a. Table: For Your Information

Section	Topic	Detail
8.1	The PALM-COEIN System	Normal menstrual bleeding occurs every 21 to 35 days with varying amount of flow and generally lasts 5 days with no bleeding between menses. Abnormal Uterine Bleeding (AUB) is any deviation from the normal menstrual cycle and is categorized according to the PALM-COEIN system. In 2011 the International Federation of Gynecology and Obstetrics (FIGO) introduced this system of nomenclature to describe abnormal bleeding in reproductive-aged women. The system was adopted by ACOG in 2012 and is shown here. Abnormal Uterine Bleeding (AUB) • Heavy menstrual bleeding (AUB/HMB) • Intermenstrual bleeding (AUB/IMB) PALM: Structural Causes • **P**olyp (AUB-P) • **A**denomyosis (AUB-A) • **L**eiomyoma (AUB-L) ▪ Submucosal myoma (AUB-LSM) ▪ Other myoma (AUB-LO) • **M**alignancy & hyperplasia (AUB-M) COEIN: Nonstructural Causes • **C**oagulopathy (AUB-C) • **O**vulatory dysfunction (AUB-O) • **E**ndometrial (AUB-E) • **I**atrogeneic (AUB-I) • **N**ot yet classified (AUB-N)
8.1	Medications and Herbs Associated with AUB	▪ Hormonal contraceptives ▪ Menopausal hormone therapy ▪ Levothyroxine ▪ Anticoagulants (warfarin, heparin) ▪ NSAIDs ▪ SSRIs ▪ Tricyclic antidepressants ▪ Tamoxifen ▪ Antipsychotics (first generation, risperdone) ▪ Corticosteroids ▪ Ginko ▪ Ginseng ▪ Motherwort ▪ Chasteberry ▪ Danshen

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>8.1</td><td>Age-based Differential Diagnosis of AUB</td><td>The most common causes of AUB vary by the age of the client. Age-based common differential diagnoses include:
<table>
<tr><th>13-18 years</th><th>19-39 years</th><th>40 years to Menopause</th></tr>
<tr><td>▪ Anovulatory cycles
▪ Hormonal contraceptive use
▪ Pregnancy
▪ Pelvic infection
▪ Coagulopathies
▪ Tumors</td><td>▪ Pregnancy
▪ Structural lesions (polyp, leiomyoma)
▪ Anovulatory cycles
▪ Hormonal contraception
▪ Endometrial hyperplasia
▪ Endometrial cancer</td><td>▪ Anovulatory cycles
▪ Endometrial hyperplasia
▪ Endometrial cancer
▪ Endometrial atrophy
▪ Leiomyoma</td></tr>
</table></td></tr>
<tr><td>8.1</td><td>Definition and Etiology of Amenorrhea</td><td>Amenorrhea is defined as the absence of menstruation and is categorized as
▪ Primary amenorrhea — the absence of menarche by the age of 16 in sexually developed women or by age 14 in the absence of secondary sex characteristics
▪ Secondary amenorrhea — cessation of menses for at least 3 usual cycle lengths or 6 months, whichever is less, in non-breast-feeding women

The etiology of amenorrhea can be categorized based primarily on the anatomical location:
▪ Central compartment, consisting of the hypothalamus and pituitary, which is responsible for the cyclical release of LH and FSH
○ Hypothalamic dysfunction
• Functional — weight loss, eating disorders, exercise, stress, severe acute or prolonged illness
• Congenital
• Inflammatory or infiltrative disease
• Brain tumor or injury
• Idiopathic
○ Pituitary dysfunction
• Hyperprolactinemia
• Other pituitary tumors
• Empty sella syndrome</td></tr>
</table>

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td></td><td></td><td>

Pituitary infarct

Ovary, which responds to these gonadotropins

Ovarian dysfunction

Anovulation
Ovarian failure — physiologic (menopause), surgical (oophorectomy), radiation, chemotherapy or premature (idiopathic, genetic)

End-organ, consisting of the endometrium and outflow tract (cervix and vagina)

End organ dysfunction

Primary amenorrhea secondary to anatomical abnormality
Uterus — scarring (Asherman syndrome)
Cervix — obstruction secondary to scarring (LEEP, cone, cryotherapy, post abortion)
Vagina — anatomical defect associated with primary amenorrhea

Evaluation is directed toward identifying the etiology and offering management strategies.
</td></tr>
<tr><td>8.1</td><td>Potential Cause of Amenorrhea by History/Symptom</td><td>
<table>
<tr><th>History/Symptom</th><th>Potential Cause</th></tr>
<tr><td>Acne</td><td>Hyperandrogenism (ovarian or adrenal source)</td></tr>
<tr><td>Cervical surgery, prior</td><td>Cervical stenosis</td></tr>
<tr><td>Curettage, recent</td><td>Asherman syndrome</td></tr>
<tr><td>Galactorrhea (See 8.4)</td><td>Hypothyroidism
Pituitary tumor
Medications</td></tr>
<tr><td>Headache</td><td>Hypothalamic disease
Pituitary disease</td></tr>
<tr><td>Hirsutism</td><td>Hyperandrogenism (ovarian or adrenal source)</td></tr>
<tr><td>Hot flashes</td><td>Ovarian failure
Central failure</td></tr>
<tr><td>Irregular menses, prior history of</td><td>Anovulation</td></tr>
<tr><td>Pregnancy symptoms</td><td>Pregnancy</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>Premenstrual symptoms, cyclic</td><td>Cervical stenosis (obstruction)</td></tr>
<tr><td>Recent discontinuation of hormonal contraceptive</td><td>Anovulation
Hypothalamic amenorrhea</td></tr>
<tr><td>Vaginal dryness</td><td>Ovarian failure
Central failure</td></tr>
<tr><td>Visual changes</td><td>Hypothalamic disease
Pituitary disease</td></tr>
<tr><td>Weight loss</td><td>Hypothalamic amenorrhea</td></tr>
</table>
</td></tr>
<tr><td>8.1</td><td>PCOS Diagnostic Criteria</td><td>
<table>
<tr><th>National Institutes of Health (1990)</th><th>Rotterdam Criteria (2003)</th></tr>
<tr><td>Menstrual irregularity due to oligo- or anovulation (> 35 d cycles or < 8 menses/year)
WITH
Hyperandrogenism (hirsutism, acne, etc).
OR
Hyperandrogenemia (elevated free or total testosterone and/or elevated DHEAS)

In the absence of any other etiology (congenital adrenal hyperplasia, and androgen-secreting tumors.)</td><td>Two out of three of the following required
Oligo- and/or anovulation
Clinical and/or biochemical signs of hyperandrogenism
Polycystic ovaries (by ultrasound, specific criteria)
In addition, other etiologies of hyperandrogenism / anovulation must be excluded.

(European Society of Human Reproduction and Embryology / American Society for Reproductive Medicine)</td></tr>
<tr><td colspan="2">NIH criteria allow clinical diagnosis without imaging, but require presence of irregular menses. Rotterdam criteria includes broader spectrum of presentation. Regardless, it is clear oligo- and/or anovulation and hyperandrogenism are key components of this disorder.</td></tr>
</table>
</td></tr>
<tr><td>8.1</td><td>Differential Diagnosis of PCOS</td><td>

Androgen secreting tumor
Exogenous androgens
Cushing’s syndrome
Congenital adrenal hyperplasia
Acromegaly
Genetic defects in insulin action
Primary hypothalamic amenorrhea
Primary ovarian failure
Thyroid disease
Prolactin disorders

</td></tr>
</table>

Section	Topic	Detail
8.1	Clinical Characteristics and Sequelae of PCOS	▪ Menstrual dysfunction ▪ Hyperandrogenism ▪ Increased risk of endometrial hyperplasia and carcinoma ▪ Anovulatory infertility ▪ Obesity and insulin resistance ▪ Increased risk decreased glucose tolerance/Type 2 diabetes ▪ Dyslipidemia ▪ Increased risk of metabolic syndrome
8.2	Pelvic Masses	▪ Pelvic masses may be due to pelvic pathology or can arise from organs that are not part of the genital tract. Although they may cause symptoms, masses are often found incidentally during examination. ▪ In younger women, pelvic masses are usually benign and are most commonly functional ovarian cysts, masses due to infection, benign neoplasms, or pregnancy. ▪ Uterine leiomyomas are a common cause of pelvic masses and are present in about 25% of reproductive aged women (not common in younger women). ▪ As the client's age increases, so does the risk of malignancy. Pelvic masses in perimenopausal and menopausal women carry the highest risk of malignancy.
8.3	Major Causes of Secondary Dysmenorrhea	**Gynecologic Disorders** ▪ Endometriosis ▪ Adenomyosis ▪ Cervical stenosis (Stenosis without obstruction is a very rare cause.) ▪ Pelvic infection/adhesions ▪ Uterine fibroids ▪ Uterine polyps Congenital obstructive malformations of the uterus or vagina **Non-Gynecologic Disorders** ▪ Inflammatory bowel disease ▪ Irritable bowel syndrome ▪ Psychogenic disorders
8.3	Physical Exam Findings Suggestive of Endometriosis	The following findings are **suggestive** of endometriosis: ▪ Pelvic tenderness ▪ Fixed, retroverted uterus ▪ Tender uterosacral ligaments ▪ Uterosacral ligament nodularity ▪ Enlarged ovaries ▪ Adnexal mass ▪ Visible lesions in the vagina or on the cervix
8.3	Classification and Evaluation of	Women frequently present for care with a complaint of pelvic pain. Pelvic pain may be either acute or chronic. To be classified as chronic, pain must exist for more than 6 months. Pain can also be described as cyclic or non-cyclic in

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td></td><td>Pelvic Pain</td><td>terms of its relationship with the menstrual cycle. Pain can be caused by physical factors, psychological factors, or a combination of the two. In some cases, chronic pelvic pain may be associated with negative cognitive, behavioral and social consequences.

When evaluating clients with pelvic pain, the priority is to rule out life-threatening conditions or problems that might cause long-term morbidity. The etiology of chronic pelvic pain (CPP) is multifactorial with possible sources in the GI, GU, CNS or musculoskeletal systems.</td></tr>
<tr><td>8.3</td><td>Historical factors that increase the risk of chronic pelvic pain</td><td>▪ Physical or sexual abuse (40-50% of women with CPP have a history)
▪ PID (18-35% of women with PID will develop CPP)
▪ Endometriosis (seen laparoscopically in 33% of women with CPP)
▪ Interstitial cystitis (38-85% of women with CPP may have IC)
▪ Irritable bowel syndrome (symptoms seen in 50-80% of CPP)</td></tr>
<tr><td>8.3</td><td>PQRST Approach to Evaluation of Pain</td><td>When evaluating pelvic pain, using a PQRST approach may help to identify the source
▪ P — Precipitating or alleviating factors, previous treatments
▪ Q — Quality (is pain sharp, dull, or throbbing?)
▪ R — Radiation (or is pain fixed or variable?)
▪ S — Severity (use a pain scale)
▪ T — Temporal factors (associated with menses? intercourse? penetration?)</td></tr>
<tr><td>8.3</td><td>Character of Pelvic Pain and Potential Cause</td><td>
<table>
<tr><th>Character of pain</th><th>Potential cause</th></tr>
<tr><td>Colicky pain, often without tenderness</td><td>Contraction of obstructed hollow viscus (ex. intestine, ureter, gallbladder, appendix)</td></tr>
<tr><td>Sudden onset of severe generalized pelvic pain</td><td>Abrupt loss of blood supply (ex. ovarian torsion) or sudden perforation of a viscus and subsequent spillage of its contents into the peritoneal cavity</td></tr>
<tr><td>Insidious onset of pain over several hours</td><td>Inflammation of a viscus (ex. salpingitis, appendicitis)</td></tr>
<tr><td>Localized pain</td><td>A problem with on ovary or tube or part of the uterus</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>Pain involving the entire abdomen</td><td>Generalized inflammation of the peritoneal cavity (ex. secondary to spillage of blood, pus, or intestinal contents)</td></tr>
<tr><td>Pain with a tender adnexal mass</td><td>Ovarian cyst, ectopic pregnancy, or abscess</td></tr>
<tr><td>Pain with vomiting</td><td>Acute appendicitis, cholecystitis, or infrequently, salpingitis or pyelonephritis (vomiting occurs early) bowel obstruction (vomiting occurs late)</td></tr>
</table>
</td></tr>
<tr><td>8.3</td><td>Rome Criteria for Diagnosis of Irritable Bowel Syndrome (IBS)[R2]</td><td>Recurrent abdominal pain or discomfort (uncomfortable sensation not described as pain) at least 3 days/month in the last 3 months associated with two or more of the following:
▪ Improvement with defecation
▪ Onset associated with a change in frequency of stool
▪ Onset associated with a change in form (appearance) of stool

Criteria must be fulfilled for the prior 3 months with symptom onset at least 6 months prior to diagnosis.</td></tr>
<tr><td>8.3</td><td>Interstitial Cystitis (IC)</td><td>Definition/Diagnosis: Pelvic pain, pressure, or discomfort related to the bladder, typically associated with persistent urge to void or urinary frequency, in the absence of infection or other pathology. There are currently no biological markers for use in diagnosis. The diagnosis of IC remains one of exclusion.
▪ Symptoms include
○ Bladder pain (or pressure or discomfort) which often increases with bladder filling and may diminish during voiding and is associated with a persistent urge to void, urinary frequency, or both.
○ Urinary urgency that may be relieved by voiding
○ Urinary frequency
○ Other symptoms
• Nocturia
• Cyspareunia</td></tr>
</table>

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>8.4</td><td>Galactorrhea</td><td colspan="4">Galactorrhea is persistent discharge of milk from multiple duct openings in the nipple (usually bilateral) that occurs spontaneously or persists for more than 6 months after pregnancy or nursing. It is caused by an elevation in prolactin levels. The primary concern is the possibility of a prolactin-secreting pituitary tumor (prolactinoma) that may require medical or surgical treatment. The combination of galactorrhea and amenorrhea is particularly suspicious for prolactinoma. Common causes include:
▪ Physiologic conditions
○ Pregnancy and postpartum
○ Breast stimulation
▪ Neoplastic processes
▪ Hypothalamic-pituitary disorders
▪ Systemic diseases
○ Hypothyroidism
○ Chronic renal failure
○ Cushing's disease
○ Acromegaly
▪ Medications and herbs
▪ Chest wall irritation (i.e., shingles)
▪ Idiopathic
○ Hyperprolactinemia
○ Euprolactinemia</td></tr>
<tr><td>8.4</td><td>Medications and Herbs Associated with Galactorrhea</td><td>Antidepressants and anxiolytics
▪ Alprazolam
▪ Buspirone
▪ Monoamine oxidase inhibitors
▪ Selective serotonin reuptake inhibitors
▪ Citalopram
▪ Fluoxetine
▪ Paroxetine
▪ Sertraline
▪ Tricyclic antidepressants

Antihypertensives
▪ Atenolol
▪ Methyldopa
▪ Reserpine
▪ Verapamil</td><td>Antipsychotics
▪ Histamine H_2-receptor blockers
▪ Cimetidine
▪ Famotidine
▪ Ranitidine

Hormones
▪ Conjugated estrogen and medroxyprogesterone
▪ DMPA
▪ Oral contraceptive

Phenothiazines
▪ Chlorpromazine
▪ Prochlorperazine
▪ Others</td><td>Other drugs
▪ Amphetamines
▪ Anesthetics
▪ Arginine
▪ Cannabis
▪ Cisapride
▪ Cyclobenzaprine
▪ Danazol (Danocrine)
▪ Dihydroergotamine
▪ Isoniazid
▪ Metoclopramide
▪ Octreotide
▪ Opiates
▪ Rimantadine
▪ Sumatriptan
▪ Valproic acid</td><td>Herbs
▪ Anise
▪ Blessed thistle
▪ Fennel
▪ Fenugreek seed
▪ Marshmallow
▪ Nettle
▪ Red clover
▪ Red raspberry
(Adapted from Pena, K., Rosenfeld J. 2001)</td></tr>
</table>

Section	Topic	Detail
8.4	Hirsutism	Hirsutism is a sign of increased androgen action on hair follicles. It is due to either increased circulating levels of androgens (endogenous or exogenous) or increased sensitivity of hair follicles to normal levels of circulating androgens. Hirsutism is most often the result of benign conditions such as PCOS/chronic anovulation, but in rare cases may signal more serious pathology. The most common causes include: ▪ PCOS (70-80%) ▪ Hyperandrogenic insulin resistant acanthosis nigricans syndrome (3%) ▪ Nonclassic adrenal hyperplasia (2-8%) ▪ Ovarian/adrenal androgen-secreting tumors (rare) ▪ Medications/supplements ▪ Idiopathic (5-15%) ▪ Cushings Syndrome (rare) The goal of clinical evaluation is to differentiate between benign causes and other conditions with potentially serious sequelae such as tumors, late-onset adrenal hyperplasia and Cushing's syndrome.
8.4	Medications Associated with Hirsutism	▪ Anabolic steroids ▪ Danazol ▪ Metoclopramide ▪ Methyldopa ▪ Phenothaizines ▪ Progestins ▪ Reserpine ▪ Testosterone ▪ DHEA
8.5	Diagnosis of Menopause	Currently, there is no single test of ovarian function that will predict or confirm menopause. Usually, diagnosis can be made based upon medical/menstrual history and symptoms. While tests of ovarian function (FSH, estradiol, LH, testosterone, inhibin, prolactin) may be useful in differentiating various causes of amenorrhea such as primary ovarian insufficiency, hypothalamic hypogonadotropic amenorrhea and PCOS, no tests are routinely recommended for confirming menopause. In addition, there are no blood tests to diagnose menopause early and reliably enough to guarantee a woman that she is no longer at risk for pregnancy. During the perimenopausal years, day-to-day fluctuations of both gonadotropins and hormones can be quite extreme: FSH levels can temporarily crest to very high levels, and estradiol levels can plunge into the menopausal range. For this reason, hormone tests also are not reliable indicators of when to discontinue hormonal contraceptive methods that may mask the symptoms of menopause. Fortunately, the diagnosis of menopause need not be made precisely. Some experts recommend that healthy women continue their hormonal contraceptives until age 53 to 55, when the likelihood of pregnancy is very slight.

Section	Topic	Detail
8.5	Transitioning From DMPA to Menopausal Hormone Therapy (MHT)[R3]	DMPA can suppress gonadotropins, so measuring FSH or LH is not informative of menopausal state. DMPA use decreases endogenous estrogen levels. Long-term DMPA users in their 40s may benefit from estrogen supplementation. Kaunitz supplements long-term DMPA users in their 40s with 1.25 mg of conjugated estrogen (or equivalent drug). Arbitrarily at age 55, each woman, if she wants to and understands the risks and benefits, can be switched to conventional MHT. This is easy and minimizes need for laboratory testing, addresses the bone density issue, contraception, and vasomotor concerns while maintaining amenorrhea.
8.5	Progestin-only Therapy	Progestin-only therapies have been used off-label to treat hot flashes of varying severity. Oral MPA, DMPA and megestrol acetate have all demonstrated efficacy. Short-term use of these drugs is reasonable in women without contraindications to progestin who do not wish to use estrogen but are not opposed to trying another hormone.
8.5	Potential Causes of Osteoporosis and Fragility Fractures[R4]	**Lifestyle Factors** ▪ Low calcium intake ▪ Alcohol (≥3 drinks/d) ▪ Smoking ▪ Vitamin D insufficiency ▪ High salt intake ▪ Inadequate physical activity ▪ Falling ▪ Excess Vitamin A ▪ Immobilization ▪ Thinness **Hypogonadal States** ▪ Androgen insensitivity ▪ Anorexia nervosa / bulimia ▪ Athletic amenorrhea ▪ Hyperprolactinemia ▪ Panhypopituitarism ▪ Premature ovarian failure **Endocrine Disorders** ▪ Adrenal insufficiency ▪ Cushing's syndrome ▪ Diabetes mellitus (Types I and II) ▪ Hyperparathyroidism ▪ Thyrotoxicosis ▪ Central adiposity **Genetic Factors** ▪ Cystic fibrosis ▪ Ehlers-Danlos ▪ Gaucher's disease ▪ Glycogen storage diseases ▪ Hemochromatosis ▪ Homocystinuria ▪ Hypophosphatasia ▪ Idiopathic hypercalciuria **Miscellaneous** ▪ AIDS/HIV ▪ Alcoholism ▪ Amyloidosis ▪ Chronic metabolic acidosis ▪ Chronic obstructive lung disease ▪ Congestive heart failure ▪ Depression ▪ End stage renal disease ▪ Idiopathic scoliosis ▪ Muscular dystrophy ▪ Post-transplant bone disease ▪ Sarcoidosis ▪ Weight loss **Hematologic Disorders** ▪ Hemophilia ▪ Multiple myeloma ▪ Systemic mastocytosis ▪ Leukemia and lymphomas ▪ Sickle cell disease ▪ Thalassemia ▪ Monoclonal gammopathies **Medications** ▪ Aluminum (in antacids) ▪ Anticoagulants (heparin) ▪ Anticonvulsants ▪ Aromatase inhibitors ▪ Barbiturates ▪ Cancer

Section	Topic	Detail			
		▪ Premature menopause ▪ Turner's & Klinefelter's syndromes **Rheumatic and Autoimmune Diseases** ▪ Ankylosing spondylitis ▪ Lupus ▪ Rheumatoid arthritis ▪ Other rheumatic and autoimmune diseases	▪ Marfan syndrome ▪ Menkes steely hair syndrome ▪ Osteogenesis imperfecta ▪ Parental history of hip fracture ▪ Porphyria ▪ Riley-Day syndrome	**Gastrointestinal Disorders** ▪ Celiac disease ▪ Inflammatory bowel disease ▪ Primary biliary cirrhosis ▪ Gastric bypass ▪ Malabsorption ▪ GI surgery ▪ Pancreatic disease	chemotherapeutics ▪ Cyclosporine A and tacrolimus ▪ DMPA ▪ Glucocorticoids (≥ 5 mg/d of prednisone or equivalent for ≥ 3 mos) ▪ GNRH agonists and antagonists ▪ Lithium ▪ Methotrexate ▪ Parenteral nutrition ▪ Proton pump inhibitors ▪ SSRIs ▪ Tamoxifen (premenopausal use) ▪ Thiazolidinediones ▪ Thyroid hormones
8.5	Defining Osteoporosis by BMD	WHO has established the following definitions based on BMD measurement at the spine, hip, or forearm via DEXA: ▪ Normal: BMD is within 1 SD of a "young normal" adult (T-score at -1.0 and above) ▪ Low bone mass/osteopenia: BMD is between 1.0 and 2.5 SD below that of a "young normal" adult (T-score between -1.0 and -2.5) ▪ Osteoporosis: BMD is 2.5 SD or more below a "young normal" adult (T-score at or below -2.5). Clients in this group who have experienced one or more fractures are deemed to have severe or "established" osteoporosis.			
8.5	Sleep Disorders May Not be Related to Vasomotor Symptoms	Sleep disruption related to hot flashes should be resolved if vasomotor symptoms are suppressed. Since sleep disorders, independent of hot flashes, are not uncommon in peri and menopausal women, this symptom may need to be addressed as a separate entity.			

Section	Topic	Detail
8.5	Melatonin	Some women may self-medicate with melatonin, but data on its effectiveness as a sleep aid are inconsistent. Further, there are no data addressing its effects on women with menopause-related sleep disturbances.
8.5	FRAX	FRAX is a tool that has been developed by WHO to evaluate the fracture risk of clients. It is intended for postmenopausal women and men over 50 who have not been previously treated. The FRAX® algorithms give the 10-year probability of fracture. The output is a 10-year probability of hip fracture and the 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture). This information is often helpful when deciding whether or not to initiate therapy. The tool may be accessed here: ✓ http://www.shef.ac.uk/FRAX/tool.jsp?country=9
8.6	Premenstrual Disorders	Premenstrual disorders are a constellation of symptoms, mood, behavioral and physical, which occur during the late luteal phase of the menstrual cycle and resolve soon after the onset of menses. It is estimated that 80-90% of women experience symptoms, known as menstrual molimina, around the time of menses. When symptoms negatively affect a woman's quality of life, they are described as Premenstrual Syndrome (PMS). Premenstrual Dysphoric Disorder (PMDD) is the most severe form of PMS, and results in significant impairment. In common practice, the two terms are used interchangeably. Premenstrual symptoms are multifactorial in origin and still not well understood. It is believed that some women are genetically predisposed to symptoms. Symptoms appear to be secondary to abnormal interactions between processes occurring in the central nervous system, gonadal hormones and other modulators including neurotransmitters.

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>8.6</td><td>UCSD Criteria for Premenstrual Syndrome[R5]</td><td>Criteria include cyclic manifestation of at least 1 of 6 affective symptoms and at least 1 of 4 somatic symptoms listed below during the 5 days before menses in each of the 3 prior menstrual cycles.
<table>
<tr><th>Affective</th><th>Somatic</th></tr>
<tr><td>Depression
Angry outbursts
Irritability
Confusion
Social withdrawal
Fatigue</td><td>Breast tenderness
Abdominal bloating
Headache
Swollen extremities</td></tr>
</table>
Relief of symptoms occurs within 4 days of onset of menses and does not recur until at least cycle day 13. Symptoms must be present in the absence of any pharmacologic therapy, hormone ingestion, drug or alcohol use, and must occur reproducibly during 2 cycles of prospective recording.

There must be identifiable dysfunction in one of the following: marital/relationship, difficulty parenting, poor work/school performance, increased social isolation, legal difficulties, suicidal ideation, seeking medical attention for a somatic symptom.</td></tr>
<tr><td>8.6</td><td>APA Criteria for Premenstrual Dysphoric Disorder (DSM-V)</td><td>Core Symptoms
▪ Mood swings, sudden sadness, increased sensitivity to rejection
▪ Anger, irritability
▪ Sense of hopelessness, depressed mood, self-critical thoughts
▪ Tension, anxiety, feeling on edge

Other Symptoms
▪ Difficulty concentrating
▪ Change in appetite, food cravings, overeating
▪ Diminished interest in usual activities
▪ Easy fatigability, decreased energy
▪ Feeling overwhelmed or out of control
▪ Breast tenderness, bloating, weight gain, or joint/muscle aches
▪ Hypersomnia or insomnia

Diagnosis requires ≥ 5 symptoms listed, including at least 1 core symptom, present during last week of luteal phase in most menstrual cycles of previous year. Symptoms must be relieved within a few days of onset of menses, do not</td></tr>
</table>

Section	Topic	Detail
		recur during week following menses, and should be documented prospectively in at least two consecutive cycles. Symptoms must be severe enough to interfere with work, school or other usual activities and must not represent an exacerbation of another disorder.
8.6	FDA Black Box Warning	**Suicidality in Children and Adolescents** Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of any antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of nine antidepressant drugs (SSRIs and others) in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events on drug was 4%, twice the placebo risk of 2%. No suicides occurred in these trials. Note: Adults with MDD or co-morbid depression in the setting of other psychiatric illness being treated with antidepressants should be observed similarly for clinical worsening and suicidality, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.
8.6	Intermittent vs. Continuous SSRI Treatment	Studies have shown that women prefer to take SSRIs intermittently for the treatment of PMS/PMDD. However, intermittent usage appears to be less effective than continuous for somatic complaints.
8.7	Vulvar Lesions Suspicious for Neoplasia and Vulvar Biopsy	Vulvar lesions with the following characteristics are suspicious for neoplasia and warrant biopsy ▪ Atypical lesions — discolored (white) or pigmented (red, grey, brown) ▪ Age > 50 with new vulvar lesions (except typical condyloma acuminata which resolve after 1 or 2 treatments with topical therapy) ▪ Lesions not responding to standard therapy ▪ Lesions which have changed in character (increasing size, color changes) The threshold for vulvar biopsy should be low.

Section	Topic	Detail
8.7 (1) 8.7 (2)	Vulvar Care Measures	In clients experiencing vulvar skin conditions, clinicians should discuss the following vulvar care measures which may lessen symptoms. ▪ Avoid common vulvar irritants and allergens (See FYI – Common Vulvar Irritants and Allergens, below) ▪ Clean vulva with water only; avoid prolonged, hot soaks ▪ Pat dry after bathing, do not use hair dryers ▪ Apply a preservative-free emollient like vegetable oil or petrolatum ▪ Avoid tight, synthetic, or uncomfortable clothing ▪ Wear 100% cotton underwear ▪ Use 100% cotton pads ▪ Use adequate, water-soluble lubricant with intercourse. ▪ Avoid abrasive activities, such as biking or horseback riding The following measures can be used as needed to provide symptomatic relief. ▪ Hydrate the vulva using 5- to 10-minute sitz baths in comfortable warm water 2 times daily followed by application of a thin film of petroleum jelly ▪ Apply cool packs to vulva as needed to relieve burning in the vestibule or postcoital soreness; avoid prolonged application.
8.7 (1) 8.7 (2)	Common Vulvar Irritants and Allergens	Dermatitis has been reported to occur in 20-60% of clients with chronic vulvar symptoms. Contact dermatitis is one of the most frequent types. Below is a list of known substances that are known to cause contact dermatitis. ▪ Adult or baby wipes ▪ Antiseptics ▪ Body fluids ▪ Colored or scented toilet paper ▪ Condoms containing lubricants or spermicides ▪ Contraceptive creams, jellies, foams, nonoxynol-9, lubricants ▪ Deodorants ▪ Dyes ▪ Emollients ▪ Laundry detergents ▪ Rubber products (including latex) ▪ Sanitary products, including tampons, pads ▪ Soaps, bubble bath and salts, shampoos, conditioners ▪ Tea tree oil ▪ Topical anesthetics ▪ Topical antibacterials ▪ Topical antimycotics ▪ Topical corticosteroids ▪ Topical medications including TCA, 5-FU, podofilox or podophyllin ▪ Vaginal hygiene products, including perfumes or deodorants

Section	Topic	Detail
8.7	VAIN and VIN	VAIN lesions are classified as VAIN 1, 2, or 3 in the same fashion as cervical disease. The propensity to progress to invasive disease is much less likely than with CIN. VIN was traditionally classified into 3 grades, like CIN. In 2004, the International Society for the Study of Vulvovaginal Disease (ISSVD) replaced the 3-grade classification with a single grade system. In the new system, only high-grade disease is classified as VIN. What was formerly classified is VIN 1 usually represents a self-limited infection caused by HPV.

8.8.b. Table: References

Section	R#	Reference
8.7		ACOG Committee Opinion Number 345, October 2006: Vulvodynia
8.1	R1	ACOG Committee Opinion Number 440, August 2009 (Reaffirmed 2013): The Role of Transvaginal Ultrasonography in the Evaluation of Postmenopausal Bleeding.
8.7		ACOG Committee Opinion Number 509, November 2011: Management of Vulvar Intraepithelial Neoplasia
8.3		ACOG Practice Bulletin Number 114, July 2010: Management of Endometriosis
8.1		ACOG Practice Bulletin Number 128, July 2012: Diagnosis of Abnormal Uterine Bleeding in Reproductive-Aged Women
8.1		ACOG Practice Bulletin Number 136, July 2013: Management of Abnormal Uterine Bleeding Associated with Ovulatory Dysfunction
8.7		ACOG Practice Bulletin Number 93, May 2008: Diagnosis and Management of Vulvar Skin Disorders
8.1		ACOG Practice Bulletin Number 96, August 2008: Alternatives to Hysterectomy in the Management of Leiomyomas
8.2		ACOG Practice Bulleting Number 83, July 2007: Management of Adnexal Masses
8.5		ACOG. Management of Menopausal Symptoms. Practice Bulletin No. 141, Washington: Obstet Gynecol, 2014, 202-16
8.8	R5	American College of Obstetricians and Gynecologists. Premenstrual Syndrome. Practice Bulletin, No. 15. Washington, DC: ACOG; 2001 (Reaffirmed 2008.)
8.7		Christine H Holschneider, MD. "Vulvar intraepithelial neoplasia." UpToDate. July 15, 2013. (accessed June 1, 2014). http://www.uptodate.com/contents/vulvar-intraepithelial-neoplasia?source=search_result&search=VIN&selectedTitle=1~23
8.7		Elizabeth Gunther Stewart, MD. "Dermatitis of the vulva." UpToDate. July 6, 2012. http://www.uptodate.com/contents/dermatitis-of-the-vulva (accessed June 1, 2014).
8.2		*Gynecology for the Primary Care Physician.* pages 313-319

Section	R#	Reference
8.2		Joint SOGC/GOC/SCC Clinical Practice Guideline Number 230, July 2009: Initial Evaluation and Referral Guidelines for Management of Pelvic/Ovarian Masses
8.2		Katherine T. Chen, MD, MPH. "Disorders of Bartholin gland." UpToDate. Nov 25, 2013. http://www.uptodate.com/contents/disorders-of-bartholin-gland (accessed June 1, 2014).
8.5	R3	Kaunitz AM. IN Hatcher RA, Zieman M. et al. Managing Contraception. 2005-2007.
8.1		Munro MG, Critchley HO, Broder MS et al. FIGO classification system (PALM-COEIN) for causes of abnormal uterine bleeding in nongravid women of reproductive age. Int J Gynecol Obstet. 113(2011) 3-13
8.5		National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Guideline, Washington DC: NOF, 2014.
8.5	R4	North American Menopause Society (NAMS). "2012 Hormone Therapy Position Statement of NAMS." Journal of North American Menopause Society 19, no. 3 (Jan 2012): 257-71.
FYI	R2	Rome Criteria www.romecriteria.org
8.1		SOCG Clinical Practice Guideline Number 292, May 2013: Abnormal Uterine Bleeding in Pre-Menopausal Women
8.3		SOGC Clinical Practice Guidelines Number 244, July 2010: Endometriosis: Diagnosis and Management
8.6		Yonkers, Robert F. Casper and Kimberly A. "Treatment of premenstrual syndrome and premenstrual dysphoric disorder." UpToDate. March 17, 2014. http://www.uptodate.com/contents/treatment-of-premenstrual-syndrome-and-premenstrual-dysphoric-disorder?source=search_result&search=premenstrual&selectedTitle=1~53%23H625948608 (accessed June 2014).

8.8.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIICs	CI Hot Flashes CI Menopause and Perimenopause CI Problems Sleeping CIIC Endometrial Biopsy CIIC Menopausal Hormone Therapy (MHT) CIIC Treatment of Bartholin's Duct Cyst or Abscess	Part 3, Chapter 02_08

Type	Resource	Location
	CI Getting Enough Calcium and Vitamin D CI Preventing CVD	Part 3, Chapter 02_21
	CIIC Vulvar Biopsy	Part 3, Chapter 02_09

8.8.d. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ Tables on Menopausal Hormone Therapy ✓ National Osteoporosis Foundation's Guidelines ✓ FRAX	
Training	**PPFA 2014 VOICE** Overview of AUB Evaluation of AUB Management Options in AUB Case Studies in AUB	To be posted on the CAL
	MeDC 2014 Presentation Updates in Menopausal Care	To be posted on Extranet
Sample Forms	✓ Daily Record of PMS Symptoms	

CHAPTER 9: INFECTIONS

Revised June 2014

Chapter 9 Table of Contents

9.1 SCREENING AND PREVENTION

9.1.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

9.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	Should give
CI Condoms and Female Condoms				First time dispensing
CI HIV**			●	
CI Reducing your Risk for STIs			As needed or requested based on risk assessment	
CI STI Testing				●
CIIC PEP			●	
CIIC PrEP			●	
Release When Test/Service/Consultation Will Not Be Obtained As Recommended		once		
VIS Immunization*			●	
Written information about any medication dispensed (package insert may be used)			●	

*Minors - consent of a parent or guardian **must** be obtained when required by state or federal law.
**State/local laws may require a separate consent form for HIV

✓ See Chapter 6.9 FYI —Key Points of Advice about Nonoxynol-9 (N-9)

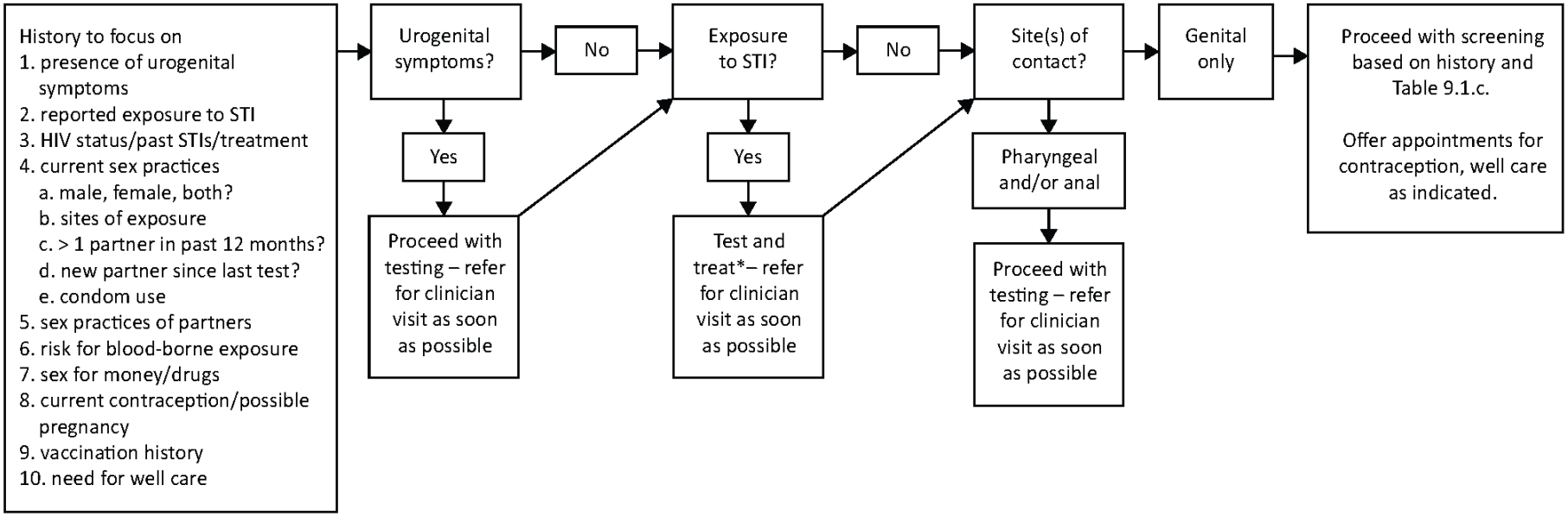
9.1.2 Screening

Screening is defined as testing in the absence of symptoms. Risk-based screening should be offered when possible. Expedited screening is acceptable.

I. Expedited STI screening
   A. **Must** include an evaluation of whether urogenital symptoms are present — if present, clients can be screened for STI/HIV, but **must** be referred for a clinician visit as soon as possible
   B. **Must** be offered based on the recommendations in Table 9.1.c. Screening Recommendations for Sexually Active People

II. Risk-based STI screening — individualize screening based on Flow Diagram 9.1.b.

9.1.b. Flow Diagram: Evaluation for Risk-Based Screening Needs*



* Testing of asymptomatic contacts to infection should be performed in
- Clients with a history of recent sex with a man with chlamydia, gonorrhea, dysuria, urethral discharge, urethritis, epididymitis, or prostatitis — even if empirical treatment is given
- Clients with a history of sex with a woman with chlamydia, gonorrhea, acute pelvic inflammatory disease or cervicitis — even if empirical treatment is given
- Clients who are contacts to a sexual partner diagnosed with or suspected of having syphilis (any stage)

III. Screening **must** be offered based on the recommendations in Table 9.1.c. (see exceptions below). Clients **must** be told exactly what they are being tested for.

9.1.c. Table: Screening Recommendations for Sexually Active People[1]

✓ FYI – National Evidence-Based Guidelines

	CT[2]	GC[2]	HIV[3]– opt out testing	Syphilis	Trichomoniasis	HSV-2[4]	HBV HCV	BV HPV
Women ≤ 25[5,6]	Annually, or more frequently if at increased risk. ✓ FYI —Risk factors GC/CT	Annually, or more frequently if at increased risk.[7] ✓ FYI —Risk factors GC/CT	At least once, repeat annually if high-risk	No routine screening; screen based on risk	No routine screening; screen based on prevalence in area or risk[8]	No routine screening	No routine screening; screen based on risk ✓ FYI — Populations at risk for Hepatitis B and C	No routine screening
Women > 25[5,6]	No routine screening; screen based on risk	No routine screening; screen based on risk[7]						
HIV+ Women	Annually	Annually	n/a	Annually	First visit and at least annually	First visit	First visit	No routine screening
MSW	Routine screening if ≤ 25 only	Routine screening if ≤ 25 only[7]	At least once, repeat annually if high-risk	No routine screening	Screening is not recommended	No routine screening	No routine screening; screen based on risk ✓ FYI — Populations at risk for Hepatitis B and C	No routine screening
MSM	Annually[9], repeat every 3-6 months	Annually[9], repeat every 3-6 months	Annually, repeat every 3-6 months	Annually, repeat every 3-6	No routine screening	No routine screening	At least once[4]	No routine screening

	CT[2]	GC[2]	HIV[3] – opt out testing	Syphilis	Trichomoniasis	HSV-2[4]	HBV HCV	BV HPV
	based on risk	based on risk	based on risk	months based on risk				
HIV+ Men	Annually[9]	Annually[9]	n/a	Annually	No routine screening	First visit[4]	First visit	No routine screening

A. Exceptions
   1. Chlamydia and Gonorrhea — Screening in low prevalence settings is not recommended because it is not cost effective and may lead to a high rate of false positive results.
   2. HIV — Screening in geographic areas with an HIV prevalence of less than 0.1% is not recommended. Individual clients who are in these settings should be tested if they
      a. Have clinical signs or symptoms suggesting HIV infection (e.g., fever or illness of unknown origin, opportunistic infection [including active tuberculosis disease] without known reason for immune suppression)
      b. Have diagnoses suggesting increased risk for HIV infection (e.g., another STI or blood borne infection)
      c. Self-reported HIV risk and specifically request an HIV test
   3. Screening may be considered at client request.

9.1.3 Prevention

I. Risk Reduction Strategies – should discuss with clients as appropriate. See Administrative Chapter 2 Client Centered Communications.

II. Condom Use
   A. Sexually active clients should be offered condoms (without nonoxynol-9) at every visit.
   B. Sexually active clients should be encouraged to practice dual-method use (i.e., use of a condom plus a highly effective contraceptive) to simultaneously prevent unintended pregnancy and acquisition/transmission of sexually transmitted infections including HIV.

III. Vaccinations – appropriate vaccinations should be encouraged and offered or client should be referred for care according to age and risk. See Chapter 20 Vaccination Services.

IV. Pre-Exposure Prophylaxis (PrEP) for HIV Prevention
   A. Clients ≥ age 18 who are candidates for PrEP (HIV-negative and at substantial risk of becoming infected with HIV) should be offered treatment or referred for care, if requested. See Flow Diagram 9.1.e.

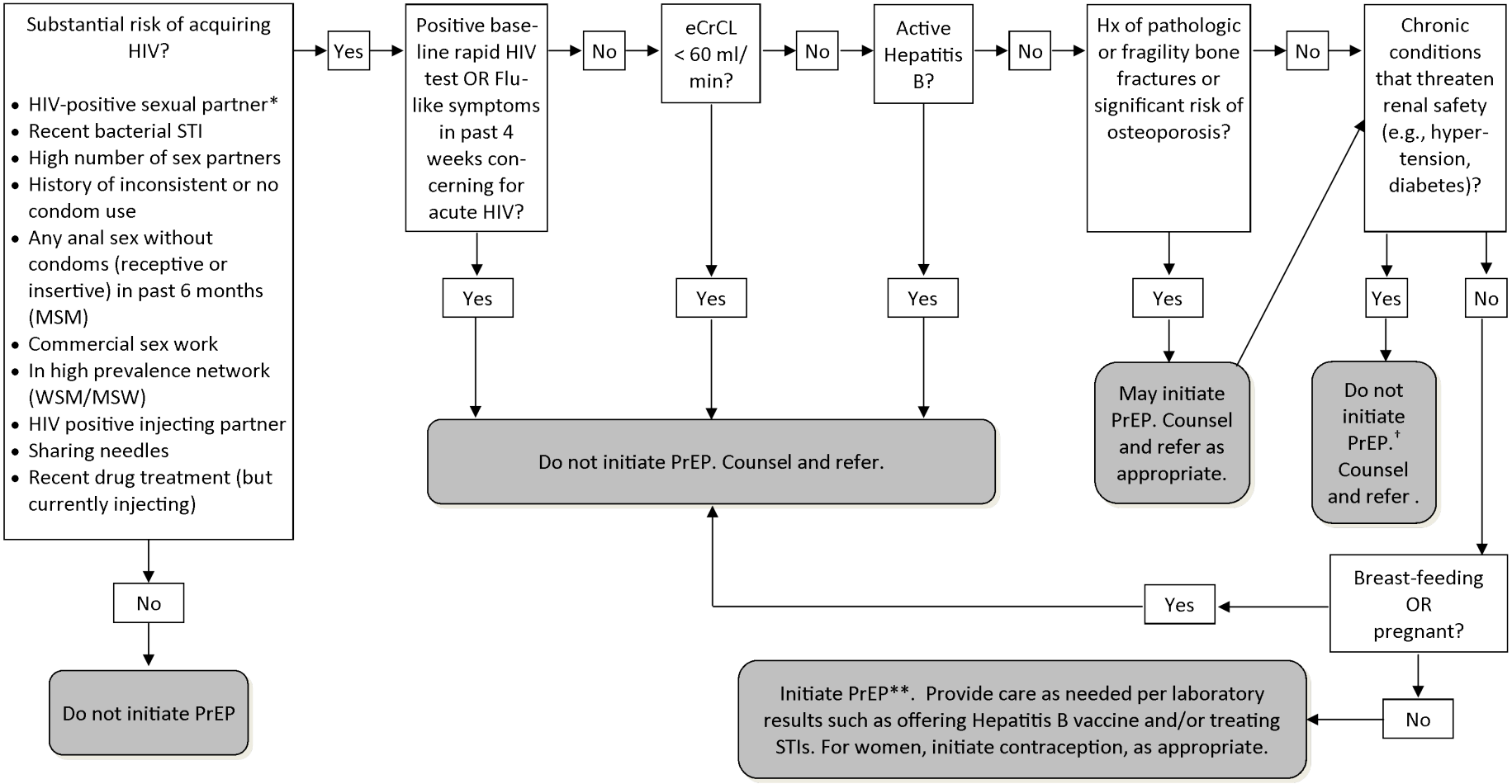
B. Evaluation for PrEP

9.1.d. Table: Evaluation for PrEP

History	Laboratory Tests and Diagnostic Imaging
Must include ▪ Current HIV status of client and partner(s) ▪ Comprehensive sexual history ▪ Social and drug history ▪ Current medications ▪ Hx renal or liver disease or osteoporosis ▪ Current method of contraception (women) ▪ Pregnancy and breastfeeding status and pregnancy intentions (women) ▪ Review of Systems	**Must** include ▪ Baseline rapid fingerstick HIV test (**must** not use oral tests prior to PrEP) ▪ Screening for STIs based on sexual practices, if not already done ○ MSM – syphilis and urethral, rectal, and pharyngeal GC/CT ○ MSW and Women – syphilis, genital GC/CT Should include ▪ HIV testing of regular sex partners with unknown HIV status If PrEP will be initiated, **must** include ▪ Repeat rapid fingerstick HIV test if > 1 week since previous test (**must** not use oral tests prior to PrEP) ▪ Creatinine with estimated creatinine clearance (eCrCl) by Cockcroft-Gault formulas ✓ Creatinine Clearance (Cockcroft-Gault Equation) ▪ HBsAg ▪ Pregnancy test, as appropriate

1. **Must** assess clients per flow diagram 9.1.e. PrEP is only for clients at ongoing, very high risk for acquiring HIV Infection. PrEP **must** not be initiated in minors.

9.1.e. Flow Diagram: Assessment of Eligibility for PrEP



*PrEP use may be one of several options to help protect the HIV-negative partner in discordant couples during attempts to conceive.

If PrEP not initiated within 1 week of negative HIV test result, **must repeat rapid HIV test.

†Affiliates that provide comprehensive primary care services may initiate PrEP in individuals with these conditions. More frequent monitoring or additional testing may be needed.

C. PrEP Management
   1. Regimen for PrEP: Tenofivir 300 mg (TDF) and emtricitabine 200 mg (FTC) (Truvada – see Table 9.1.i.) – 1 tablet daily
   2. **Must** limit supply to 90 days. **Must** confirm client remains HIV uninfected at least every 3 months prior to prescription renewals.
   3. Side effects such as headache, nausea, and flatulence can be managed with OTC medications.
   4. **Must** discontinue PrEP at client's request, if there are safety concerns and/or if HIV infection is acquired.
      a. If HIV test negative and PrEP is discontinued, **must** continue risk reduction support.
   5. **Must** monitor client per Table 9.1.j.

9.1.f. Table: Monitoring Schedule for PrEP

	Baseline*	At least every 3 months	At least every 6 months	At least every 12 months
Health Center Visit ▪ Assess risk behaviors ▪ Provide risk reduction counseling ▪ Provide condoms ▪ Assess for STI symptoms ▪ Encourage/evaluate medication adherence ✓ See Administrative Chapter 2 Client Centered Communications	●	●		
Evaluate need to continue PrEP as component of HIV prevention				●
Rapid fingerstick HIV test and assessment for signs or symptoms of acute infection	●	●		
Creatinine and calculation of eCrCl	●		●**	
Pregnancy test, as appropriate†	●	●		
STI tests for sexually active adults	●	○††	●	
HBsAG	●			

*One month after initiation of PrEP consider health center visit to assess and confirm HIV-negative test status, assess for early side effects, discuss any difficulties with medication adherence, and answer questions.

A rise in serum creatinine is not a reason to withhold treatment if eCrCl ≥ 60 ml/min. If eCrCl is declining steadily but still remains ≥ 60 ml/min **must refer to nephrologist.

†If client becomes pregnant while on PrEP, provide pregnancy options counseling. If client desires to continue pregnancy, refer out for both prenatal care and PrEP management. If client desires abortion, may provide abortion and continue PrEP at affiliate.

††If STI symptoms are present, test and treat as needed.

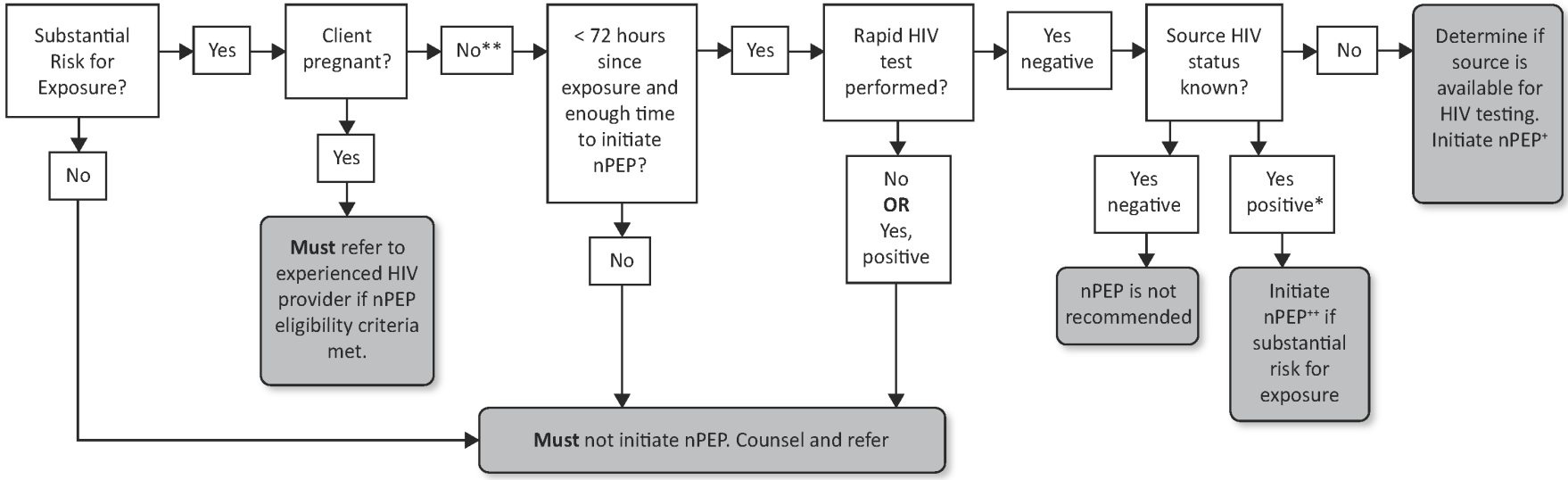
D. Referral
   1. If HIV test positive, **must** refer out for HIV care.
   2. If signs or symptoms of acute HIV infection, **must** refer out for HIV care.
   3. If eCrCl < 60 ml/min or eCrCl declining steadily after PrEP initiation, **must** refer to nephrologist.
   4. If acute or chronic HBV not being managed, **must** refer out unless affiliate provides comprehensive primary care services.
   5. If history of pathologic or fragility bone fractures or significant risk of osteoporosis, **must** refer out.
   6. If pregnant and client desires to continue pregnancy, **must** refer out for prenatal care and PrEP management.

V. Non-Occupational Post-Exposure Prophylaxis (nPEP) for HIV Prevention
   A. Clients who are candidates for nPEP should be offered treatment or referred for care. See Flow Diagram 9.1.h.
   B. Evaluation

9.1.g. Table: Evaluation for nPEP

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Must include ▪ Current HIV status of client ▪ Current HIV status of source, if known ▪ Type and timing of exposure(s)* ○ Type of sexual activity to determine risk level ✓ FYI —Risk for HIV Exposure for Purposes of nPEP ○ Sexual assault ○ Condom use ○ Needle-sharing ▪ Possibility of other recent HIV exposures ▪ Current STIs or genital ulceration ▪ Current medications ▪ Hx anemia or chronic kidney disease ▪ Breastfeeding status ▪ Possibility of pregnancy/need for EC	**Must** include ▪ Vital signs ▪ Assessment of skin and mucous membranes involved in exposure ▪ Genital exam, as indicated by history and symptoms (if any)	**Must** perform baseline rapid HIV test Should screen for ▪ GC/CT ▪ Syphilis ▪ Pregnancy, if indicated by history Consider HBV and HCV testing If nPEP will be initiated, **must** perform ▪ CBC ▪ Basic metabolic panel (BMP) ▪ Liver function studies
* nPEP should only be used for infrequent exposures. Persons who engage in behaviors that result in frequent, recurrent exposures that would require sequential or near-continuous courses of antiretroviral medications (eg, discordant sex partners who rarely use condoms, or injection drug users who often share equipment) should not take nPEP. These clients should be referred for or offered pre-exposure prophylaxis (PrEP).		

9.1.h. Flow Diagram: Assessment of Eligibility for nPEP*



*Call the National Clinicians Consultation Center PEPline at 1-888-448-4911 to review the case if there are questions about whether the exposure warrants the provision of nPEP.

**Prescribe emergency contraception, as indicated

[†]If possible, obtain information about the source's history of antiretroviral treatment, resistance profile, and current viral load; but do not delay the initiation of nPEP. Consider referral of the exposed client to an HIV provider, as choice of antiretrovirals for nPEP will be determined by the source's medication and resistance profile

[††]Breastfeeding women should be instructed to discontinue breastfeeding for 3 months after initiation of nPEP.

C. Management of nPEP
   1. Regimens for nPEP
      a. Recommended regimen — Raltegravir 400 mg twice daily plus tenofivir and emtricitabine (Truvada) once daily for 28 days (See Table 9.1.i.)
      b. Preferred alternative regimens
         i. Darunavir plus ritonavir plus tenofivir and emtricitabine (Truvada)
         ii. Atazanavir plus ritonavir plus tenofivir and emtricitabine (Truvada)

iii. Lopinavir/ritonavir (Kaletra) plus tenofovir and emtricitabine (Truvada)
iv. Fosamprenavir plus ritonavir plus tenofivir and emtricitabine (Truvada)
v. Any of the above protease inhibitor regimens plus zidovudine and lamivudine (Combivir)

2. Supply – a 7-day prescription may be given if the client needs to follow-up on lab results prior to continuing the entire 28-day course (follow up on testing of the source; CBC to rule out severe anemia for clients for whom zidovudine is prescribed; BUN/creatinine to rule out renal insufficiency).
3. Monitoring – **must** monitor client per Table 9.1.j.

9.1.i. Table: Anitretroviral Medications* Used for nPEP

Agent/Class	Standard Adult Dosage	Side Effects/Toxicities
Integrase Inhibitors		
Raltegravir (Isentress)	400 mg tablet twice daily	Flatulence. Severe potentially life threatening and fatal skin reactions have been reported, including Stevens-Johnson syndrome, TEN, and hypersensitivity reactions.
NRTI's		
Tenofovir/emtricitabine (TFV/FTC, Truvada)	1 tablet once daily 200 mg FTC/300 mg TFV	TFV: nausea, vomiting, diarrhea; headache; asthenia; flatulence; and renal impairment FTC: minimal toxicity; lactic acidosis and hepatic steatosis is a rare but possibly life-threatening event
Zidovudine/lamivudine (ZDV/3TC, Combivir)	1 tablet twice daily 300 mg ZDV/150 mg 3TC	ZDV: anemia, neutropenia, GI intolerance; headache; insomnia; asthenia, myopathy 3TC: minimal toxicity; lactic acidosis and hepatic steatosis is a rare but possibly life-threatening event
Protease Inhibitors/PI's		
Atazanavir (Reyataz)	300 mg once daily with ritonavir 100 mg daily	Indirect hyperbilirubinemia; increased PR interval
Darunavir (Prezista)	800 mg once daily with ritonavir 100 mg daily	Diarrhea, nausea, vomiting; asthenia; ⇧transaminases; hyperglycemia, fat redistribution; lipid abnormalities; pancreatitis

Agent/Class	Standard Adult Dosage	Side Effects/Toxicities
Fosamprenavir (Lexiva)	1400 mg once daily with ritonavir 100 mg daily, or 700 mg with ritonavir 100 mg twice daily	Diarrhea, nausea, vomiting; asthenia; ⇧transaminases; hyperglycemia, fat redistribution; lipid abnormalities; pancreatitis
Lopinavir/ritonavir (Kaletra)	1 tablet twice daily 400 mg lopinavir/100 mg ritonavir	Diarrhea, nausea, vomiting; asthenia; ⇧transaminases; hyperglycemia, fat redistribution; lipid abnormalities; pancreatitis
Ritonavir (Norvir)	100 mg in conjunction with a PI	Lipid abnormalities, multiple dug-drug interactions

*None of the antiretroviral agents has an FDA-approved indication for PEP.

9.1.j. Table: Monitoring Schedule for nPEP

	Baseline*	Week 1	Week 2	Week 4	Week 12	6 months
Health center visit	●	●*	●**	●**	●	●
Pregnancy test, as indicated	●					
CBC† BMP	●		●	●		
Rapid HIV test	●			●	●	●
STI screening	●		○††			
Hepatitis B and C	○††					○††

*Visit may be in-person or by phone

**GI side effects such as nausea and diarrhea can be managed with OTC antidiarrheal medications, or Rx compazine or loperamide

†Repeat CBC at 2 and 4 weeks only if prescribed zidovudine, as part of the combination pill Combivir.

††Consider testing as appropriate

VI. Management of Follow-up Testing Results

A. If HIV test done at 4 weeks is positive, continue nPEP and refer immediately to an experienced HIV provider.

B. If HIV test done at 12 weeks is positive, refer to an HIV provider. Provide the HIV provider with all available information about the antiretrovirals used for nPEP.

C. If client develops laboratory abnormalities at week 2 while taking nPEP (such as a drop in Hgb on zidovudine, or an increase in creatinine on tenofovir), discontinue the medication and refer the client to a primary care provider.

9.2 EVALUATION AND MANAGEMENT OF THE CLIENT WITH POSITIVE SCREENING TEST RESULTS OR SYMPTOMS

9.2.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

9.2.a. Table: Requirements for Written Materials as Indicated for Clients with Positive Screening Test Results or Symptoms

Document	Document #	**Must** sign	**Must** give	**Must** offer	Should give
CI Acute Pelvic Inflammatory Disease			●		
CI Directions for Sex Partners — Chlamydia (client delivered)			●		
CI Directions for Sex Partners — Gonorrhea (client delivered)			●		
CI Directions for Sex Partners — Trichomoniasis (client delivered)			●		
CI Genital Herpes			●		
CI STI Testing					●
CI Urinary Tract Infection (UTI)			●		
CIIC Treatment of Genital Warts			●		
CIIC Treatment of Molluscum Contagiosum			●		
CIIC Treatment without Testing			●		
CIIC Vulvar Biopsy		●	●		
Information on any medication dispensed (package insert may be used)			●		
Release When Test/Service Consultation Will Not Be Obtained As Recommended		Once			
Request for Surgery or Special Procedures		●		●	

9.2.2 Evaluation

I. Comprehensive sexual risk history - A comprehensive sexual risk history **must** be taken. One approach is the Five P's: Partners, Prevention of Pregnancy, Protection from STDs, Practices, and Past History of STDS

✓ CDC Clinical Prevention Guidance - Box 1 The Five P's

II. Evaluation by condition - After completion of the comprehensive sexual risk history and history of the chief complaint, clients **must** be evaluated according to 9.2.b.

9.2.b. Table: Evaluation of the Symptomatic Client*

✓ FYI — Physical Examination When Evaluating for an STI

Condition	Physical Examination	Laboratory Tests and Diagnostic Imaging
Cervicitis ✓ FYI — Cervicitis	**Must** include ▪ Pelvic exam ▪ Bimanual	Should include ▪ GC/CT tests, as indicated ▪ HSV test, as indicated ▪ HIV test, as indicated ▪ Evaluation for BV and trichomoniasis Note: Although Mycoplasma genitalium causes cervicitis, no FDA-cleared tests are available. This organism responds to medications used to treat chlamydia.
Chancroid ✓ FYI — Chancroid	If chancroid is suspected **must** refer to provider/health department with expertise in sexually transmitted infections.	
External Genital Warts (EGW) ✓ FYI — External Genital Warts	**Must** include ▪ Women - pelvic exam ▪ Men – inspection of external genitalia Notes: If perianal warts are present, should perform or refer for anoscopy to evaluate for intra-anal warts.	At time of original diagnosis, should include ▪ Syphilis test(s) ▪ Tests for other STIs and HIV, as indicated Vulvar/penile/perianal biopsy ▪ For women > age 50, vulvar biopsy **must** be performed for new vulvar lesions (except typical EGW which resolve after 1 or 2 treatments with topical therapy). ▪ Biopsy should be performed if EGW do not respond to therapy. ▪ Men with penile lesions suspicious for PIN **must** undergo penile biopsy before treatment.

Condition	Physical Examination	Laboratory Tests and Diagnostic Imaging
		Note: With immunosuppression, squamous cell carcinomas arising in or resembling genital warts may occur more frequently. Therefore, more liberal use of biopsy in lesions that do not respond to therapy is appropriate. (*CDC Guidelines*)
Genital herpes ✓ FYI — Genital herpes	**Must** include ▪ Examination of lesions ▪ Palpation of inguinal lymph nodes ▪ Speculum exam, if indicated	Should include ▪ For symptomatic clients -- direct test of the lesion(s) that can differentiate HSV-1 from HSV-2 ▪ For first episode -- syphilis test(s) ▪ Tests for other STIs and HIV, as indicated Other recommended testing ▪ HSV-2 serology to evaluate recurrent lesions suspicious for genital herpes but too old for direct testing/direct testing negative. Only type-specific (glycoprotein Gg-based) serology tests should be used. Note: Routine HSV-1 serology testing is not recommended
Molluscum Contagiosum ✓ FYI — Characteristics and Appearance of Molluscum Contagisum	**Must** include ▪ Women - pelvic exam ▪ Men – inspection of external genitalia Note: Using acetic acid may be helpful if diagnosis is uncertain or EGW are suspected.	Should include ▪ Tests for other STIs and HIV, as indicated
PID ✓ FYI — PID	**Must** include ▪ Temperature ▪ Pelvic exam ▪ Bimanual ▪ Rectovaginal exam, as indicated	Should include ▪ GC/CT tests ▪ Evaluation for BV and trichomoniasis ▪ Pregnancy test Consider performing ▪ Wet prep for white blood cells ▪ C-reactive protein ▪ ESR ▪ HIV, as indicated

Condition	Physical Examination	Laboratory Tests and Diagnostic Imaging
Syphilis	See 9.2.4	
Urethritis ✓ FYI — Urethritis	**Must** include ▪ Inspection of external genitalia ▪ Palpation of testes and epididymis ▪ "Milking" or stripping of the urethra by client ▪ Prostate exam, if acute prostatitis is suspected Notes: ▪ Classify discharge as bloody, mucoid, mucopurulent, purulent or serous. ▪ Consider prostatic massage if discharge cannot be elicited by stripping by client. Note the presence of tenderness that indicates acute prostatitis	Should include ▪ GC/CT tests Considering performing ▪ Leukocyte esterase test on first void urine if no discharge on examination
Urinary Tract Infection in women (See Chapter 12.3 for managing UTI in men)	**Must** include ▪ Temperature ▪ Lower abdominal examination ▪ Evaluation for costovertebral angle tenderness ▪ Pelvic exam, if indicated	Should include ▪ Evaluation of a midstream, clean-catch urine specimen ▪ Dipstick urinalysis of uncentrifuged sample (leukocyte esterase [LE], nitrite) or microscopic examination of urine sediment (the latter is preferred) ▪ Urine culture and sensitivity if pregnant and client is continuing with the pregnancy, if pyelonephritis is suspected, or if there is a recurrence within 1 to 2 weeks of completing therapy, or as otherwise indicated ▪ Microscopic evaluation of urethral discharge, when present ▪ Wet mount + KOH prep of vaginal discharge, when indicated ▪ Tests for STIs, if indicated Note: do not use midstream, clean catch urine specimen for gonorrhea and chlamydia NAAT tests

Condition	Physical Examination	Laboratory Tests and Diagnostic Imaging
Vaginal Infections ✓ FYI — Trichomoniasis ✓ FYI — Classification of Vulvovaginal Candidiasis	**Must** include inspection of the ▪ Vulva ▪ Vaginal walls — to evaluate amount, character, and color of discharge ▪ Cervix — to observe for edema, erythema, friability, lesions, and mucopus Should include bimanual to evaluate uterine or adnexal tenderness, cervical motion tenderness	**Must** include laboratory confirmation by ▪ Wet prep + KOH prep + amine test + vaginal pH **and/OR** ▪ FDA-approved tests for trichomoniasis and/or BV Should perform, as indicated: ▪ Other tests for STIs and HIV ▪ Fungal culture (for recurrent candida)
*Definitions: pelvic exam - inspection of external genitalia and speculum exam; wet prep– NaCl suspension; KOH prep – KOH suspension		

9.2.3 Management

I. Management of positive screening test results
   A. **Must** treat according to the current CDC STD Treatment Guidelines or recommendations of local/state health department
   B. Should test all clients diagnosed with acute STI for other STIs and HIV. See specific conditions in Table 9.2.c.

II. Management of clients who report exposure
   A. Should treat presumptively according to the current CDC STD Treatment Guidelines or recommendations of local/state health department.
   B. Should test for STIs and HIV as determined by risk.

III. Empiric therapy – in some cases, a presumptive diagnosis can be made on the basis of clinical presentation, and empiric treatment is permitted. However, indicated diagnostic testing should still be performed. See Table 9.2.c.

IV. Client-delivered Partner Therapy (may be offered if permitted by state law)
   A. **Must** provide client with
      1. Medication for the partner **OR** a prescription in accordance with state laws/regulations
      2. Written information as noted in Table 9.2.a.
   B. Clients deliver the treatment to their partners and are responsible for giving their partners the appropriate medication and CIs.

V. Management by condition - **must** treat per Table 9.2.c.

9.2.c. Table: Management by Condition

Condition	Management	Follow-up/Referrals/Partner Management
Bacterial Vaginosis	▪ **Must** treat per CDC STD Treatment Guidelines or recommendations of local/state health department ✓ CDC STD Treatment Guidelines ▪ Indications for treatment ○ Symptomatic infection ○ Positive clinical criteria or confirmatory commercially available tests ▪ Pregnancy ○ Symptomatic BV **must** be treated. ○ Topical clindamycin is contraindicated in the second half of pregnancy. ○ Treatment for asymptomatic women is optional, but may be considered in women who are at high risk for preterm delivery.	Follow-up ▪ Test of cure not necessary. ▪ Advise client to return for reevaluation if symptoms fail to resolve, or they recur after treatment. ▪ Pregnancy – consider follow-up evaluation 1 month after completion of treatment to evaluate whether therapy was effective. Referrals — should refer women with multiple recurrences Partner Management —Routine treatment of sex partners is not recommended.
Cervicitis & CT/GC Infections	▪ **Must** treat per CDC STD Treatment Guidelines or recommendations of local/state health department ✓ CDC STD Treatment Guidelines ▪ Empiric treatment - consider for clients who are suspected of having gonorrhea and/or chlamydia when: ○ Client at risk for STI ○ CT/GC prevalence high in population ○ Client not likely to return for follow up and/or treatment. ○ >10 WBC/HPF in vaginal fluid in the absence of trichomoniasis ○ A sex partner was recently treated for CT and/or	**Follow-up** ▪ Test of Cure (TOC) is generally not recommended. TOC is indicated 1 to 3 weeks after treatment in the following situations: ○ GC/CT • Client is pregnant • Persistent symptoms despite therapy • Not treated with recommended antibiotic ○ GC only - if treated with regimen other than dual therapy with an injectable cephalosporin • TOC by culture preferred. NAAT acceptable if culture not available. • If NAAT TOC positive, make every effort to perform

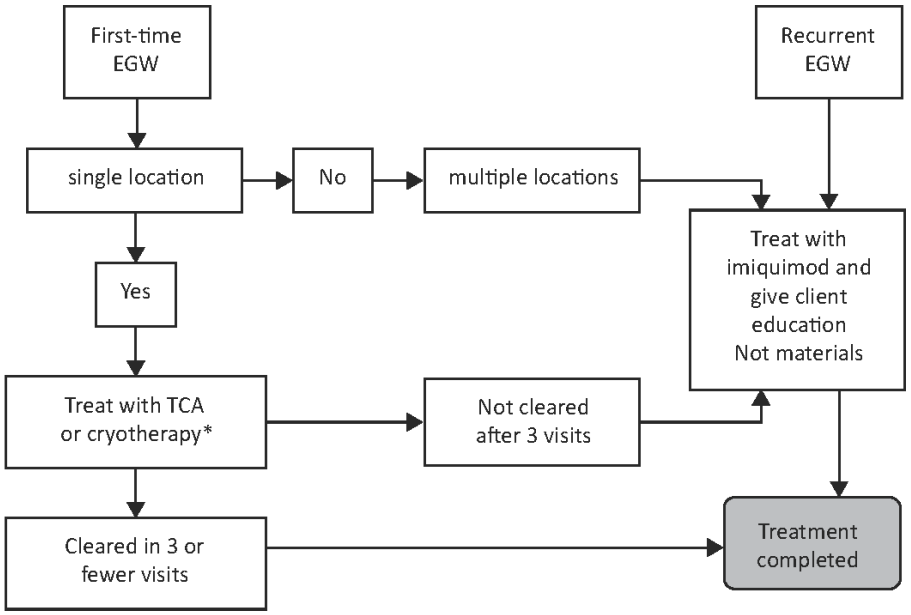
<table>
<tr><th>Condition</th><th>Management</th><th>Follow-up/Referrals/Partner Management</th></tr>
<tr>
<td></td>
<td>
GC — base client's treatment on sex partner's treatment
○ Prior to invasive procedures, whether or not procedure postponed.
▪ Treatment based on lab results
<table>
<tr><th>GC Test</th><th>CT Test</th><th>Treatment Recommendation</th></tr>
<tr><td>Positive</td><td>Positive</td><td>Treat for CT and GC</td></tr>
<tr><td>Negative</td><td>Positive</td><td>Treat for CT.</td></tr>
<tr><td>Positive</td><td>Negative</td><td>Treat for GC with dual therapy.
▪ Injectable cephalosporin preferred regimen for GC; oral cephalosporin is acceptable alternative only when administration of injectable is not possible and site of infection is genital
▪ Only injectable cephalosporin recommended for pharyngeal GC.</td></tr>
<tr><td>Negative</td><td>Negative</td><td>If CT treatment already started, complete course.</td></tr>
</table>
▪ Penicillin allergies
○ Severe allergic reaction to penicillin (IgE mediated allergy) such as anaphylaxis, hypotension, laryngeal edema, wheezing, angioedema and/or uticaria - must consult with an infectious disease
</td>
<td>
confirmatory culture.

Note: TOC using NAATs—wait at least 3 weeks post treatment for CT TOC to avoid false positive. Best to wait 10 to 14 days post treatment for GC TOC to avoid false positives. Culture will be negative by 1 week.

▪ Suspected treatment failure or positive NAAT TOC after ruling out medication non-compliance or re-infection
○ CT - Antibiotic resistance rare. Most likely causes are non-compliance with medication or re-infection. Re-testing and retreatment as indicated. Ensure partners all treated.
○ GC
• After treatment with alternative regimens
♦ Give ceftriaxone 250 mg as single intramuscular dose and azithromycin 2 g orally as single dose
♦ Consult infectious disease specialist
♦ Report to CDC through local or state health department
• After treatment with recommended does of injectable cephalosporin
♦ Perform culture and susceptibility testing of relevant clinical specimens
♦ Consult infectious disease specialist
♦ Report to CDC through local or state health department

▪ Testing for reinfection – must be recommended following
</td>
</tr>
</table>

Condition	Management	Follow-up/Referrals/Partner Management
	specialist ✓ FYI —using Cephalosporins for Clients with a History of PCN Allergy ○ Mild allergic reaction to penicillin -3rd generation cephalosporins may be prescribed or administered.	diagnosis of CT and/or GC 3 months after treatment or whenever client presents for care within the following 12 months. Also consider if client returns reporting medicine non-compliance or re-exposure **Partner Therapy** ▪ All sex partners in the 60 days prior to diagnosis should be referred for evaluation and treatment. ▪ For GC, because ceftriaxone injection is preferred regimen for treatment, client-delivered partner therapy should be considered as last resort (i.e. the partner would not be treated otherwise)
Chancroid	If chancroid is suspected **must** refer to provider/health department with expertise in sexually transmitted infections.	
External Genital Warts (EGW)	▪ **Must** treat per CDC STD Treatment Guidelines or recommendations of local/state health department or with other FDA approved therapy ✓ CDC STD Treatment Guidelines ▪ One possible treatment algorithm for non-pregnant women and men, based on a pharmacoeconomic study at several Planned Parenthood affiliates (Fine 2007) – see Algorithm 9.2.d. Management of EGW	

<table>
<tr><th>Condition</th><th>Management</th><th>Follow-up/Referrals/Partner Management</th></tr>
<tr><td></td><td colspan="2">9.2.d. Algorithm: Management of EGW
 

* Apply every 1 to 2 weeks, but can be as frequent as every 4 to 7 days, depending upon response to therapy. After first treatment, client should return in one week for reevaluation. If intense skin reaction is seen, subsequent treatments should be provided at 10 to 14 day intervals. If first treatment is well tolerated, treatment can be given weekly. Treatment may be continued for as long as response is evident.
**If lesions do not respond after 3 treatments, or if lesions respond but do not completely resolve after 6 treatments, the modality should be changed. If there is no response to a second treatment modality, biopsy should be performed or the client should be referred to an expert in vulvar lesions.</td></tr>
<tr><td>Genital herpes</td><td>▪ Must counsel and treat per CDC STD Treatment Guidelines or recommendations of local/state health department
✓ CDC STD Treatment Guidelines
○ For clients with recurrent HSV, both suppressive</td><td>Follow-up
▪ For new HSV diagnoses consider at least 1 follow-up visit for counseling and management of long-term disease.
▪ For clients on suppressive therapy, annual assessment of need to continue therapy is recommended.</td></tr>
</table>

Condition	Management	Follow-up/Referrals/Partner Management
	and episodic therapy should be offered.	**Referrals** - **Must** refer the following ▪ Urinary retention requiring catheterization (unless affiliate offers Level II or Level IIII GYN services) ▪ Pain not relieved by oral narcotic analgesics ▪ Systemic HSV infection, including herpes encephalitis, disseminated herpes, outbreaks that include eyes or throat, or extensive involvement of extra genital skin surfaces
Molluscum Contagiosum	▪ Most cases spontaneously regress within 6 to 12 months. Treatment may be offered for cosmetic purposes and to avoid further autoinoculation or spread to others. ▪ Treatment of choice is sharp curettage with a lancet or hollow needle tip. ▪ TCA or BCA applications, cryotherapy, or patient-applied imiquimod also are successful.	Follow-up ▪ Should be offered in 4 weeks to evaluate and treat new lesions or ▪ Ask client to self-examine and return only if old lesions persist or new lesions develop **Referrals** – **Must** refer the following ▪ Extensive cases (more than 50–100 lesions) ▪ Frequent recurrences ▪ Lesions >1cm
PID	▪ **Must** treat per CDC STD Treatment Guidelines or recommendations of local/state health department. ✓ CDC STD Treatment Guidelines ▪ PID with IUC in place ○ Removal not required if clear signs of clinical improvement after initiation of treatment and client's clinical course can be followed closely. ○ IUC **must** be removed if client does not respond to treatment for PID. ○ Contraceptive counseling **must** be provided if IUC is removed. ▪ Hospitalization is required when	**Follow-up** ▪ IUC Users ○ **Must** advise return visit in 24-48 hours • If no improvement, consider removal ♦ If removed, **must** advise return in 24 hours ♦ If not removed, **must** refer for hospitalization **and** ○ 4-7 days after completion of treatment ▪ Non-IUC Users ○ **Must** advise return visit in 48-72 hours for reevaluation **and**

Condition	Management	Follow-up/Referrals/Partner Management
	○ Surgical emergencies, e.g., appendicitis or ectopic pregnancy, cannot be excluded ○ Client is pregnant, even if abortion is planned ○ Client is clinically unresponsive to oral antimicrobial therapy ○ Client is unable to follow or tolerate outpatient oral regimen ○ Client has severe illness (either acute or chronic), nausea and vomiting, or a high fever — greater than 102.2°F ○ Client has tubo-ovarian abscess	○ 4-7 days after completion of treatment **Referrals – must** refer the following ▪ Pelvic pain or tenderness worsens ▪ Client unable to comply with treatment regimen ▪ Pelvic or adnexal mass developed since initial exam ▪ Fever has not subsided ▪ Client is pregnant **Partner Management** All sex partners in 60 days preceding the onset of client's symptoms should be offered treatment with regimen for CT/GC.
Syphilis	See 9.2.4	
Trichomoniasis	▪ **Must** treat per CDC STD Treatment Guidelines or recommendations of local/state health department ✓ CDC STD Treatment Guidelines ▪ Indications for treatment ○ Trichomoniasis confirmed by wet prep, culture, or other FDA-cleared test ○ Trichomonads on Pap ○ Asymptomatic client who reports partner was treated for trichomoniasis	**Follow-up** ▪ Test of cure not necessary. ▪ Advise client to return for reevaluation if symptoms fail to resolve or if they recur after treatment. ▪ Testing for reinfection should be considered 3 months after treatment. **Referrals – must** refer if trichomoniasis is unresponsive to therapy or medications are contraindicated. **Partner Management** ▪ Client-delivered partner therapy may be offered if permitted by state law. ▪ All recent sex partners should be referred for evaluation and treatment.

<table>
<tr><th>Condition</th><th>Management</th><th>Follow-up/Referrals/Partner Management</th></tr>
<tr>
<td>Urethritis in Men (and lab confirmed CT/GC)</td>
<td>
▪ Must treat per CDC STD Treatment Guidelines or recommendations of local/state health department
✓ CDC STD Treatment Guidelines
▪ Empiric treatment
○ Treatment should be offered if
• Any signs of urethritis present
• Client reports partner was treated for GC and/or CT
○ Confirmed urethritis should be treated for both gonorrhea and chlamydia. If gonococcal infection can be ruled out, treat for chlamydial infection.
○ If diagnostic criteria absent, empiric treatment of symptomatic clients is recommended only for clients at high risk for infection who are unlikely to return for follow-up. Otherwise, treatment should be deferred and client should be tested for GC/CT
▪ Treatment based on lab results
<table>
<tr><th>GC Test</th><th>CT Test</th><th>Treatment Recommendation</th></tr>
<tr><td>Positive</td><td>Positive</td><td>Treat for CT and GC</td></tr>
<tr><td>Negative</td><td>Positive</td><td>Treat for CT.</td></tr>
<tr><td>Positive</td><td>Negative</td><td>Treat for GC with dual therapy.
▪ Injectable cephalosporin preferred regimen for GC; oral cephalosporin is acceptable alternative only when administration of injectable is</td></tr>
</table>
</td>
<td>
Follow-up
▪ TOC – for test of cure, see Cervicitis above
▪ If treatment failure suspected, see Cervicitis above
▪ Testing for reinfection is recommended following diagnosis of CT and/or GC 3 months after treatment or whenever client presents for care within the following 12 months

Referrals – must refer the following:
▪ Acute epididymitis — unless affiliate provides Men’s Sexual and Reproductive Health Services
▪ Acute orchitis or suspicion of testicular torsion —to surgeon or ER immediately
▪ Prostatitis that does not improve with treatment
▪ Masses or other lesions of genital skin, scrotum, or testes, found on exam — unless affiliate provides Men’s Sexual and Reproductive Health Services

Partner Management
▪ Client-delivered partner therapy may be offered if permitted by state law.
▪ All sex partners in the 60 days prior to diagnosis should be referred for evaluation and treatment.

Note about GC: Due to fact that ceftriaxone injection is preferred regimen for treatment of GC, client-delivered partner therapy for GC should be considered as a last resort (i.e. the partner would not be treated otherwise)
</td>
</tr>
</table>

<table>
<tr><th>Condition</th><th>Management</th><th>Follow-up/Referrals/Partner Management</th></tr>
<tr>
<td></td>
<td>
<table>
<tr><td></td><td></td><td>not possible and site of infection is genital
▪ Only injectable cephalosporin recommended for pharyngeal GC.</td></tr>
<tr><td>Negative</td><td>Negative</td><td>If CT treatment already started, complete course.</td></tr>
</table>
▪ Penicillin allergies
○ Severe allergic reaction to penicillin (IgE mediated allergy) such as anaphylaxis, hypotension, laryngeal edema, wheezing, angioedema and/or uticaria - must consult with an infectious disease specialist
○ Mild allergic reaction to penicillin - 3rd generation cephalosporins may be prescribed or administered.
✓ FYI —using Cephalosporins for Clients with a History of PCN Allergy
</td>
<td></td>
</tr>
<tr>
<td>Urinary Tract Infection in Women (See Chapter 12.3 for managing UTI in men)

✓ FYI – Symptoms of UTI
✓ FYI – Cranberry Supplementation in the Prevention</td>
<td>
▪ If bacteruria confirmed, treat for cystitis with appropriate medications.
<table>
<tr><th>First line treatments for uncomplicated lower UTI</th><th>Alternative treatments</th></tr>
<tr><td>▪ Nitrofurantoin monohydrate macrocrystals (100 mg) twice daily x 5 days or
▪ Trimethoprim-</td><td>▪ Ciprofloxacin (250 mg) twice daily x 3 days* or
▪ Levofloxacin (250 mg) daily x 3 days*</td></tr>
</table>
</td>
<td>
Follow-up
▪ Clients treated for pyelonephritis must be advised to make contact (telephone or visit) within 48 hours for follow-up evaluation.
▪ Clients treated for lower UTI must be instructed to call for an appointment if symptoms have not improved after 3 days of treatment.
▪ If symptoms recur within 1 week of completion of treatment, consider treatment failure due to a resistant organism or reinfection (less likely). Either refer the client or change
</td>
</tr>
</table>

<table>
<tr><th>Condition</th><th>Management</th><th>Follow-up/Referrals/Partner Management</th></tr>
<tr>
<td>of Recurrent UTI</td>
<td>
<table>
<tr><td>sulfamethoxazole (TMP-SMX) (160/800 mg [1 double strength tablet]) twice daily x 3 days</td><td>* Fluoroquinolones are preferred for recurrences within 2 weeks, but should be avoided as initial therapy for uncomplicated lower UTI to help prevent emergence of resistant organisms.</td></tr>
</table>

If pyuria (WBCs in urine) confirmed in uncontaminated urine sample but bacteria absent, treat for urethritis and ensure testing for GC/CT.
If urethral discharge present and WBCs confirmed on microscopy, treat for urethritis and ensure testing for GC/CT.
If bacteruria, pyuria, or urethral discharge not present, routine antibiotic therapy for UTI is not indicated. Once vaginitis has been excluded, symptomatic therapy, e.g., phenazopyridine may be offered. Consider other causes of dysuria, such as CT and genital herpes.
If neither bacteruria nor pyuria present, but UTI still suspected, especially with pregnancy, send urine culture and initiate empiric antibiotic therapy. Treatment should be discontinued if culture reveals no growth.
If client's pattern of lower UTIs appears related to sexual intercourse, regimen of antibiotic prophylaxis may be offered. Example: nitrofurantoin 50 mg post intercourse.

</td>
<td>
antibiotics and perform urine culture and sensitivity (if not yet done).

If culture is positive, give client a course of medication that has proven sensitivity. Consult an affiliate physician if organism is resistant to all drugs listed in the affiliate medical protocol.
If culture shows no growth, consider possibility of urethritis, and test for urethral chlamydia and gonorrhea. Presumptive treatment may be started while awaiting results.
If symptoms persist despite these measures, refer for further evaluation.

Referrals

Clients with UTI who have been treated at the affiliate must be referred if

Condition worsens
Hematuria persists
Condition is unresponsive to treatment after 72 hours of therapy with an antibiotic the organism is sensitive to and with the onset of any of the conditions listed below.

Clients with UTI and any of the following conditions must not be treated at the affiliate and must be referred promptly

Nausea, vomiting, or anorexia that may preclude use of oral antibiotics
Severe immune compromise that could affect response to treatment
Findings consistent with peritonitis

</td>
</tr>
</table>

<table>
<tr><th>Condition</th><th>Management</th><th>Follow-up/Referrals/Partner Management</th></tr>
<tr>
<td></td>
<td>
Established Clients — Prescriptions for lower UTI treatment for established clients may be provided after telephone evaluation and without a clinic visit if history is obtained by an APC, nurse, or physician. There must be no history consistent with STI, pregnancy, or of urinary lithiasis, chills, fever, flank pain, or those conditions listed under “referrals”.

Treatment for pyelonephritis — may be offered only to non-pregnant clients who agree to make contact (telephone or visit) for follow-up within 48 hours of initiating therapy and who have none of the conditions listed under “referrals”.
<table>
<tr><th>First line treatments for uncomplicated pyelonephritis</th><th>Alternative treatment</th></tr>
<tr>
<td>▪ Ciprofloxacin (500mg) twice daily x 7 days or
▪ Ciprofloxacin (1000 mg extended release) once daily x7 days or
▪ Levofloxacin (750 mg) once daily x5 days</td>
<td>▪ Trimethoprim-sulfamethoxazole (TMP-SMX) (160/800 mg [1 double strength tablet]), twice daily x 14 days</td>
</tr>
</table>
</td>
<td>
○ Significant dehydration that requires IV fluid replacement
○ Suspicion of sepsis
○ History of active or chronic renal disease (other than UTI)
○ Known anatomic variants which may predispose to upper UTI

▪ Clients with history of 3 occurrences of UTI in the past 12 months who present with a UTI must be treated and then referred for evaluation of underlying anatomic or physiologic predisposing conditions, unless these conditions were excluded previously.
</td>
</tr>
<tr>
<td>Vulvovaginal candidiasis</td>
<td>
▪ Must treat per CDC STD Treatment Guidelines or recommendations of local/state health department
✓ CDC STD Treatment Guidelines
▪ Candidal vulvitis — Non-fluorinated topical
</td>
<td>Follow-up - If condition resolves as expected, no follow-up necessary.</td>
</tr>
</table>

Condition	Management	Follow-up/Referrals/Partner Management
	corticosteroids appropriate for genital application may be added to antifungal therapy in order to treat vulvar inflammation. ▪ Indications for treatment ○ Symptomatic candidiasis, confirmed by KOH prep or culture or other tests for yeast ○ Candidal hyphae on Pap test in a symptomatic client — Offer treatment, exam not necessary. ○ Prophylactic antifungal treatment in woman with predisposition to candidiasis when exposed to inciting factor (e.g., broad spectrum antibiotic use). ○ Symptoms suggestive of and vaginal discharge characteristic of VVC, but microscopic evaluation failed to confirm candida and unable to perform fungal culture — consider empiric treatment. Note: Antifungal prophylaxis should not be used when there is no previous history of candidal infection.	

9.2.4 Evaluation and Management of Syphilis

I. Interpretation and management of positive screening test results in asymptomatic clients

✓ FYI – Syphilis Screening and Testing Algorithms

A. When interpreting and managing positive screening tests, Tables 9.2.e. and 9.2.f. **must** be followed.

9.2.e. Table: Interpretation and Management of Positive Screening Tests with Initial Non-Treponemal (RPR/VDRL) Tests in Asymptomatic Clients (Routine Screening)

RPR or VDRL (Non-treponemal screening test)	TP-PA, EIA/CIA (Treponemal confirmatory test)	Interpretation	Management - treat per CDC STD Guidelines, as indicated *If not done already, assess for prior history/treatment for syphilis, perform risk assessment, physical exam (i.e., skin, oral, anogenital, ocular, neurologic) as indicated.*
Positive	Positive	Untreated syphilis likely	▪ Determine whether early, late or unknown duration or refer for evaluation ✓ FYI — Four Stages of Syphilis Infection ✓ FYI — Laboratory findings based upon stage of syphilis ▪ Treat per CDC STD Treatment Guidelines or refer for treatment ✓ CDC STD Treatment Guidelines
Positive	Negative	Biologic false positive likely	▪ No further evaluation for syphilis is necessary ▪ Other conditions that can cause biologic false positive results should be considered ✓ FYI — Causes of Biologic False Positive VDRL or RPR
Abbreviations: EIA-enzyme immunoassay; CIA-chemiluminescence immunoassay; RPR-rapid plasma reagin; VDRL-Venereal Disease Research Laboratory; TP-PA-Treponema pallidum particle agglutination assay			

9.2.f. Table: Interpretation and Management of Positive Screening Tests with Initial Treponemal (EIA/CIA) Tests in Asymptomatic Clients (Routine Screening)

EIA or CIA	RPR or VDRL	TP-PA or FTA/ABS*	Possible Interpretations†	Management - treat per CDC STD Guidelines, as indicated *If not done already, assess for prior history/treatment for syphilis, perform risk assessment, physical exam (i.e., skin, oral, anogenital, ocular, neurologic) as indicated.*
Positive	Positive	Not done or Positive or Negative	Latent syphilis Prior syphilis (treated or untreated) Early (incubating)	▪ If previously untreated, treat for appropriate stage of syphilis or refer for treatment. ✓ CDC STD Treatment Guidelines ▪ If treatment given, obtain quantitative RPR/VDRL on the day of treatment and at recommended intervals to monitor response. ▪ If previously treated **and** 4-fold increase in titer, manage as treatment failure

EIA or CIA	RPR or VDRL	TP-PA or FTA/ABS*	Possible Interpretations†	Management - treat per CDC STD Guidelines, as indicated *If not done already, assess for prior history/treatment for syphilis, perform risk assessment, physical exam (i.e., skin, oral, anogenital, ocular, neurologic) as indicated.*
			syphilis	versus re-infection or refer for treatment. ▪ If previously treated with recommended therapy **and** 4-fold decrease in titer, no further action necessary.
Positive	Negative	Positive	Latent syphilis Prior syphilis (treated or untreated) Early (incubating) syphilis	▪ If previously untreated, treat for appropriate stage of syphilis or refer for treatment. ✓ CDC STD Treatment Guidelines ▪ If treatment given because incubating syphilis suspected, obtain quantitative RPR/VDRL on day of treatment. If RPR/VDRL negative, repeat in 2 to 4 weeks to see if seroconversion occurred. ▪ If previously treated, negative clinical exam, and no recent risk of exposure, no further action necessary.
Positive	Negative	Negative	Latent syphilis Prior syphilis (treated or untreated) Early (incubating) syphilis False positive EIA	▪ If previously untreated and client at risk for syphilis, repeat testing in 2 to 4 weeks. If RPR/VDRL and TP-PA still negative, no further action necessary. ▪ If previously treated, negative clinical exam, and no recent risk of exposure, no further action necessary.

Abbreviations: EIA-enzyme immunoassay; CIA-chemiluminescence immunoassay; RPR-rapid plasma reagin; VDRL-Venereal Disease Research Laboratory; TP-PA-Treponema pallidum particle agglutination assay;
* If TP-PA not available, FTA-ABS (fluorescent treponemal antibody-absorption test) may be used, but sensitivity and specificity are lower than that of TP-PA.
†Likelihood of interpretation depends on client's risk factors for syphilis and past medical history.
Adapted from California Department of Public Health

II. Evaluation and Management of Symptomatic Clients

A. Evaluation

9.2.g. Table: Evaluation of Symptomatic Clients

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Must include ▪ HPI ○ History of genital, anal or oral sores, ulcers or other lesions, rash, lymph node enlargement, sore throat, alopecia, constitutional symptoms such as fever, headache, fatigue or night sweats, ▪ Neurologic ○ Headache, photophobia, neck stiffness, nausea, vomiting, visual changes, dizziness, seizures, aphasia, focal weakness, hemiplegia and cranial nerve palsies (including hearing loss or tinnitus) ▪ Sexual history ○ Recent sexual contact with a person with syphilis or other STIs, date of last sexual contact ○ Previous history of diagnosis of or treatment for syphilis; date treatment received, subsequent follow-up, including titer levels ▪ Behavioral risk markers ○ Male with male sex partner(s) ○ Female with bisexual male partner(s) ○ Exchange of money or drugs for sex ○ Incarceration or partner incarceration ○ Illicit drug use ○ Multiple or anonymous partner ○ Whose sex partners participate in these activities	**Must** include ▪ Oral cavity (chancre, mucous patches) ▪ Lymph nodes ▪ Skin of torso, palms and soles (rash) ▪ Neurologic system including cranial nerves, especially II, VI, VII, VIII ▪ Genitalia and perianal area (chancre, rash, mucous patches, condyloma lata)	**Must** include ▪ Non-treponemal serologic tests for syphilis (RPR, VDRL) and confirmatory treponemal tests (FTA, TPPA, EIA/CLIA) **OR** ▪ Reverse Sequence Serology Screening - treponemal EIA/CIA test reflexed to a non-treponemal test (VDRL or RPR). ▪ Other tests for STIs and HIV

III. Diagnosis and Management in a Symptomatic Client

A. When interpreting and managing laboratory testing, Tables 9.2.h. and 9.2.i. **must** be followed.

9.2.h. Table: Interpretation and Management of Testing Results with Initial Non-treponemal (RPR/VDRL) in Symptomatic Clients

RPR or VDRL (Non-treponemal screening test)	FTA, TP-PA, EIA/CIA (Treponemal confirmatory test)	Interpretation	Management – treat per CDC STD Guidelines, as indicated
Client with new genital ulcer or suspicious genital lesion*			
Positive	Positive	Primary syphilis	▪ Treat or refer for treatment ✓ CDC STD Treatment Guidelines ▪ See follow up below
Positive	Negative	Biologic false positive likely	▪ Repeat RPR or VDRL in 2 to 4 weeks if no other etiology identified. If reactive then repeat TP-PA or FTA-ABS ○ If TP-PA or FTA-ABS is negative, RPR/VDRL is biologic false positive ▪ Consider other etiologies ○ HSV ○ Other conditions ✓ FYI — Causes of Biologic False Positive VDRL or RPR
Client with new onset rash, atypical warty lesion or other signs and symptoms of secondary syphilis ✓ FYI – Four Stages of Syphilis Infection			
Positive	Positive	Secondary syphilis	▪ Treat or refer for treatment ✓ CDC STD Treatment Guidelines
Positive	Negative	Biologic false positive	
*If risk factors (MSM or high risk sexual behavior) or clinical exam with classic features of syphilitic ulcer, presumptive treatment is recommended.			

9.2.i. Table: Interpretation and Management of Testing Results with Initial Treponemal EIA/CIA in Symptomatic Clients (e.g., Genital Ulcer or Rash)

✓ FYI —Jarisch Herxheimer Reaction

EIA or CIA	RPR or VDRL	TP-PA or FTA/ABS*	Possible Interpretations†	Management - treat per CDC STD Guidelines, as indicated
Positive	Positive	Not done or Positive or Negative	Probable early syphilis Prior syphilis (treated or untreated)	▪ Treat for appropriate stage of syphilis (primary or secondary). ✓ CDC STD Treatment Guidelines ▪ Obtain quantitative RPR/VDRL on the day of treatment and at recommended intervals to monitor response.
Positive	Negative	Positive	Probable early syphilis Prior syphilis (treated or untreated)	▪ Treat for appropriate stage of syphilis (primary or secondary). ✓ CDC STD Treatment Guidelines ▪ Obtain quantitative RPR/VDRL on the day of treatment. If RPR/VDRL negative, repeat in 2 to 4 weeks to see if seroconversion occurred.
Positive	Negative	Not done or Negative	Possible early syphilis Prior syphilis (treated or untreated) False positive EIA – alternative diagnosis	▪ Reassess client. If alternate diagnosis favored or confirmed by laboratory testing, no further action necessary. ▪ If clinical suspicion for syphilis persists, treat for appropriate stage of syphilis. ▪ If treatment given, obtain quantitative RPR/VDRL on the day of treatment. If RPR/VDRL negative, repeat in 2 to 4 weeks to see if seroconversion occurred.

Abbreviations: EIA-enzyme immunoassay; CIA-chemiluminescence immunoassay; RPR-rapid plasma reagin; VDRL-Venereal Disease Research Laboratory; TP-PA-Treponema pallidum particle agglutination assay

* If TP-PA not available, FTA-ABS (fluorescent treponemal antibody-absorption test) may be used, but sensitivity and specificity are lower than that of TP-PA.

† Likelihood of interpretation depends on client's risk factors for syphilis and past medical history.

Adapted from California Department of Public Health

IV. Follow up, Referrals, and Partner Management for Clients Treated for Syphilis

9.2.j. Table: Follow-up, Referrals, and Partner Management for Clients Treated for Syphilis

<table>
<tr><td rowspan="4">Follow Up
Tests must be quantified to the highest titer and titer on day of treatment must be used to assess treatment response
Always use the same testing method (RPR or VDRL) in sequential testing; cannot compare titers from the 2 tests</td><td>Stage</td><td>Schedule</td></tr>
<tr><td>Primary and secondary</td><td>1 to 2 weeks and 4 weeks after treatment: clinical follow-up
6 and 12 months: serologic follow-up for HIV negative clients (on-site or by referral)</td></tr>
<tr><td>Latent</td><td>6, 12, and 24 months after treatment: serologic follow-up (on site or by referral)</td></tr>
<tr><td>In pregnancy</td><td>28 to 32 weeks gestation, at delivery, and following the recommendations for the stage of disease: serologic follow-up
Monthly serologic titers in women at high risk for reinfection or in geographic areas in which the prevalence of syphilis is high should be considered. The clinical and antibody response should be appropriate for the stage of disease.
Note: Majority of women will deliver before serologic response to treatment can be assessed definitively. Inadequate maternal treatment is likely if delivery occurs within 30 days of therapy, if clinical signs of infection are present at delivery, or if the maternal antibody titer is 4-fold higher than the pretreatment titer</td></tr>
<tr><td>Referrals</td><td colspan="2">Must refer the following clients:
Tertiary syphilis diagnosed or suspected
With neurologic symptoms or signs who require lumbar puncture for evaluation of possible central nervous system involvement – see CDC STD Treatment Guidelines
If pregnant and allergic to penicillin
If HIV-positive
When quantitative VDRL or RPR does not decrease by 4-fold within 12 months of treatment for primary, secondary or early latent syphilis or within 24 months of treatment for late latent syphilis</td></tr>
</table>

<table>
<tr><td>Partner Management</td><td>

Client-delivered partner therapy is not appropriate.
All at-risk sex partners should be evaluated and managed in consultation with local health department:

<table>
<tr><th>Client with</th><th>At risk sex partners include those exposed</th></tr>
<tr><td>Primary syphilis</td><td>Within 3 months of diagnosis plus the duration of symptoms of the person diagnosed</td></tr>
<tr><td>Secondary syphilis</td><td>Within 6 months of diagnosis plus the duration of symptoms of the person diagnosed</td></tr>
<tr><td>Early latent</td><td>up to 1 year preceding diagnosis</td></tr>
</table>
</td></tr>
</table>

9.3 ADDITIONAL INFORMATION

9.3.a. Table: For Your Information

Section	Topic	Detail
9.1	National Evidence-Based Guidelines	National evidence-based guidelines support screening for chlamydia and gonorrhea among women age 25 and younger. However, there are no national guidelines supporting routine chlamydia or gonorrhea screening among heterosexual men. CDC published permissive guidelines for chlamydia screening among young males in areas/venues with high prevalence (e.g., STD clinics, correctional facilities, adolescent clinics) or risk factors (recent history of CT/GC).
9.1	Risk Factors for GC/CT in Females	▪ History of CT, GC, urethritis, or PID within the last 2 years ▪ Concurrent STI — CT, GC, syphilis, HIV, trichomoniasis ▪ Sexual contact to partner with chlamydia, gonorrhea, or symptoms consistent with GC/CT, Trichomonaisis, syphilis, or HIV ▪ New partner or partners in the past 3 months ▪ Multiple partners in the past year ▪ Having sex in exchange for money or drugs ▪ Suspects recent partner has other partner(s) ▪ In some areas, certain race/ethnic groups (e.g., African Americans) are at higher risk of chlamydia/gonorrhea infections

Section	Topic	Detail	
9.1	Populations Needing Hepatitis B and Hepatitis C Screening	**Hepatitis B** ▪ Persons born in geographic regions with HBsAg prevalence of ≥2% ▪ U.S.-born persons not vaccinated as infants whose parents were born in regions with high HBV endemicity (≥8%) ▪ Past or current injection drug users ▪ Men who have sex with men ▪ Persons receiving cytotoxic or immunosuppressive therapy ▪ Persons with liver disease of unknown etiology (persistently elevated ALT or AST levels) ▪ Hemodialysis patients ▪ All pregnant women ▪ Infants born to HBsAg-positive mothers ▪ Household contact, needle-sharing, or sex contact of person known to be HBsAg positive ▪ All persons with HIV infection	**Hepatitis C** ▪ Persons who ever injected illegal drugs, including those who injected once or a few times many years ago. ▪ Persons who received a blood transfusion or organ transplant before July 1992. ▪ Persons who received clotting factor concentrates before 1987. ▪ Persons who were ever on long-term dialysis. ▪ Children born to HCV-positive women. ▪ Healthcare, emergency medical, and public safety workers after needlesticks, sharps, or mucosal exposures to HCV-positive blood. ▪ Recipients of blood or organs from a donor who later tested HCV positive ▪ Persons with evidence of chronic liver disease. ▪ All persons with HIV infection
9.1	PreExposure Prophylaxis for Prevention of HIV[R8]	PreExposure Prophylaxis (PrEP) is defined as the administration of antiretroviral medications to individuals who are not infected with HIV and are at the highest risk of acquiring HIV infection. In 2012, PrEP was recommended by the CDC as part of a comprehensive HIV-prevention strategy. The single pill, fixed dose of tenofovir and emtricitabine has been approved by the FDA for this indication. Both drugs are HIV reverse transcriptase inhibitors. The advantages include once daily oral dosage, known safety and tolerability, and potent antiretroviral activity. Clinical trials demonstrated that adherence to the medication regimen was the most important factor in reducing risk of HIV infection.	

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>9.1</td><td>Risk for HIV Exposure for Purposes of nPEP</td><td>
<table>
<tr><td>Substantial Risk for HIV Exposure</td><td>Exposure of
Vagina, rectum, eye, mouth, or other mucous membrane, nonintact skin, or percutaneous contact</td><td>with
Blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid that is visibly contaminated with blood</td><td>when
The source is known to be HIV-infected</td></tr>
<tr><td>Negligible Risk for HIV Exposure</td><td>Exposure of
Vagina, rectum, eye, mouth, or other mucous membrane, intact or nonintact skin, or percutaneous contact</td><td>with
Urine, nasal secretions, saliva, sweat, or tears if not visibly contaminated by blood</td><td>regardless
Of the known or suspected HIV status of the source</td></tr>
</table>
Estimated Risk Based on Exposure Type
<table>
<tr><th>Exposure Route</th><th>Estimated Risk per 10,000 Exposures</th></tr>
<tr><td>Blood transfusion</td><td>9,000</td></tr>
<tr><td>Needle-sharing injection drug use</td><td>67</td></tr>
<tr><td>Receptive anal intercourse</td><td>50</td></tr>
<tr><td>Percutaneous needle stick</td><td>30</td></tr>
<tr><td>Receptive penile-vaginal intercourse</td><td>10</td></tr>
<tr><td>Insertive anal intercourse</td><td>6.5</td></tr>
<tr><td>Insertive penile-vaginal intercourse</td><td>5</td></tr>
<tr><td>Receptive oral intercourse</td><td>1</td></tr>
<tr><td>Insertive oral intercourse</td><td>.5</td></tr>
</table>
</td></tr>
<tr><td>9.2</td><td>Physical Examination When Evaluating for an STI</td><td>Examination for concurrent additional STIs, if indicated, should include a search for
▪ The same pathogen in different places — for example, if there are condyloma on the vulva, look for similar lesions around the anus, in the vagina or on the cervix</td></tr>
</table>

Section	Topic	Detail
		▪ Different pathogens in the same place — for example, if there is a trichomonas vaginitis, look for concurrent bacterial vaginosis or candidiasis ▪ Other conditions — if there are genital warts, look for cervicitis, urethritis, genital ulcers, etc.
9.2.b.	Cervicitis	**Cervical Findings that Suggest Cervicitis** The following may be associated with cervicitis or other types of cervical abnormalities: ▪ Post-coital bleeding, bleeding upon contact with the cervix ▪ Erythema — increased redness with ectropion ▪ Surface abnormalities — edema, hypertrophic ectropion, or ulcers ▪ Cervical or vaginal discharge or purulent cervical mucus Gonorrheal and chlamydial cervical infections sometimes present as cervicitis ▪ Cervical mucous — yellow or greenish cervical discharge ▪ Easily induced endocervical bleeding (contact bleeding) ▪ WBCs on wet mount of cervical discharge Leukorrhea (>10 WBC per high power field on microscopic examination of vaginal fluid) in the absence of a trichomoniasis infection has been associated with chlamydial and gonococcal cervicitis. **Cervicitis for which no infectious etiology can be determined** Apart from the infections noted above, numerous non-infectious and infectious systemic inflammatory processes and local insults can cause cervicitis. The former group includes Behcet's disease, sarcoidosis, ligneous conjunctivitis, and tuberculosis. Substances that erode the endocervical mucous plug or cause an irritant mucositis can also cause signs of cervicitis. Commonly used, commercially available douching and “feminine deodorant” preparations often include detergents that have surfactant properties, and many include various chemicals such as antihistamines and cornstarch, which can irritate genital mucosa.
9.2.b.	Chancroid	Chancroid is one of three STIs characterized by genital ulcers. The others are syphilis, and genital herpes. Other STIs, such as lymphogranuloma venereum (LGV), as well as non-infectious conditions, such as Behcet’s disease, Crohn’s disease, and some malignancies, might also cause genital ulcers.

Section	Topic	Detail
		Even after complete diagnostic evaluation, at least 25% of clients who have genital ulcers have no laboratory-confirmed diagnosis. Chancroid is a relatively uncommon STI in the U.S., although some geographic areas have had consistently higher rates. Chancroid presents with a painful genital ulcer. One-third of clients have painful adenopathy. Suppurative inguinal adenopathy is diagnostic. Diagnosis of chancroid is based on the following ▪ Typical clinical characteristics of a chancroid episode ▪ Negative tests for syphilis and HSV ▪ Documentation of a positive culture for *Hemophilus ducreyi* — In parts of the U.S. where chancroid is prevalent, it is important to culture for the causative organism (*Hemophilus ducreyi*). However, the culture media is not widely available commercially, and false negatives are common.
9.2.b.	Genital Warts[R9]	▪ Approximately 40 types of HPV can infect the genital tract. Most genital warts are caused by HPV types 6 and 11, viral types that are rarely associated with pre-malignant or malignant squamous cell lesions of the external genitalia. ▪ Although condom use will not prevent transmission to or from uncovered areas, recent studies suggest that consistent condom use significantly reduces the risk of genital HPV infection among newly sexually active young women and that regression of HPV lesions in women and men is accelerated by condom use. ▪ Many experts believe that the value of ongoing condom use to prevent transmission of HPV within mutually monogamous relationships is limited, because it is likely that exposure of the partner has already occurred. However, if an infected person has a new sex partner, use of condoms should be recommended to decrease the risk of transmission to a previously uninfected person. ▪ The primary goal of treating visible genital warts is the removal of symptomatic warts. In most clients treatment can induce wart-free periods. If left untreated, visible genital warts may increase in size and number, remain unchanged, or resolve on their own. ▪ Existing data indicate currently available treatment may reduce, but may not eradicate infectivity and transmission in the long term.

Section	Topic	Detail
		▪ Typical genital warts are exuberant papillary "cauliflower" papules which may appear as pink, grey, or white lesions that may bleed if macerated or traumatized. In women, they often involve the hymeneal ring, inner and outer labia, perineum, perianal skin, and posterior fourchette. Less commonly, they are seen on the clitoris and urethra. The spectrum of vaginal warts ranges from small, isolated papules to large, fungating lesions. In men, genital warts most commonly occur on the shaft of the penis and are seen, less frequently, on the scrotum, the perineal area, and within the urethra. ▪ The second major type of genital wart is the "flat condyloma," which appears as a slightly-raised, flesh-colored skin papule. In women, they often present on the cervix, inner aspect of the inner labia, and on the vaginal wall. In men, they appear on the penile shaft. ▪ Intra-anal warts are seen predominantly in clients who have had receptive anal intercourse — these warts are distinct from perianal warts which can occur in men and women who do not have a history of anal sex.
9.2.b.	Genital Herpes	Genital herpes is one of three STIs characterized by genital ulcers. The others are syphilis, and chancroid. Other STIs, such as lymphogranuloma venereum (LGV), as well as non-infectious conditions, such as Behcet's disease, Crohn's disease, and some malignancies, might also cause genital ulcers. Even after complete diagnostic evaluation, at least 25% of clients who have genital ulcers have no laboratory-confirmed diagnosis. Genital herpes is caused by the herpes simplex virus (HSV), which persists indefinitely in spinal dorsal nerve roots and can reactivate and lead to later recurrences. Most cases of recurrent genital herpes are caused by HSV type-2, although HSV type-1 ("oral" herpes) may also cause genital herpes. Herpes can be horizontally transmitted to a sex partner or vertically transmitted to a fetus, but transmission can be reduced with early detection and appropriate interventions. Counseling is critical to the management of clients diagnosed with genital HSV infections. See CDC STD Treatment Guidelines for recommended counseling.

Section	Topic	Detail
9.2.b.	Characteristics and Appearance of Molluscum Contagiosum	▪ Lesions are asymptomatic, discrete, dome-shaped, two to five mm papules that may be flesh-toned or yellow-white. ▪ Lesions characteristically contain a central umbilication (dimple) with waxy caseous material within. ▪ Distribution of the lesions centers on the trunk, inner thighs, and genitalia, but they may occur on any skin surface. ▪ Molluscum may be confused with folliculitis when surrounding erythema is present. ▪ Papules may have the appearance of a cluster of herpetic lesions when they occur in close groups.
9.2.b.	Criteria for making a diagnosis of PID	Minimum criteria when no other cause(s) of the illness can be determined (most notably, when ectopic pregnancy and appendicitis are ruled out): ▪ Uterine tenderness **or** adnexal tenderness **or** cervical motion tenderness Most women with PID have either mucopurulent cervical discharge or evidence of WBC on a saline preparation of vaginal fluid. If the cervical discharge appears normal and no white blood cells appear on wet prep, the diagnosis of PID is unlikely, and alternative causes of pain should be investigated. Additional criteria supporting the diagnosis of PID ▪ Abnormal cervical or vaginal mucopurulent discharge ▪ Elevated C-reactive protein ▪ Elevated ESR ▪ Laboratory documentation of cervical infection with C. trachomatis or N. gonorrhoeae ▪ Oral temperature over 101^{o}F ▪ Presence of WBC on saline microscopy of vaginal secretions The most specific diagnostic criteria for PID ▪ Endometrial biopsy with histologic evidence of endometritis ▪ Laparoscopic abnormalities consistent with PID ▪ Transvaginal sonography or MRI techniques showing thickened, fluid filled tubes, with or without free pelvic fluid or tubo-ovarian complex

Section	Topic	Detail
9.2.b.	Urethritis	Urethritis can result from infectious and noninfectious conditions. The etiology of the majority of cases of nonchlamydial non-gonococcal urethritis is unknown. *Ureaplasma urealyticum*, *Mycoplasma genitalium*, *T. vaginalis*, HSV, and adenovirus can cause urethritis. Any of the following signs will establish the diagnosis of urethritis: ▪ Mucopurulent or purulent discharge ▪ Gram stain of urethral secretions showing ≥ 5 WBC per oil immersion field —presumptive diagnosis of gonorrhea is established by the presence of gram-negative intracellular diplococci (GNID) (preferred test) ▪ Positive leukocyte esterase test on first-void urine ▪ Microscopic examination of first-void urine sediment showing ≥ 10 WBC's per HPF (not recommended) ▪ A positive genital gonorrhea or chlamydia test
9.2.c.	Using Cephalosporins for Clients with a History of Penicillin Allergy	The risk of allergic reaction to cephalosporin in clients with a history of penicillin allergy is dramatically lower in 3rd and 4th generation cephalosporins. Ceftriaxone and cefixime are 3rd generation cephalosporins. About 1-3% of all clients will have a primary sensitivity to cephalosporins. The risk of anaphylaxis with cephalosporin in the general population is 0.001 to 0.1 percent. Whereas the literature reports a 5-17% risk of allergic reaction among clients with a penicillin allergy who take a 1st generation, cephalosporin, the risk drops to 1-3% for 3rd and 4th generation cephalosporins. (The same rate as primary sensitivity.)[R3] In setting a medico-legal standard, the American Academy of Pediatrics Guidelines state that "third generation cephalosporins can be used to treat penicillin allergic patients as long as the penicillin reaction is not severe (i.e., not IgE mediated)"[R4, R5]

Section	Topic	Detail	
9.2.c.	Symptoms of UTI[R6]	**Signs and symptoms of lower UTI** ▪ Dysuria (pain or burning on urination) ▪ Frequency of urination ▪ Urgency to void ▪ Nocturia that continues from daytime frequency ▪ Suprapubic pressure or pain ▪ Foul-smelling urine ▪ Hematuria ▪ Low-grade fever and malaise	**Signs and symptoms of upper UTI — acute pyelonephritis** ▪ Unilateral or bilateral flank pain ▪ Fever > 38ºC (100.8ºF) (with no other source of fever) ▪ Chills
9.2.c.	Cranberry Supplementation in the Prevention of Recurrent UTI[R7]	Often when a client is referred to a urologist for recurrent UTI no underlying abnormalities are found. These women are candidates for suppressive therapy. A 2009 Cochrane review found that cranberry supplementation – whether by juice, tablet, or capsule – may decrease the number of symptomatic UTIs over a 12 month period, particularly for women with recurrent infections. The optimal dose and duration of cranberry supplementation has not been established. However, cranberry tablets or capsules may have improved adherence over cranberry juice. The mechanism of action of cranberry is unknown but has been postulated to involve the prevention of bacterial adherence to the bladder wall.	
9.2.b.	Trichomoniasis in Women	In women, undetected and untreated trichomoniasis infections may lead to complications in pregnancy, upper tract infection and atypical pelvic inflammatory disease. It may also increase the risk of acquiring HIV.	
9.2.b.	Classification of Vulvovaginal Candidiasis	**Uncomplicated VVC** ○ Sporadic or infrequent VVC AND ○ Mild-to-moderate VVC AND ○ Likely to be Candida albicans AND ○ Nonimmunocompromised women	**Complicated VVC** ○ Recurrent VVC — four or more episodes of symptomatic VVC in one year OR ○ Severe VVC — extensive vulvar erythema, edema, excoriation, and fissure formation OR ○ Non-albicans candidiasis — i.e. *C. glabrata*

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td></td><td></td><td>OR
Women with uncontrolled diabetes, debilitation, or immunosuppression, or those who are pregnant</td></tr>
<tr><td>9.2.e.</td><td>Laboratory findings based upon stage of syphilis</td><td>▪ Primary — VDRL or RPR becomes positive 14–90 days after contact or 7- 10 days after the appearance of the chancre. Although the course may be variable, FTA and TP-PA may become positive before VDRL or RPR.
▪ Seropositivity by stage in individuals with syphilis<table><tr><th></th><th>RPR/VDRL</th><th>FTA/TPPA</th></tr><tr><td>Primary</td><td>78%</td><td>84%</td></tr><tr><td>Secondary</td><td>100%</td><td>100%</td></tr><tr><td>Latent</td><td>95%</td><td>100%</td></tr><tr><td>Tertiary</td><td>71%</td><td>96%</td></tr></table></td></tr>
<tr><td>9.2.e.</td><td>Causes of biologic false positive VDRL or RPR</td><td>▪ Connective tissue disease — lupus, arthritis
▪ Hansen's disease (leprosy)
▪ Hepatitis
▪ Infectious mononucleosis
▪ Intravenous drug use
▪ Lyme disease
▪ Pregnancy
▪ Old age
▪ Pinta (Mexico)
▪ Yaws (Africa)</td></tr>
<tr><td>9.2.4</td><td>Syphilis Screening and Testing Algorithms[R1]</td><td>A presumptive diagnosis of syphilis is possible with the use of two types of serologic tests: 1) nontreponemal tests (e.g., Venereal Disease Research Laboratory [VDRL] and RPR) and 2) treponemal tests (e.g., fluorescent treponemal antibody absorbed [FTA-ABS] tests, the T. pallidum passive particle agglutination [TP-PA] assay, various EIAs, and chemiluminescence immunoassays). The use of only one type of serologic test is insufficient for diagnosis, because each type of test has limitations, including the possibility of false-positive test results in persons without syphilis.

Historically, screening for syphilis has been performed using a non-treponomal test (RPR or VDRL) first, followed by a treponemal test (EIA/CIA). In the past decade the use of a treponemal test (EIA/CIA) first has become increasingly more common and is referred to as Reverse Sequence Serology Screening. Labs utilizing treponemal tests should reflex all positive specimens to a quantitative</td></tr>
</table>

Section	Topic	Detail
		nontreponemal test (RPR or VDRL). If the EIA/CIA is positive and the nontreponemal test is also positive, the laboratory should report *both* results to the provider. If the nontreponemal test is negative, then the laboratory should perform a different treponemal test (preferably one based on different antigens than the original test) to confirm the results of the initial test. Clinicians are faced with a significant diagnostic challenge when the initial EIA/CIA testing is positive but subsequent RPR/VDRL testing is negative (discordant serology). It may be challenging to determine whether these test results represent cases of prior treated syphilis, early or latent syphilis, or false positive screening tests. Notably, treponemal tests such as EIA/CIA often remain positive for life, even when a patient has been adequately treated. Though a second treponemal test (TP-PA) can be helpful in resolving discrepancies, some laboratories do not routinely perform this test. Treponema pallidum particle agglutination assay (TP-PA) is preferred as a reflex second treponemal test over the fluorescent treponemal antibody absorbed test (FTA-ABS)
9.2.4	Jarish-Herxheimer Reaction[R2]	The **Jarisch-Herxheimer reaction** is a self-limited reaction to antitreponemal therapy. It is characterized by fever, malaise, nausea, and vomiting. It may be associated with chills and exacerbation of secondary rash. This reaction occurs within 24 hours after therapy and usually resolves within 24 hours. It is not an allergic reaction to penicillin. It occurs more frequently after treatment with penicillin and treatment of early syphilis, especially at the secondary stage. Antipyretics can be used to manage symptoms, but they have not been proven to prevent this reaction. In pregnant women treatment for syphilis may precipitate early labor.
9.2.e	Four Stages of Syphilis Infection	Syphilis is one of three STIs characterized by genital ulcers. The others are herpes and chancroid. Other STIs, such as lymphogranuloma venereum (LGV), as well as non-infectious conditions, such as Behcet's disease, Crohn's disease, and some malignancies, might also cause genital ulcers. Even after complete diagnostic evaluation, at least 25% of clients who have genital ulcers have no laboratory-confirmed diagnosis. Syphilis is caused by the bacteria *Treponema pallidum* and is characterized by episodes of active

Section	Topic	Detail
		disease interrupted by periods of latent infection. The incubation period is estimated to be between 10 and 90 days. Many cases of syphilis are associated with mild or unnoticed symptoms. The usual method of diagnosis is by serologic testing rather than by recognition of clinical symptoms or signs. Of note, symptomatic stages may be overlapping (e.g., primary and secondary, secondary and neurosyphilis). **Primary syphilis (symptoms and signs present)** ▪ Painless chancre, which may be the first symptom/sign, lasting 10–14 days. ▪ The chancre starts as a solitary papule, progresses to an indurated painless ulcer with a "rolled edge", frequently with an erythematous border. Chancres are often painless and indurated, but these features cannot be used reliably to distinguish them from genital herpes. ▪ Five percent of chancres occur on breasts, lips, or mouth. ▪ HIV-infected clients may present with multiple chancres. **Secondary syphilis (symptoms and signs present)** ▪ Occurs 3 to 6 weeks after the primary chancre appears (4 weeks to 4 months after exposure); and lasts weeks to months without treatment. ▪ Signs vary o Rash (75-90%): macular, papular, squamous (scale), pustular (rare), combination; usually nonpruritic; may involve palms and soles in 60% o Generalized lymphadenopathy (70-90%) o Constitutional symptoms (50-80%), most commonly malaise o Mucous patches (5-30%): flat patches involving oral cavity, pharynx, larynx, and genitals o Condylomata lata (5-25%): moist, heaped, wart-like papules that occur in warm intertriginous areas (most commonly, gluteal folds, perineum, perianal); teeming with treponemes o Alopecia (10-15%): patchy occipital and bitemporal, loss of lateral eyebrows **Latent syphilis (NO symptoms or signs present)** ▪ Asymptomatic with serologic evidence of disease. Treatment varies for early versus late latent and

Section	Topic	Detail
		unknown duration syphilis. ▪ Early latent syphilis is defined as infection present for less than 1 year, as evidenced by any of the following within the past year: o Documented seroconversion o A four-fold or greater increase in VDRL or RPR titer o Reliable history of primary or secondary symptoms o Contact with a person known to have infectious syphilis ▪ Late latent syphilis is defined as having untreated infection for longer than one year. ▪ Since evidence of infection within the past year is often difficult to document, most latent cases are treated clinically as unknown duration. **Tertiary syphilis (symptoms or signs present)** ▪ Left untreated, one-third of individuals with syphilis will progress to tertiary syphilis ▪ Signs vary: o Central nervous system — dementia, meningitis, peripheral neuropathy o Cardiovascular — aortic aneurysm or aortic valvular insufficiency o Other organ system involvement — gummas, iritis, uveitis **Neurosyphilis** ▪ Can occur during any stage of syphilis, even primary syphilis. Neurologic history and exam is recommended for all clients diagnosed with syphilis. ▪ Characterized by cognitive dysfunction, motor or sensory deficits, ophthalmic or auditory symptoms, cranial nerve palsies, and symptoms or signs of meningitis. ▪ CSF examination is indicated to guide treatment.

9.3.b. Table: References

Section	R#	Reference
9.1		California Department of Public Health Sexually Transmitted Diseases Control Branch. "California Guidelines for Chlamydia Screening and Diagnostic Testing Among Women in Family Planning and Primary Care Settings." California Department of Public Health. October 2011. http://www.cdph.ca.gov/pubsforms/Guidelines/Documents/CT-Screening-Guidelines-Women-FP-PrimaryCare.pdf (accessed June 2014).
9.1.2		California Department of Public Health Sexually Transmitted Diseases Control Branch." California Sexually Transmitted Disease Screening Recommendations 2010." California Department of Public Health. June 2011. http://www.cdph.ca.gov/pubsforms/Guidelines/Documents/CA-STD-Screening-Recommendations.pdf (accessed June 2014).
9.2.4		California Department of Public Health Sexually Transmitted Diseases Control Branch."Primary Syphilis Algorithm." April 2011. http://www.stdhivtraining.org/resource.php?id=38&ret=clinical_resources (accessed June 2014).
9.2.4		California Department of Public Health Sexually Transmitted Diseases Control Branch."Secondary Syphilis Algorithm." April 2011. http://www.stdhivtraining.org/resource.php?id=42&ret=clinical_resources (accessed June 2014).
9.2.4	R1	California Department of Public Health Sexually Transmitted Diseases Control Branch. Use of Treponemal Immunoassays for Screening and Diagnosis of Syphilis. August 2013. http://www.cdph.ca.gov/pubsforms/Guidelines/Documents/Treponemal_Immunoassays_for_Syphilis_Screening_and_Diagnosis.pdf (accessed June 2014).
9.1.3		Centers for Disease Control and Prevention. "Interim guidance for clinicians considering the use of preexposure prophylaxis for the prevention of HIV infection in heterosexually active adults." MMWR Morb Mortal Wkly Rep 61, no. 31 (2012): 586-589.
Throughout		Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines. 2010. http://www.cdc.gov/sTD/treatment/2010/toc.htm (accessed June 2014).
9.1.3		Centers for Disease Control and Prevention. "Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States: recommendations from the US Department of Health and Human Services." MMWR Recomm Rep 54, no. RR-2 (2005): 1-20.
9.1.3		Centers for Disease Control and Prevention. "Interim guidance: preexposure prophylaxis for the prevention of HIV infection in men who have sex with men." MMWR Morb Mortal Wkly Rep 60, no. 3 (2011): 65-8. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a1.htm Accessed May1, 2014
9.2.4	R2	Centers for Disease Control and Prevention. "Self-Study STD Modules for Clinicians - Syphilis." Centers for Disease Control and Prevention. August 2013. http://www2a.cdc.gov/stdtraining/self-study/syphilis/default.htm (accessed June 2014).

Section	R#	Reference
9.1.3		Centers for Disease Control and Prevention. "Update to Interim Guidance for Preexposure Prophylaxis (PrEP) for the Prevention of HIV Infection: PrEP for Injecting Drug Users." MMWR. Morbidity and mortality weekly report 62, no. 23 (2013): 463. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6223a2.htm?s_cid=mm6223a2_w Accessed May 1, 2014
FYI	R3	Greenberger PA. 8. Drug Allergy. J. Allergy Clin Immunol 2006;117(2 Suppl Mini Primer):S464-70.
FYI	R6	Gupta, K et al. International Clinical Practice Guidelines for the Treatment of Acute Uncomplicated Cystitis and Pyelonephritis in Women: A 2010 Update by the Infectious Diseases Society of America and the European Society for Microbiology and Infectious Diseases. Clinical Infectious Diseases 2011;52(5):e103–e120.
9.1.3		Hennepin County Public Health Clinic / Red Door Clinical Services. 2013 Clinical Guidelines. Subject. Pre-Exposure prophylaxis (PrEP) for HIV prevention: promoting Safe and Effective Use in Clinical Setting.
FYI	R7	Jepson RG, Craig JC. Cranberries for preventing urinary tract infections. Cochrane Database of Systematic Reviews 2008, Issue 1. Art. No.: CD001321. DOI: 10.1002/14651858.CD001321.pub4
9.1.3		Kuhar, David T., David K. Henderson, Kimberly A. Struble, Walid Heneine, Vasavi Thomas, Laura W. Cheever, Ahmed Gomaa, and Adelisa L. Panlilio. "Updated US Public Health Service guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for postexposure prophylaxis." Infection Control and Hospital Epidemiology 34, no. 9 (2013): 875-892.
9.1.3		Mayer, Kenneth H., Matthew J. Mimiaga, Marcy Gelman, and Chris Grasso. "Raltegravir, tenofovir DF, and emtricitabine for postexposure prophylaxis to prevent the sexual transmission of HIV: safety, tolerability, and adherence."JAIDS Journal of Acquired Immune Deficiency Syndromes 59, no. 4 (2012): 354-359.
9.1.3		New York State Department of Health AIDS Institute. "HIV Prophylaxis Following Non-Occupational Exposure." HIV Clinical Resource. July 2013. http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-non-occupational-exposure/#top (accessed June 2014).
FYI	R5	Pichichero ME. A review of evidence supporting the American Academy of Pediatrics recommendation for prescribing cephalosporin antibiotics for penicillin-allergic patients. Pediatrics 2005;115(4):1048-57.
FYI	R4	Pichichero ME. Cephalosporins can be prescribed safely for penicillin-allergic patients. J of Family Practice 2006;55(2):106-12.
9.1.3 FYI	R8	Preexposure prophylaxis for the prevention of human immunodeficiency virus. Committee Opinion No. 595. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:1133–6.
		The Region IX Infertility Prevention Project Advisory Committee. "Chlamydia Clinical Guidelines." February 2009.

Section	R#	Reference
		http://www.cardeaservices.org/documents/ipp/2009%20Region%20IX%20Chlamydia%20Clinical%20Guidelines.pdf (accessed June 2014).
9.1.3		US Public Health Service. "Preexposure Prophylaxis for the Prevention of HIV Infection in the United States." A Clinical Practice Guideline. 2014. http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf (accessed 5 20, 2014).
FYI	R9	Winer R et al. Condom use and the risk of genital human papillomavirus infection in young women. NEJM 2006;354:2645-2654.

9.3.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIIC	CI Acute PID CI Directions for Sex Partners – Chlamydia CI Directions for Sex Partners – Gonorrhea CI Directions for Sex Partners – Trichomoniasis CI Genital Herpes CI HIV Test CI Reducing Your Risk for STIs CI STI Testing CI UTI CIIC PEP CIIC PrEP CIIC STI Treatment Without Testing CIIC Treatment of Genital Warts CIIC Treatment of Molluscum Contagiosum CIIC Vulvar Biopsy	Part 3, Chapter 02_09
	CI Condoms and Female Condoms	Part 3, Chapter 02_06
Client Education	✓ Take Charge of Your Sexual Health	

9.3.d. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ CDC STD Treatment Guidelines ✓ CDC STD Treatment Guidelines App	
	CDC Treatment Guidelines – One-Pager	Part 3, Chapter 02_09
Training	✓ CDC STD Curriculum Self-Study Modules	
	2014 MeDC Presentation PEP and PrEP Implementation	To be posted on Extranet
	PPFA 2014 VOICE Overview of Pep and PrEP HIV Screening Recommendations Client Communication & Education on HIV Contraception and HIV	To be posted on the CAL
Sample Forms	Sample Letter Notification STI	Part 3, Chapter 01_08

[1] Frequency of screening should be guided by client's risk (e.g., multiple or anonymous partners, new partners, sex in conjunction with illicit drug use, especially methamphetamine, partners who participate in high-risk activities). The time frame for assessing the need for screening based on reported risk factors is "since the last STI test." All screening recommendations are regardless of reports of condom use.

[2] All persons diagnosed with GC or CT should be rescreened at 3 months or whenever client presents for care within the following 12 months.

[3] HIV testing may be anonymous or confidential. Any positive screening test **must** be followed up with a confirmatory test (e.g., Western blot or immunofluorescent assay (IFA) test). Clients **must** be referred for care, on- or off-site, as indicated.

[4] Screening for HSV-1 is not recommended.

[5] Women who identify as women who have sex with women may still be at risk for STI/HIV.

[6] See Chapter 15 Prenatal and Postpartum Care for screening recommendations for pregnant women receiving prenatal care

[7] There is no clear evidence or specific guidelines on screening women or heterosexual men for pharyngeal or rectal gonorrhea. Consider screening on an individual basis.

[8] Screening for Trichomoniasis in women can be considered in those at high risk for infection (i.e., new or multiple partners, history of STD, exchange sex for payment, and use injection drugs)

[9] Screen for urethral infection in men who have had insertive anal or oral intercourse during the preceding year, rectal infection in men who have had receptive anal intercourse during the preceding year, pharyngeal infection with gonorrhea in men who report receptive oral intercourse during the preceding year; testing for pharyngeal infection with chlamydia is not recommended.

CHAPTER 10: INFERTILITY

Revised June 2014

Chapter 10 Table of Contents

CHAPTER 10: INFERTILITY

Revised June 2014

10.1 CLIENT EDUCATION AND INFORMED CONSENT

10.1.1 Requirements

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

10.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	**Must** offer
CI Semen Testing			●	
CIIC Endometrial Biopsy		●	●	
Other written material about infertility*				
Release When Test/Service/Consultation Will Not Be Obtained As Recommended		Once		
Request for Surgery or Other Special Services		●		●
*Client education and instructions should include causes of infertility in general and the client's diagnoses, when determined, tests to be ordered, specific services/treatments/medications to be provided including fee schedules, possible emotional issues—an important part of treatment of the infertile woman/couple due to the stresses involved in the diagnostic workup and treatment of infertility, referral sources				

10.1.2 Indications for Infertility Services

✓ FYI Causes of Infertility

I. Involuntary infertility after unprotected intercourse with the same male partner for 1 year or more, in the absence of a known cause of infertility
   A. If the client ≥ age 35, workup should begin at 6 months of attempted conception
   B. Male partner should be involved in the evaluation
   C. When there is a male partner, semen analysis **must** be performed early in the course of the evaluation before proceeding to invasive tests or procedures

II. Presence of known, pre-existing male or female factors affecting fertility

III. Single women or same-sex female couples who desire pregnancy — when there is a partner, she should be involved in the evaluation (Advanced infertility)

IV. History of recurrent pregnancy loss (Advanced infertility)

10.1.3 Initial Evaluation

10.1.b. Table: Initial Evaluation

EVALUATION	FEMALE	MALE
History*	Should include ▪ Menstrual history (with attention to regularity, flow, changes (especially recent changes) and associated dysmenorrhea) ▪ History of galactorrhea, acne, hirsutism ▪ History suggestive of thyroid dysfunction ▪ History of eating disorders ▪ History of pregnancy attempts (with attention to coital frequency and timing, client understanding, results of previous evaluations) ▪ History of STI	Should include ▪ Gonadal toxin exposure including heat ▪ History of pregnancy attempts (with attention to coital frequency and timing, client understanding, results of previous evaluations) ▪ History of STI
Physical Exam**	Should include ▪ Height, weight, BMI, pulse and BP ▪ Notation of body habitus and hair distribution ▪ Thyroid palpation ▪ Breast examination, looking specifically for expressible galactorrhea ▪ Abdominal exam for masses, hepatosplenomegaly, and any lower abdominal pain ▪ Female genital examination **must** include o Inspection of vagina and cervix o Observation of cervical mucous to correlate with menstrual cycle (Mucous should become progressively more watery and stretchy [Spinnbarkeit] closer to ovulation.) o Bimanual examination to evaluate uterine size and presence or absence of adnexal pathology and cul-de-sac nodularity, as well as tenderness or pain ▪ Other as indicated	Should include ▪ Genital examination when semen analysis is abnormal or refer to andrologist or urologist. Exam should include o Inspection of the penis and scrotum, i.e., testicular size, position, consistency, evaluation for varicocele in standing position with Valsalva maneuver o Prostate examination ▪ Other as indicated

EVALUATION	FEMALE	MALE
Laboratory The following tests should be considered at initiation, unless reliable written results from previous testing are available.	▪ Routine well woman age appropriate screening tests ▪ CT/GC, as indicated ▪ TSH and PRL in the presence of obvious ovulatory dysfunction ▪ In clients ≥ age 35, serum FSH and estradiol level on cycle day 3 (2 to 5 are appropriate) is highly recommended as a marker of ovarian reserve. ▪ Preconception labs† including o Blood type and Rh, rubella, Rubeola, Varicella, RPR, HIV o Cystic fibrosis screening o Other screening tests, if appropriate (i.e., Ashkenazi panel, hemoglobin electrophoresis for sickle cell/sickle cell trait or thalassemias) ▪ Pelvic ultrasound for baseline evaluation of the pelvis (preferably in first 2 weeks of cycle) to rule out masses or cysts on ovaries, tubes or uterus	▪ Semen analysis
*See Chapter 21.1.2 Periodic Well-Woman Screening ✓ **FYI Female Physical Exam Findings Critical in Suggesting a Diagnosis † See Chapter 21.2 Preconception		

10.2 BASIC INFERTILITY — EVALUATION AND MANAGEMENT

10.2.1 Evaluation

✓ FYI – Minimal Evaluation

I. Female Factor — Assessment of Ovulation - options include

✓ FYI – Ovulation

A. Basal body temperature charting
B. Luteinizing (LH) urine or serum testing — a positive test indicates only normal hypothalamic-pituitary cycling, not ovulation
   1. Calculate time of LH testing based on woman's history of normal cycle length
   2. Best way to assess time of ovulation
   3. Begin testing 2 to 3 days before anticipated LH surge, or about 4 to 5 days before ovulation

4. Good to use for timing of coitus and/or insemination

C. Serum progesterone – to confirm ovulation and evaluate adequacy of hormonal support to ovulation and endometrium
   1. Timing is critical for interpretation of results — best performed 7 to 9 days after LH surge
   2. Values >3 ng/ml indicates ovulation, >10 ng/ml considered optimal for pregnancy

D. Endometrial biopsy — request cycle day dating for histological proof of adequate end organ response of endometrium to progesterone production
   1. Best performed 2 to 3 days before anticipated menses (10 to 12 days post LH surge)
   2. **Must** use contraception in sample cycle or do highly sensitive pregnancy test before biopsy to ensure client is not pregnant

E. Ultrasound evaluation
   1. Follicular development
   2. Adequate endometrial growth and response

II. Male Factor — Semen Analysis

✓ FYI – Male Factor Evaluation

A. Semen analysis **must** be performed prior to initiation of ovulation induction, even if male has demonstrated prior fertility. A man can become infertile within a short time, or may have been subfertile when he conceived previously.

B. Prior to semen collection, the client should abstain from intercourse or masturbation for 48 to 72 hours. When a specimen is received, client should be asked when he last ejaculated prior to the sample.

C. Semen **must** be collected in a sterile container without the use of a condom or lubricants and kept at body temperature. Once collected
   1. It **must** be received and examined (health center or off-site) within 2 hours of collection.
   2. Ensure specimen container is labeled with client's name, date, and time.
   3. Make sure that none of the specimen was lost in collection. Check volume and confirm with client.

D. Repeat semen analysis may be ordered unless
   1. No sperm on specimen. Refer to specialist (andrologist/urologist).
   2. If large number of WBCs present, treat with antibiotic and repeat semen analysis in 6 to 8 weeks. Acceptable antibiotic regimens include
      a. Ciprofloxacin 500mg PO BID x 2 weeks
      b. Doxycycline 100mg PO BID x 2 weeks
   3. **Must not** repeat semen analysis any sooner than 6 to 8 weeks to confirm abnormal findings.
   4. If, following above management, there are any abnormal sperm parameters, refer to andrologist/urologist.

5. May initiate IUI in the interim if semen analysis is within acceptable parameters. (See intrauterine insemination under management, below.)

III. Tubal Factor

✓ FYI Tubal Factor

A. Clients with normal indicators of ovulation and normal semen analysis should be evaluated for tubal factor.
B. Tubal evaluation **must** be done by third cycle of unsuccessful insemination.
C. Options for tubal evaluation include
   1. Hysterosalpingogram (HSG)
      a. **Must** be done after cessation of menses but before ovulation to assure that client is not pregnant
      b. **Must** be referred to a radiologist who is experienced in utilizing fluoroscopic visual intensive equipment with or without clinician involvement within a radiology department
   2. Sonohysterogram
      a. **Must** be done after cessation of menses but before ovulation to assure that client is not pregnant
      b. May be performed within the affiliate with ultrasound equipment. If so, **must** be done by an experienced physician.
      c. **Must** prescribe antibiotics (e.g., Doxycycline 100mg BID x 3 days) so that 1 to 2 doses are given before the procedure if history of STD or PID, history of tubal disease or in the presence of abnormal findings
   3. If tubal abnormality identified, **must** refer out unless affiliate is approved for advanced infertility and has protocols for management of the condition.

IV. Other Potential Causes of Infertility
A. Uterine factor — If uterine abnormality identified, **must** refer out
B. Cervical factor
C. Endometriosis
D. Luteal phase defect

✓ FYI – Luteal Phase Defect

10.2.2 Management

I. Ovulatory Dysfunction
A. May initiate trial of ovulation induction with clomiphene citrate (see below) without further evaluation when a woman has an FSH < 11 on cycle day 3 and

1. Periods are irregular (but not more than 45 days apart, without a more extensive workup)
2. Male has caused previous conception within 2 years or normal semen analysis
3. Negative STD history

B. Clomiphene Citrate (CC)

✓ FYI – Clomiphene Citrate

1. Begin CC on cycle day 3, 4, or 5 in doses of 50 mg (1 tablet/day) for 5 days.
2. If 50 mg does not induce ovulation, increase to 100 mg/day.
3. **Must** not be prescribed beyond 6 months of good ovulatory response (the majority of women who get pregnant on clomid will do so by cycle 4 to 6).
4. **Must** be discontinued if client develops visual symptoms such as scotomata.
5. Monitoring may include BBT, ultrasound, serum hormone levels, LH kit testing and luteal phase serum P.
6. Ovulation generally occurs 5 to 7 days after the last tablet of CC, but may occur up to 12 days later. If LH testing is done, it **must** begin 2 or more days after the last medication to prevent measuring only the gonadotropin elevation caused by the CC.
7. Routine pelvic exam or ultrasound at the initiation of each cycle is only warranted when pain or other clinical concerns are present or in clients with significant PCOS.
8. IUI (see below) should be added when using CC empirically for unexplained infertility as it seems to increase pregnancy rates. Due to the antiestrogenic effects of CC on cervical mucus, IUI is often incorporated with CC treatment.
9. A persistently thin endometrium is felt to be due to the antiestrogenic effects of CC as well, and may indicate a need to move on to gonadotropin therapy despite an ovulatory response.
10. After 3 to 6 months of ovulatory treatment, **must** refer out unless affiliate provides Advanced Infertility. Treatment is appropriate even if PCOS is suspected diagnosis.

C. PCOS – may manage or refer

1. If BMI is >30, start with weight loss of 10% of body weight; will improve ovulatory function or response to drug treatment in many clients.
2. Treat with glucocorticoid suppression when etiology of hyperandrogenism appears to be the adrenal gland (elevated DHEA-S):
   a. Initiate prednisone 5 mg q HS and repeat DHEA-S in 6 weeks.
3. Initiate clomiphene citrate (CC) to induce ovulation – see CC above.
4. Add metformin

a. Oral hypoglycemic agent that acts by reducing hepatic gluconeogenesis, decreased intestinal absorption of glucose and increased peripheral glucose uptake and utilization.
b. Start at low dose (500mg/day) and increase at weekly intervals.
c. Doses of 1,500 to 2,000 mg/day have resulted in ovulation in anovulatory women with PCOS (-40% on average).
d. Extended release (XR) dosing at night is better tolerated.
e. In some reports, metformin combined with CC results in improved ovulatory response, especially in women with PCOS who failed to respond to CC alone.
f. Side effects of metformin are primarily gastrointestinal in nature, especially nausea, diarrhea, and bloating. Side effects are dose and time dependent, decreasing with continued use. While most recommend discontinuation with pregnancy, there is no reported teratogenicity.

5. If no ovulatory response to these therapies, initiation of gonadotropins or laparoscopic surgery (ovarian cystotomies) may be considered.
6. NOTE: these clients are particularly prone to ovarian hyperstimulation (OHSS); great care **must** be taken to prevent complications. Affiliates **must** have an OHSS emergency protocol in place.

D. Intrauterine Insemination (IUI)
1. Indications include male factor, cervical factor, as a component of ovulatory treatment, and unexplained infertility.
2. Prior to IUI, male partner **must** be screened for STIs, including: HIV, Hepatitis B. (All tests **must** have been performed within 1 year of insemination.)
   a. If screen is positive for hepatitis B, refer to specialist for evaluation and evaluate female partner. If female partner is negative, begin vaccination series.
   b. If screen is positive for HIV, explain risks and benefits of IUI and/or IVF.
3. Treat other positive STI tests. (See Chapter 9 Infections and CDC STD Treatment Guidelines.) In addition, may initiate insemination process only if semen analysis is within the following parameters:
   a. Count > 5 x 106/cc (for IUI –intrauterine insemination)
   b. Motility > 25%
   c. Morphology > 5%
4. If semen analysis is not within above parameters, **must** refer for IVF/ICSI.

E. Unexplained Infertility – Refer for Treatment

10.3 ADDITIONAL INFORMATION

10.3.a. Table: For Your Information

Section	Topic	Detail
10.1.2	Causes of Infertility	Involuntary infertility affects about 15% of couples of reproductive age in the United States, and rates increase with the advancing age of each partner, especially for women over 40 years old. Approximately 40% of infertility is due to male factor(s). Another 40% can be attributed to female factor(s). About 10% is due to a problem with the couple. The remaining 10% is unexplained.
10.1.b.	Female Physical Exam Findings Critical in Suggesting a Diagnosis	Specific attention should be directed to findings of galactorrhea, thyroid enlargement or evidence of ovarian dysfunction such as acanthosis nigricans, hirsutism, acne or other signs of virilization. Basic vital signs as well as calculation of BMI are useful: ▪ BMI < 18 suggests hypothalamic ovulatory dysfunction. ▪ Galactorrhea suggests hyperprolactinemia with or without evidence of a pituitary tumor. ▪ BMI > 30 especially in the presence of acanthosis nigricans or hirsutism suggests insulin resistance and some variation of PCOS. ▪ PRL and TSH testing prior to initiation of treatment is recommended in women with abnormal menstrual patterns.
10.2.1	Minimal Evaluation	The minimal evaluation of an infertile couple should include evaluation for the 3 primary causes of infertility: female factor (ovulatory dysfunction), male factor (abnormal semen analysis) and tubal factor. This can be accomplished through ▪ Testing ovulatory function and/or ovarian reserve ▪ Semen analysis ▪ Tubal evaluation (most commonly via hysterosalpingogram (HSG) although sonohysterosalpingogram or laparoscopy may also be performed)
10.2.1	Ovulation	Over one third of infertile women have an ovulatory disorder, contributing to their infertility problem. The process of ovulation includes the growth of the ovarian follicle containing a mature oocyte (egg), release of that egg at the time of ovulation, passage of the egg to the distal portion or fimbriated end of the tube, and conversion of the now empty follicle into a corpus luteum producing

Section	Topic	Detail
		adequate amounts of progesterone**.** Normal ovulation occurs 14+/- 2 days before the next menses.
10.2.1	Male Factor Evaluation	Approximately 40% of infertility is due to male factor(s). Normal semen analysis: ▪ Volume ≥ 1.5 but < 5 cc ▪ Count ≥ 20 x 10^6/cc ▪ Motility > 50% motile ▪ Normal Morphology – depending on criteria used by lab > 14% or > 40%
10.2.1	Tubal Factor	40% of infertile women have a tubal problem. Hysterosalpingogram (HSG) is good for assessment of both uterus and tubal patency. Sonohysterogram is excellent for assessment of uterine cavity, not as good for assessment of tubal patency, allows for simultaneous evaluation of ovaries and other pelvic structures.
10.2.1	Luteal Phase Defect	Luteal phase defect has historically been defined as a delay of more than 2 days in the development of the endometrium when compared to the actual day of the cycle. The concept of a luteal phase defect is controversial, as is the question of whether it actually plays any role in infertility. It can be diagnosed using a timed endometrial biopsy but, given the controversy, many practitioners find it hard to justify performing the test, and instead measure serum progesterone levels, which may be too variable. Luteal phase defect can be treated using clomiphene citrate (especially in cases of PCOS), or exogenous progesterone regimens such as vaginal progesterone (200 mg suppositories BID, Crinone 8% qhs or Endometrin 100mg BID) or IM progesterone in oil 50mg/day beginning 2 to 3 days after ovulation /LH Surge.
10.2.2	Clomiphene Citrate (CC)	Clomiphene Citrate (CC) is a nonsteroidal compound with both estrogenic agonist and antagonist actions. It is hypothesized to act by binding to estradiol receptors at the hypothalamic level, thus reducing negative feedback. Increased GnRH and gonadotropin release drive ovarian follicular response. It works best in eugonadotropic women with normal endogenous estrogen levels. CC can treat luteal phase deficiency, especially when it is the result of poor preovulatory follicular development, although direct progesterone replacement may also be used. It can also be combined with IUI as empiric treatment for unexplained infertility.

Section	Topic	Detail
		In general, 60% of anovulatory women will ovulate with CC; 40% of these will conceive. Once an ovulatory response is established, treatment for up to 6 cycles is appropriate. The pregnancy rate diminishes greatly after 6 cycles. Most CC induced pregnancies are singleton with 7% twin gestations and <1% triplets. The rates of birth defects are similar to those in spontaneous conceptions. Side effects include vasomotor symptoms (20%), adnexal tenderness and ovarian cysts (5%), and, rarely, blurring of vision or scotomata (<2%). Severe ovarian hyperstimulation syndrome with CC therapy is rare.

10.3.b. Table: References

Section	Reference
Throughout	Speroff, Leon, and Mark A. Fritz. Clinical Gynecologic Endocrinology and Infertility. Philadelphia: Lippincott Williams and Wilkins, 2005. http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf Accessed May 21, 2014
Throughout	Centers for Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: recommendations of CDC and the U.S.
Throughout	Office of Population Affairs. MMWR. Morbidity and Mortality Weekly Report. Available at: http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf; Accessed May 21, 2014

10.3.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIIC	CI Testing Your Semen	Part 3, Chapter 02_10
	CIIC Endometrial Biopsy	Part 3, Chapter 02_08
	CI Hysterosalpingogram (HSG)	Part 3, Chapter 02_05
Client Education	✓ Resolve - The National Infertility Association Client Education ✓ American Society for Reproductive Medicine Client Fact Sheets and Information Booklets	

10.3.d. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ American Society for Reproductive Medicine Practice Committee Documents	
	✓ CFR – Code of Federal Regulations Title 21	

CHAPTER 11: INTIMATE PARTNER VIOLENCE

Revised June 2014

Chapter 11 Table of Contents

CHAPTER 11: INTIMATE PARTNER VIOLENCE

Revised June 2014

11.1 CLIENT EDUCATION AND INFORMED CONSENT

11.1.1 Requirements

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

11.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** give	Should give	**Frequency**
CI Healthy Relationships			To adolescents	When appropriate
Reproductive coercion safety card intervention *Did You Know Your Relationship Affects Your Health?*		To women who have sex with men		At least annually and/or When it is known that client has a new partner. There is no need to inquire about changes in sexual partners during supply visits.

11.2 SCREENING

11.2.1 Prior to screening **must**

I. Inform client of any limits of confidentiality due to state reporting laws, prior to asking about IPV or abuse or giving a self-administered form

✓ FYI — Sample Script to Inform Client About Limits of Confidentiality

II. Determine if client's sexual partners are men, women, or both in order to tailor the assessment. For women who exclusively have sex with women, assessment for IPV is required but screening for reproductive coercion is not indicated.

11.2.2 How and When of Screening

11.2.a. Table: How and When of Screening

How?	▪ In a language the client can understand. ▪ In a private and confidential setting — away from partners, friends or relatives (except children under three) attending the visit. ▪ Through self-administered questionnaire or interview

	▪ By using the reproductive safety card ✓ FYI — Using the Safety Card to Screen for IPV and RC
What type of visit?	**Must** screen during ▪ Well-person visit ▪ Prenatal care ○ First prenatal visit ○ at least once per trimester ○ postpartum check-up ▪ Contraceptive visit — excluding pick-up and injection-only visits ▪ Abortion visit ✓ FYI — Red Flag, Frequent Supply Visits
When?	▪ At least annually ▪ New partner reported ▪ Any time there are concerns such as signs and symptoms of abuse, frequent requests for STI testing, and/or frequent requests for pregnancy testing

11.3 INTERVENTIONS

11.3.1 For disclosure of reproductive coercion

I. Staff should offer visit-specific harm reduction strategies

✓ FYI — Important Concepts and Sample Scripts for Harm Reduction

11.3.2 For disclosure of current or past IPV

I. Acknowledge the trauma in a non-judgmental way.
II. Provide support and validation.

11.3.3 For disclosure of current IPV

I. Help identify support systems (friends, family, and community groups).
II. Assess immediate safety

A. Offer to help place call to police and provide information on obtaining a restraining order, if client desires immediate assistance.
B. Find out if partner is in the health center and if client feels she/he is in immediate danger.
C. Connect client with an IPV advocate by phone or in-person before she/he leaves the clinic.
D. Admit or assist in admitting client to emergency room or hospital if needed.

III. Assess and document the impact of abuse on client's health.
IV. File reports with appropriate state agencies where required by law.
V. Offer birth control. Consider private methods such as LARC.
VI. Make referrals to local resources.
VII. Offer at least one follow-up appointment at the affiliate.

11.3.4 For disclosure of past IPV

I. Provide information and education, as needed.
II. Address safety concerns, review options and give anticipatory guidance, as appropriate per client needs.

11.3.5 For clients who report being unsafe, staff **must** assess immediacy of danger:

I. If unsafe, get current location and contact information and call the police. Have client call 911.
II. If not in immediate danger, give options and local phone numbers/resources for
A. Local domestic violence agency
B. Police (for information on how to obtain a restraining order, etc.)

11.4 FOLLOW-UP AND REFERRAL

11.4.1 Follow-Up

I. Clients currently in abusive relationships should be offered a follow-up visit solely for the assessment of IPV.

11.4.2 Referrals

I. Offer client a list of local resources
II. If possible, make arrangements for client or allow client to make own arrangements while still at the health center

III. Offer National Domestic Violence Hotline: 800-799-SAFE (7233); 800-787-3224 TTY or National Teen Dating Violence Hotline: 1-866-331-9474; 1-866-331-8453 TTY; National Sexual Assault Hotline; 1.800.656.HOPE

11.5 ADDITIONAL INFORMATION

11.5.a. Table: For Your Information

Section	Topic	Detail
11.2.1	Sample Script to Inform Client About Limits of Confidentiality	"I'm really glad you came in today (fill in the blank for visit type). Before we get started, I want you to know that everything you share with me is confidential, unless (fill in state law here — likely this script will look very different for an adolescent than an adult) you tell me that you are being hurt or forced to have sex by someone or are suicidal — those things I would have to report, ok?"
11.3.a.	Using the Safety Card to Screen for IPV and RC	When appropriate, it is useful to start with assessment for reproductive coercion and not IPV. Questions about reproductive coercion are much more closely linked to the reason for a reproductive health visit than IPV. Beginning assessments with reproductive coercion allows for a simple segue into questions about IPV and sexual assault. The Futures Without Violence reproductive coercion safety card intervention *Did You Know Your Relationship Affects Your Health?* is an evidence-based tool to initiate the assessment and provide client education. The cards can be used as a prompt and guide by health care providers to assess for IPV and reproductive coercion by adjusting the wording from "does my partner….." to "does your partner…." ✓ Card: *Did You Know Your Relationship Affects Your Health?* Use this link to order the reproductive health safety cards: ✓ http://www.futureswithoutviolence.org/plannedparenthood
11.3.a.	Red Flag, Frequent Supply Visits	A possible sign of reproductive coercion is when a woman comes in more often than would be expected for contraceptive supplies.
11.4.1	Important Concepts and Sample Scripts for Harm Reduction	For clients in a coercive relationship some controlling partners may monitor bleeding patterns and menstrual cycles. For these women the safest option may be the Copper IUC as it does not

Section	Topic	Detail
		change their cycle. For IUC users, it is also recommended to discuss cutting the strings short in the cervical canal — so it cannot be felt by her partner. Likewise, emergency contraception is often packaged in a large box with bold script —one harm reduction strategy is to offer an envelope so she can put the pills there or in an empty pill bottle to avoid suspicion. **What to do if you get a "yes" to pregnancy pressure or birth control sabotage — use it as an introduction to screen for IPV**: ▪ "I'm really glad you told me about what is going on. It happens to a lot of women, and it is so stressful to worry about getting pregnant when you don't want to be. I want to talk with you about some methods of birth control your partner doesn't have to know about…like the IUC, implant, and emergency contraception." **What to do if you get a "yes" to difficulty negotiating condoms:** ▪ "I'm really glad you told me about what is going on — it happens to a lot of women. It's really stressful to worry about getting pregnant when you don't want to be. Let's talk about some methods of birth control that aren't dependent on your partner and he doesn't have to know about — like emergency contraception and the IUC." **What to do to regarding partner notification of a positive STI:** ▪ "I know it can be hard to talk about this — especially if you are worried your partner will blame you for the STI. What do you think will happen when he hears that he needs to get treated? Are you worried that he might hurt you?" ▪ "As you may know, it's important to treat everyone you have been recently sexually active with for the infection. There are a couple of ways we can do this to help you be safer:" o "We can talk to him about it in clinic and explain about transmission in case he gets angry or blames you." o "We can have someone call him anonymously from the health department saying that

Section	Topic	Detail
		someone he has slept with in the past year has (name of STI) and he needs to come and be treated." ○ "If you decide you want to tell him yourself, you may want to tell him in a public place with lots of people around where you can leave easily if you need to."

11.5.b. Table: References

Section	Reference
Throughout	Chamberlain L. Levenson R. Reproductive health and partner violence guidelines: An integrated response to intimate partner violence and reproductive coercion. 2010, Family Violence Prevention Fund, San Francisco, CA.

11.5.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIIC	CI Healthy Relationships	Part 3, Chapter 02_11
Client Education	✓ Futures Without Violence Client Safety Cards	

11.5.d. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ Addressing Intimate Partner Violence, Reproductive and Sexual Coercion: A Guide for Obstetric, Gynecologic, and Reproductive Health Care Settings	
Training	**CAL Courses** Intimate Partner Violence (IPV) and Reproductive Coercion Series	

CHAPTER 12: MEN'S SEXUAL AND REPRODUCTIVE HEALTH SERVICES

Revised June 2014

Chapter 12 Table of Contents

CHAPTER 12: MEN'S SEXUAL AND REPRODUCTIVE HEALTH SERVICES

Revised June 2014

12.1 CLIENT EDUCATION AND INFORMED CONSENT

12.1.1 Requirements

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

12.1.a. Table: Requirements for Written Materials as indicated

Document	Document #	**Must** sign	**Must** give	Should give	**Must** offer
CI BPH				●	
CI Erectile Dysfunction				●	
CI Premature Ejaculation				●	
CIIC Skin Biopsy		●	●		
CIIC Tests for Prostate Cancer			●		
Information on any medication dispensed (package insert may be used)			●		
Release When Test/Service/Consultation Will Not Be Obtained		Once			
Request for Surgery or Other Special Services		●			●
*Minors - Consent of a parent or guardian **must** be obtained when required by state law.					

12.2 SCREENING

12.2.a. Table: Screening

Type	When	How	Treatment/Follow up/Referrals
Colorectal Cancer Screening - should be recommended ✓ FYI - DRE/FOBT and Hemoccult Testing	Initiate routine screening ▪ Beginning at age 50 or 45 if African American if average risk ▪ Beginning at age 40 (or 10 years younger than the age at which the youngest affected relative was diagnosed) if at increased risk	Screen using one of the following methods: ▪ Colonoscopy ▪ Fecal occult blood testing (FOBT) or fecal immunochemical testing (FIT) ▪ Flexible sigmoidoscopy ▪ Double contrast barium enema	Frequency of screening - determine according to method of screening used ▪ FOBT or FIT – every year ▪ Colonoscopy – every 10 years ▪ Flex sigmoidoscopy, double contrast barium enema, and CT colonography – every 5 years

Type	When	How	Treatment/Follow up/Referrals
		▪ Computed tomography colonography ▪ Stool DNA NOTE: Screening should not be performed using in-office FOBT or FIT with sample collected from digital rectal exam. If gFOBT is performed for screening, instruct client to test 2 or 3 samples (depending on the product) on 3 consecutive bowel movements at home. If any test is positive, colonoscopy **must** be done.	▪ Stool DNA – no interval determined **Referrals — must** refer to a specialist if any test result is abnormal
Prostate Cancer Screening – should discuss with men who present for well-person care ✓ FYI – Prostate Cancer Screening Controversies	The American Cancer Society (ACS) recommends beginning discussions ▪ At age 50 if low risk ▪ At age 45 if high risk (African-American men and men who have a close relative — father, brother, or son — who had prostate cancer before age 65) ▪ By age 40-45, if very high risk (more than 2 first-degree relatives with a history of prostate cancer)	Screening PSA with or without a DRE (if DRE abnormal, diagnostic PSA **must** be drawn) Note: Normal PSA < 4.0 ✓ FYI - Causes of an elevated serum PSA	**Frequency of Screening** ▪ If PSA > 2.5, annual screening is recommended. ▪ If PSA < 2.5, every other year screening is recommended. Note: 5-alpha reductase inhibitors can lower PSA levels. **Referrals — must** refer the following to a specialist ▪ Screening PSA ≥ 4.0 ▪ Discrete nodules on DRE
Testicular Cancer Screening	It is not recommended to routinely examine testicles for testicular cancer for asymptomatic male adolescents and adults and may cause harm. It is also not recommended to routinely counsel about testicular self-exam for cancer for male adolescents and adults and may cause harm. There is also no evidence that teaching young men how to examine themselves		

Type	When	How	Treatment/Follow up/Referrals
	for testicular cancer would improve health outcomes, even among men at high risk, including men with a history of undescended testes or testicular atrophy. The American Cancer Society (ACS) advises men to be aware of testicular cancer and to seek prompt medical evaluation if a testicular mass is found.		

12.3 EVALUATION AND MANAGEMENT

12.3.1 Conditions that may be managed by affiliates

I. Men's sexual and reproductive health services are limited to the management and treatment of the conditions listed in 12.3.2 Evaluation and Management by Condition.
   A. A targeted history **must** be completed.

✓ FYI - Asking about Sexual Function

   B. After completion of the targeted history and history of the chief complaint, clients **must** be evaluated and managed according to tables in 12.3.2 Evaluation and Management by Condition.

Important Information

Must refer the following conditions to Emergency Room (ER) immediately:

- Non-reducible inguinal or femoral hernia
- Testicular torsion
- Orchitis
- Restrictive paraphimosis
- Priapism
- Restrictive balanitis
- Obstructive phimosis (inability to urinate)

12.3.2 Evaluation and Management by Condition Tables

12.3.a. Table: Balanitis

Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
▪ Pain and swelling at glans penis ▪ Itching ▪ Inability to easily retract foreskin ▪ Inability to void ▪ Redness ▪ Discharge	**Must** include ▪ Penis Should include ▪ Signs of systemic infection, lymphadenopathy and other non-genital findings ▪ Vital signs as indicated	Consider the following ▪ KOH wet prep or fungal culture ▪ GC/CT tests especially if urethral discharge noted ▪ Fasting glucose and HIV as indicated ▪ Culture of discharge, but may be of limited value due to contamination	▪ If phimosis is present, **must** refer to ER or specialist immediately. ▪ If phimosis is not present, have client retract foreskin daily and soak with warm water. ▪ Clotrimazole 1% or Miconazole 2% BID for 1 to 3 weeks if KOH wet prep is positive or there is high clinical suspicion for fungal disease. ▪ Nystatin is not sufficient. ▪ Consider bacitracin ointment TID or betamethasone 0.05 % in addition, based on symptoms. **Follow-up/Referrals** ▪ If unable to visualize urethral meatus and/or symptoms are worsening, **must** refer to ER or specialist immediately. ▪ RTC as needed if symptoms not improving despite adherence to treatment.

12.3.b. Table: Epididymitis

Epididymitis			
Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
▪ Groin pain ▪ Scrotal pain and swelling	**Must** include ▪ Temperature ▪ Inguinal lymph nodes	**Must** include ▪ GC/CT tests ▪ UA and urine culture	▪ If testicular torsion is suspected, **must** refer to ER or specialist immediately. ▪ For infectious causes **must** treat per CDC STD

Epididymitis			
Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
▪ Abdominal pain ▪ Flank pain ▪ Discharge from urethra ▪ Dysuria ▪ Fever ▪ Nausea	▪ Testicles ▪ Cremasteric reflex ▪ Prostate exam, if insertive anal sex is practiced Consider other vital signs as indicated by history and exam	Gram stain of urethral discharge is recommended.	Treatment Guidelines or recommendations of local/state health department ✓ CDC STD Treatment Guidelines ▪ For noninfectious causes make sure client is also not at risk for infection: 7-day course of NSAIDs Follow-up **must** be offered 3 to 7 days after treatment is started ▪ Should client instruct client to return if symptoms do not improve in 48 hours ▪ Change therapy as indicated by lab results. ▪ Referral **must** be made if no improvement in symptoms with appropriate treatment.

12.3.c. Table: Erectile Dysfunction (ED)

Erectile Dysfunction (ED)				
Signs and Symptoms	History	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
Any perceived difficulty to attain or maintain an erection. Note: Depression or anxiety symptoms may	**Must** include ▪ Family and self-history of cardiac disease, depression/ anxiety, diabetes, HTN diseases,	**Must** include BP Should include ▪ The abdomen ▪ Penis ▪ Testicles ▪ Secondary sexual	As indicated by exam and history.	**Treatment** is based on etiology such as psychosocial stressor vs. underlying medical condition. **Oral Medications** ▪ The medications listed below are contraindicated in the following situations: ○ Anatomical penile deformation ○ Any client use of nitrates ○ Bleeding disorders or active peptic ulceration

Erectile Dysfunction (ED)				
Signs and Symptoms	History	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
coexist with ED.	hyperlipidemia, liver, peptic ulcer, and retinitis pigmentosa ▪ Drug use, ETOH, and tobacco ▪ Social issues ▪ Medication list	characteristics ▪ Lower extremity pulses		○ Cardiovascular disease (e.g., MI, stroke, or life-threatening arrhythmia within 6 months; BP<90/50 or >170/110; unstable angina) ○ Retinitis pigmentosa ○ Predisposition to priapism ○ When sexual activity is inadvisable or contraindicated ▪ Sildenafil citrate (Viagra) 25, 50, 100 mg tablets ○ One tablet about 1 hour before sexual activity. ○ Initial dose 50 mg. Dose can be adjusted 25–100 mg per use. ○ For men ≥ 65 initial dose is 25 mg. ▪ Vardenafil (Levitra) 2.5, 5, 10, 20 mg tablets ○ One tablet once daily, about 1 hour before sexual activity. ○ Initial dose 10 mg. Dose can be adjusted 2.5–20 mg per day. ○ For men ≥ 65 initial dose is 5 mg. ▪ Tadalfil (Cialis) 5, 10, 20 mg tablets ○ One tablet daily before sexual activity. ○ Initial dose 10 mg. Dose can be adjusted 5–20 mg per day. **Referrals** ▪ Clients with the following conditions **must** be referred out unless affiliate provides comprehensive family practice:

Erectile Dysfunction (ED)				
Signs and Symptoms	History	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
				○ Diabetes mellitus, HIV, known coronary artery disease, liver or renal disease, and peripheral vascular disease ○ On multiple HTN medications ▪ Clients with anatomical defects of the penis **must** be referred out. ▪ Refer to AASECT-certified sex therapist, if indicated. ▪ Refer to primary care provider for management of other medications if it's thought they are contributing to ED. ▪ Refer to specialist for penile injections and/or vacuum/constrictive devices. **Follow-up — must** be 1 month after starting medications: ▪ Review of lab results, side effects, symptom relief, and need for refills **must** be done. ▪ If client has stable follow-up, a 6-month supply can be prescribed. Follow-up **must** occur twice yearly after that.

12.3.d. Table: Hydrocele

Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
▪ Most are asymptomatic and develop gradually ▪ May be a sensation of heaviness or mild discomfort that radiates to the back ▪ Pain may increase with hydrocele size Note: Hydrocele masses are most often superior and anterior to the testis.	**Must** include ▪ The abdomen ▪ Epididymis ▪ Inguinal lymph nodes ▪ Scrotum ▪ Testicles ▪ Transillumination of the entire hydrocele Should perform ▪ Vital signs, as indicated by history and exam. Note: The hydrocele may be more noticeable with standing.	**Must** order ▪ Scrotal ultrasound if diagnosis is uncertain or if entire hydrocele does not transilluminate. Should consider ▪ UA and GC/CT, if hydrocele is tender.	▪ Small, painless hydroceles – observation only ▪ If pain or increasing size develops, **must** recommend follow-up with a surgeon. ▪ Consider workup for renal mass when an adult man presents with a rapidly expanding hydrocele ▪ If associated with other findings (e.g., testicular mass), **must** recommend follow-up for further evaluation. **Follow-up** RTC as needed per increase in size or pain, per infection protocol if infection found to be cause of a reactive hydrocele, or per cancer protocol if other signs or symptoms are present that would be concerning for testicular cancer secondary to reactive process.

12.3.e. Table: Inguinal Hernia

Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
▪ Bulge when sitting, standing, or straining, with or without pain	**Must** include ▪ The abdomen ▪ Cremasteric reflex ▪ Epididymis ▪ Inguinal lymph nodes ▪ Scrotum ▪ Testicles ▪ Transillumination of scrotum ▪ Search for a bulge in the groin or scrotum and ensure that bulge is easily reducible Should perform ▪ Vital signs as indicated by history and exam Notes: ▪ Hernias, unlike hydroceles, do not transilluminate. ▪ Hernias may be accompanied by hydroceles. ▪ Bowel sounds may be heard over the bulge.	**Must** order scrotal ultrasound if diagnosis is uncertain	▪ **Must** refer non-reducible hernias to ER or specialist immediately. ▪ **Must** refer reducible hernias to surgeon for evaluation, observation, and treatment options. Many clients will opt for observation alone for some time, but the client **must** make that decision with the surgeon.

12.3.f. Table: Orchitis

Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
▪ Acute testicular pain and swelling ▪ Chills, fatigue, fever, headache, malaise, myalgia, and nausea (Mumps symptoms usually precede orchitis resulting from the virus) ▪ Testicles usually enlarged, indurated, and tender with an erythematous and edematous scrotal skin.	**Must** include ▪ Temperature ▪ The abdomen ▪ Cremasteric reflex ▪ Epididymis ▪ Inguinal lymph nodes ▪ Scrotum ▪ Testicles Should perform other vital signs as indicated by history and physical	May consider ▪ UA ▪ CBC with differential ▪ GC/CT ▪ gram stain of urethral discharge ▪ scrotal ultrasound Because immediate referral is required, labs may be done by referral clinician.	**Must** refer to ER immediately.

12.3.g. Table: Penile Lesions

Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
▪ New mole, papule, skin change, ulcer on penis, or wart ▪ Lesions may or may not be painful ✓ FYI - Pearly Penile Papules	**Must** include ▪ Examination of entire genital skin ▪ Inguinal lymph nodes ▪ Scrotal contents including testicles	Should consider ▪ HIV ▪ HSV culture ▪ RPR ▪ culture	Treatment should be based on exact diagnosis. ▪ STI related lesions should be treated based on STI protocols. See Chapter 9 Infections. ▪ Any lichen sclerosis and non-benign lesions should be referred to dermatologist or primary care provider. ▪ If suspicious for cancer **must** refer to specialist.

12.3.h. Table: Premature ejaculation (PE)

Signs and Symptoms	Physical Exam	Laboratory Testing	Treatment/Follow Up / Referrals
▪ Ejaculation before penetration or soon after sexual thought or stimulation Note: If problem occurs in > 50 percent of attempted sexual activity, a dysfunctional pattern usually exists for which treatment may be appropriate.	**Must** include ▪ Basic genital exam ▪ Depression/anxiety screening ▪ General affect Should perform ▪ Vital signs as indicated by history and physical Note: History is more important than PE in determining treatment options for most cases.	Notes: ▪ If no other medical problems exist, no specific conventional laboratory tests aid or affect treatment. ▪ In the over-40 population, consider erectile dysfunction as the diagnosis causing premature ejaculation and work up per above	▪ Relaxation techniques and practice training may help. ▪ Should recommend counseling and/or certified sex therapy, as indicated. ▪ Although not FDA-approved for treatment of PE, SSRIs and drugs with SSRI-like side effects have been the most successful agents in delaying the too-rapid response in men who experience PE. **Follow-Up** Offer follow-up 1 month after initiating treatment to assess success and recommend other resources, if needed.

12.3.i. Table: Benign Prostatic Hypertrophy (BPH)

Benign Prostatic Hypertrophy (BPH)			
Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
▪ Progressive urinary frequency ▪ Nocturia ▪ Retention ▪ Urgency ▪ Urination may be hesitant or with decreased stream.	**Must** include ▪ HR, BP, temperature ▪ Respiratory ▪ The abdomen ▪ Cardiac ▪ Inguinal lymph nodes ▪ Prostate	**Must** include ▪ UA ▪ Diagnostic PSA Should include GC/CT, as indicated	▪ Watchful waiting ▪ Advise basic behavioral changes to reduce symptoms ▪ Consider medications if significant impact on client's quality of life ○ Dutasteride (Avodart) 0.5 mg (5-alpha reductase inhibitor*) • Dosage — One capsule daily. • Contraindicated —Pregnant women and

Benign Prostatic Hypertrophy (BPH)			
Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
Note: Client may describe dribbling.	Note: Exam may show a bilaterally large prostate with loss of the median sulcus.		women of childbearing potential should refrain from handling the capsules. Men taking Avodart should not donate blood until at least six months after their last dose to prevent pregnant women from receiving Avodart through a blood donation. • Precautions — Hepatic dysfunction. Monitor PSA values after 3 to 6 months. Monitor for obstructive uropathy and prostate cancer. Exclude prostate cancer. • Interactions — caution with potent CYP3A4 inhibitors • Adverse reactions — decreased libido, ejaculation disorder, gynecomastia, impotence o Finasteride (Proscar) 5 mg (5-alpha reductase inhibitor*) • Dosage — 5 mg once daily. Reevaluate 6 months, then periodically. • Contraindicated — Pregnant women and those of childbearing potential should avoid handling crushed or broken tablets. • Precautions — hepatic dysfunction. Monitor PSA levels for comparison with normal ranges. Monitor for prostate cancer, obstructive uropathy. Exclude prostate cancer. o Doxazosin (Cardura) 1, 2, 4, 8 mg (alpha-adrenergic

Benign Prostatic Hypertrophy (BPH)			
Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
			antagonist) • Dosage — initially 1mg once daily, may double dose every 1–2 weeks. Max 8 mg/day • Precautions — impaired liver function. Monitor BP for orthostatic hypertension, initially, and if dose is increased. Syncope. Exclude prostate cancer. • Adverse reactions — edema, dizziness, dyspnea, fatigue, hypertension, and (rare) priapism. o Tamsulosin HCL (Flomax) 0.4 mg (alpha-adrenergic antagonist) • Dosage — 0.4 mg once daily, may increase to 0.8 mg after 2–4 weeks if response is inadequate. Take a half hour after a meal daily. Do not open, crush, or chew. • Precautions — Rule out prostate cancer. Syncope. • Interactions — Do not use with other alpha blocker. Caution with cimetidine, warfarin, clarithromycin, azoles. • Adverse reactions — abnormal ejaculation, amblyopia, cough, decreased libido, dizziness, insomnia, postural hypotension, rhinitis, sinusitis, somnolence, syncope o Terazosin (Hytrin) 1, 2, 5, 10 mg. (alpha-adrenergic

Benign Prostatic Hypertrophy (BPH)			
Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
			antagonist) • Dosage: Initially 1 mg at bedtime. Titrate to 10 mg once daily. Usual max 20 mg/day. Reevaluate if no response after 6 weeks. • Precautions — Rule out prostate cancer. Syncope. • Interactions — Caution with verapamil, other anti-hypertensives. • Adverse reactions — asthenia, blurred vision, dizziness, impotence, nasal congestion, nausea, orthostatic hypertension, palpitations, peripheral edema, somnolence, syncope, and (rare) priapism. ○ Alfuzosin (Uroxatral) 10 mg (alpha-adrenergic antagonist) • Dosage —10 mg once daily immediately after a meal. • Contraindicated — Concomitant potent CYP3A4 inhibitors. Moderate or severe hepatic insufficiency. • Precautions — Discontinue if angina develops or worsens. Severe renal insufficiency. Hypotension. Mild hepatic impairment. History of QT interval prolongation. Exclude prostate cancer. ○ Saw Palmetto — herbal

Benign Prostatic Hypertrophy (BPH)			
Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
			• Dosage — 120 mg po BID. Take with food for less GI distress. May work best as adjunct to other BPH meds, but can try alone first. Contraindications — none • Precautions — May cause mild GI distress. ▪ Men who experience injury of the upper (e.g., hydronephrosis, renal dysfunction) or lower (e.g., urinary retention, recurrent infection) tracts may require invasive treatment approaches. **Follow-up** for clients diagnosed with BPH ▪ If treatment initiated, **must** re-evaluate in 2 to 4 weeks to check BP, side effects, and symptom improvement. ▪ Anytime a medication dose is changed, **must** re-evaluate in 2 to 4 weeks. ▪ Annually, to re-evaluate symptoms **Referrals** — **must** refer the following to a specialist ▪ DRE showing discrete nodules or definite asymmetry ▪ PSA ≥ 4.0 ▪ When there is no improvement after medication changes or dosage increases ▪ Clients on multiple BP medications, or with known CAD or diabetes mellitus who desire treatment in affiliates that don't offer comprehensive family practice services
*Warnings and Precautions section of the labels for the 5-alpha reductase inhibitor (5-ARI) class of drugs include safety information about the increased risk of being diagnosed with a more serious form of prostate cancer (high-grade prostate cancer).			

12.3.j. Table: Prostatitis – Acute

Prostatitis – Acute			
Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
▪ Back pain ▪ Blood in semen ▪ Cloudy urine ▪ Dysuria ▪ Fever ▪ Myalgia ▪ Pelvic pain	**Must** include ▪ Temperature ▪ The abdomen ▪ Genitals ▪ Prostate Notes: A boggy, tender prostate helps to make the diagnosis. **Never massage prostate for secretions in men with acute prostatitis. This can worsen bacteremia.**	**Must** include ▪ Urine culture before initiating treatment in order to ensure treatment is appropriate Consider ▪ GC/CT and trichomonas testing, as indicated by history ▪ Blood cultures and CBC before initiating treatment, as indicated by physical exam findings	▪ Initial treatment **must** cover gram-negative organisms (E. coli). Consider local resistance patterns when choosing an antibiotic. Possible regimens include o Trimethoprim-sulfamethoxazole (TMP-SMX) 1 tab po BID for 4 to 6 weeks or o Ciprofloxacin 500 mg po BID for 4 to 6 weeks or • Ofloxacin 200 mg po BID x 28 d or • Cephalosporin, if resistance is >10%, but not as monotherapy. • Hospitalization may be needed if acute presentation. ▪ Treatment regimens may be changed based on GC/CT and urine culture results. ▪ NSAIDS are helpful to decrease pain and inflammation. Follow-Up — **must** be within 48 hours ▪ Reassess for fever, pain, and relief of symptoms. ▪ Consider PSA if still symptomatic ▪ If no clinical improvement, **must** change treatment regimen based on lab results or refer Referral — **must** refer the following ▪ If no improvement within 48 hours ▪ Men with true UTI-only (without prostatitis) to evaluate for anatomical irregularities ▪ Prostatitis in HIV-positive men, which may have granulomatous and viral causes ▪ Any discrete mass or nodule palpated on prostate exam ▪ When follow-up PSA, after an initial elevated PSA is ≥ 4.0

12.3.k. Table: Prostatitis - Chronic

Signs and Symptoms	Treatment/Follow Up / Referrals
More than 3 months of symptoms or recurrent acute prostatitis	**Must** refer to specialist.

12.3.l. Table: Spermatoceles (Epididymal cysts)

Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
Tender or non-tender mass that is cystic and well circumscribed on posterior lateral border of testis	**Must** include ▪ Inguinal lymph node ▪ Testicles ▪ Transillumination of mass Should include ▪ Vital signs as indicated by history and physical Note: Spermatoceles do transilluminate.	Consider referral for scrotal ultrasound if diagnosis is uncertain Note: Needle aspiration of a spermatocele **must not** be attempted	**Treatment** ▪ Usually, only observation is required. ▪ If pain develops, **must** recommend follow-up with a surgeon to discuss surgical options. **Follow-Up** — as needed only **Referral** — as above if client requests

12.3.m. Table: Testicular Torsion

Testicular Torsion			
Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
▪ Sudden onset of testicular pain and swelling in a unilateral testis ▪ Can be accompanied by groin and	**Must** include ▪ HR, BP, temperature ▪ The abdomen ▪ Cremasteric reflex ▪ Inguinal lymph nodes ▪ Scrotum and testicles including epididymis	Note: **must** not delay referral by doing labs or referring for scrotal ultrasound	**Must** refer to surgeon or ER **immediately.** Note: Torsion reduced before 6 hours of onset has the most chance of continued viability (testes preservation of 100%

Testicular Torsion			
Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
abdominal pain ▪ Nausea, urinary complaints, and vomiting are frequent	Note: Positive findings include ▪ Absent cremasteric reflex on the side of the torsion ▪ Elevated (high-riding) and horizontal lie of the testis on the side of the torsion compared to the other testis in the standing position		when released within 4 to 6 hours of onset versus less than 20% within 12 hours) Planned Parenthood clinician **must** not try to reverse the torsion unless directed to do so by referral surgeon due to time of transfer.

12.3.n. Table: Testicular Mass/Tumor

Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
Most frequent ▪ Painless, firm, irregular mass ▪ There may also be ○ Complaint of a heaviness in the testis ○ Unexplained fatigue ○ Occasional gynecomastia ○ Sudden collection of fluid in the scrotum Signs and symptoms of metastasis include ▪ Swelling of lower extremities ▪ Back pain ▪ Respiratory symptoms such as cough, dyspnea or hemoptysis	**Must** include ▪ The abdomen ▪ Cremasteric reflex ▪ Epididymis ▪ Inguinal lymph nodes ▪ Scrotum ▪ Testicles ▪ Transillumination of the scrotum Should include vital signs, as indicated by history and exam.	**Must** refer for immediate ultrasound of testis and scrotum If a testicular tumor is palpated.	**Must** refer to urologist immediately if ultrasound shows a solid testicular tumor or if ultrasound is non-specific or uncertain.

12.3.o. Urethritis — See Chapter 9 Infections

12.3.p. Table: Urinary Tract Infection (UTI)

Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
▪ Abdominal pain ▪ Back pain ▪ Dysuria ▪ Fever ▪ General malaise ▪ Hematuria ▪ Hesitancy ▪ Increased urinary frequency ▪ Nausea, and vomiting	**Must** include ▪ BP, HR, temperature ▪ The abdomen ▪ Costal vertebral angle ▪ Epididymis ▪ Testicles ▪ penis Consider a prostate exam if ≥ 30 years old or participated in receptive anal intercourse	**Must** include ▪ GC/CT testing ▪ Urinalysis (nitrites plus leukocytes) ▪ Urine culture ▪ Culture of urethral discharge, if present Consider ▪ Diagnostic PSA if prostatitis is part of the differential ▪ Fasting glucose Note: Urine culture for men is considered to be positive if there are more than 1,000 colony-forming units /ml.	**Treatment** ▪ Initiate immediately and modify based on results of urine culture ▪ If UA positive, but prostatitis is possible, follow prostatitis protocol (above) until urine culture returns. Consider checking PSA. ▪ If UA positive, but GC or CT is possible, treat GC/CT per CDC Guidelines and start an antibiotic for UTI. ✓ CDC STD Treatment Guidelines ▪ Initial treatment for UTI should be ○ Trimethoprim-sulfamethoxazole (TMP-SMX) double strength orally twice daily for 10 days or Ciprofloxacin 500 mg orally twice daily for 10 days or Levofloxicin 500 mg orally daily for 10 days ○ Plus or minus phenazopyridine 200 mg orally 3 times daily as needed for pain (available OTC) **Follow-up** - **must** be within 24 to 48 hours ▪ Consider evaluation for trichomonas if GC/CT negative and symptoms persist. ▪ If lab results show new treatment is needed, **must** change regimen and repeat follow-up in 24 to 72 hours. **Referrals** ▪ If no clinical improvement, client **must** be referred to ER or specialist immediately. ▪ If UTI, not acute prostatitis, is the diagnosis, **must** refer to a specialist to evaluate for anatomical defects which may have led to the UTI. This is especially important if the client has had more than one UTI.

12.3.q. Table: Varicocele

Signs and Symptoms	Physical Examination	Laboratory Testing and Diagnostic Imaging	Treatment/Follow Up / Referrals
▪ Painless or dull, aching scrotal pain ▪ Worsening pain when standing and improvement when recumbent ▪ Associated testicular atrophy ▪ Infertility	**Must** include ▪ The abdomen ▪ Epididymis ▪ Inguinal lymph nodes ▪ Scrotum ▪ Testicles ▪ Asking client to perform Valsalva maneuver to see if change in size occurs and if the varicocele then returns to previous size ▪ Performing exam in both standing and recumbent positions Should include ▪ Vital signs, as indicated by history and exam Documentation **must** include whether varicocele reduces in size when recumbent. Note: Varicocele will not transilluminate.	▪ **Must** refer for scrotal ultrasound if diagnosis is uncertain. ▪ Sperm testing for fertility should be done for young men who would like to have children in the future.	Treatment ▪ Scrotal support and NSAIDS may suffice for older man who has completed his family and who presents with only mild to moderate scrotal discomfort. ▪ Observation is the treatment for small or moderate varicoceles with only mild to moderate discomfort. **Follow-up** - as needed. **Referrals** ▪ The following **must** be referred to a surgeon: o All large or unilateral, right-sided varicoceles o All varicoceles that do not decrease in size in recumbent position o Any varicoceles in men who wish to be fertile and whose sperm count has been affected ▪ The following should be referred to a surgeon: o Pain or increasing size — to discuss option of surgical excision o Testicular atrophy due to the varicocele

12.4 ADDITIONAL INFORMATION

12.4.a. Table: For Your Information

Section	Topic	Detail
12.2.a.	DRE/FOBT and Hemoccult Testing	Neither digital rectal examination (DRE) nor the testing of a single stool specimen (fecal occult blood test [FOBT]) obtained during DRE is recommended as an adequate screening strategy for colorectal cancer. Three randomized controlled trials (RCTs), all using the Hemoccult® test kit, show reductions in risk of death from colorectal cancer from 15 percent to 33 percent from periodic FOBT screening. However, there is no agreed-upon standard of care for colorectal cancer screening.
12.2.a.	Prostate Cancer Screening Controversies	The USPSTF found good evidence that PSA screening can detect early-stage prostate cancer but mixed and inconclusive evidence that early detection improves health outcomes. Screening is associated with harms, including frequent false-positive results and unnecessary anxiety, biopsies, and potential complications of treatment of some cancers that may never have affected a client's health. The USPSTF concludes that evidence is insufficient to determine whether the benefits outweigh the harms for a screened population. The National Cancer Institute explains clearly the conflict in the most recent literature and the reasons behind the softer recommendations by both ACS and the American Urological Association: National Cancer Institute: PDQ® Prostate Cancer Screening. Bethesda, MD: National Cancer Institute. ✓ Available at: http://www.cancer.gov/cancertopics/pdq/screening/prostate/HealthProfessional
12.2.a.	Causes of an Elevated Serum PSA	The major causes of an elevated serum PSA include ▪ Prostate cancer — Level of elevation of PSA varies by age. General rule of thumb is that PSA > 4.0 ng/ml needs further evaluation. ▪ Benign prostatic hyperplasia (BPH) — BPH produces more PSA per gram than normal prostate tissue. Serum PSA levels overlap considerably in men with BPH and those with prostate cancer. BPH can cause elevations of the PSA, even up to 7.0 ng/ml, however, one **must** not assume the BPH is the sole cause of the PSA elevation. A potentially confounding problem is that medical treatment for BPH can reduce serum PSA concentrations. The appropriate serum PSA-reference range for men receiving finasteride or dutasteride needs to be adjusted.

Section	Topic	Detail
		▪ Prostatitis is an important cause of an elevated PSA. Levels as high as 75 ng/ml have been reported. Thus, many clinicians will initially treat a man with an elevated serum PSA for prostatitis and then obtain a repeat serum PSA; a return of the PSA to normal is expected if prostatitis was solely responsible. Serum PSA should not be ordered as a screening test for prostate cancer until the infection has subsided.
12.3.1	Asking about Sexual Function	As part of a complete medical history, men should be asked about their sexual function. Example, "Do you have any concerns about your erections or premature ejaculation?" It is **not appropriate** to wait for the client to bring up the topic.
12.3.g.	Pearly Penile Papules	Pearly penile papules are benign lesions that are usually seen in a circumscribed area around the penis corona or sulcus. They are flesh colored, not STI-related, and usually present in men age 20–30. They are most frequently asymptomatic and more common in men that are not circumcised. Often the client presents with concerns about STIs or cancer when the lesions are new. Pearly penile papules may persist through life and require no treatment. They only require reassurance.

12.4.b. Table: References

Section	Reference
Throughout	Marcell AV and the Male Training Center for Family Planning and Reproductive Health. Preventive Male Sexual and Reproductive Health Care: Recommendations for Clinical Practice. Philadelphia, PA: The Male Training Center for Family Planning and Reproductive Health and Rockville, MD: Office of Population Affairs; 2014. (in press)
12.2.a	Rex D et al. American college of gastroenterology guidelines for colorectal cancer screening 2008. Am J Gastroenterol 2009;104:739-750.
12.2.a.	*Screening for Colorectal Cancer*, Topic Page. U.S. Preventive Services Task Force. http://www.uspreventiveservicestaskforce.org/uspstf/uspscolo.htm. Accessed May 2014

12.4.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIIC	CI Benign Prostatic Hyperplasia (BPH) CI Erectile Dysfunction (ED) CI Premature Ejaculation CIIC Skin Biopsy CIIC Tests for Prostate Cancer	Part 3, Chapter 02_12

12.4.d. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ CDC: Providing Quality Family Planning Services (QFP) ✓ Male Training Center for Family Planning & Reproductive Health Tools and Documents	
Training	✓ PPFA Male Examination Checklist	

CHAPTER 13: PREGNANCY EVALUATION AND MANAGEMENT OF COMPLICATIONS

Revised June 2014

Chapter 13 Table of Contents

13.1 CLIENT EDUCATION AND INFORMED CONSENT

13.1.1 Requirements

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

13.1.a. Table: Requirements for Written Materials as indicated

Document	Document #	**Must** sign	**Must** give	Should give	**Must** offer
CI Ectopic Pregnancy			●		
CI Miscarriage			●		
CI Molar Pregnancy			●		
CI on all available contraceptive methods				●	
CI Positive Pregnancy Test – No Pregnancy Seen on Ultrasound			●		
CI Rho(D) Immune Globulin			●		
CIIC Treatment of Miscarriage: The Abortion Pill		●	●		
CIIC Treatment of Miscarriage: Medication (Misoprostol)		●	●		
CIIC Treatment of Miscarriage: Suction Procedure		●	●		
CIIC Treatment of Miscarriage: Doing Nothing or "Wait and See"		●	●		
Danco Laboratories *Mifeprex Medication Guide*			●		
Danco Laboratories *Mifeprex Patient Agreement*		●			●
Information on any medication dispensed (package insert may be used)			●		
Release When Test/Service/Consultation Will Not Be Obtained		Once			
Request for Surgery or Special Procedure		●			●

13.2 EVALUATION OF SPECIFIC CLINICAL PRESENTATIONS

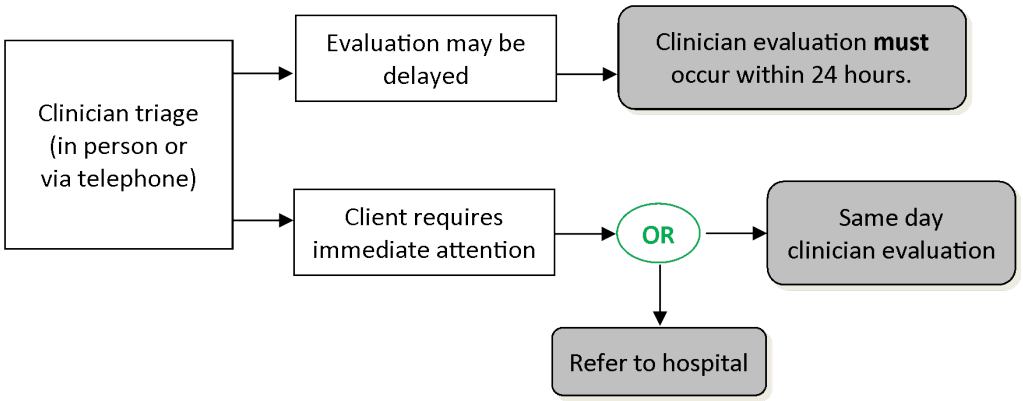
Important Information – Conditions Requiring Immediate Referral Out of Affiliate

- Ectopic pregnancy, known or strongly suspected*
- ✓ FYI — Common Symptoms of Ectopic Pregnancy
- Hemodynamic instability

*Based upon signs, symptoms, serial hCG measurements and transvaginal ultrasound or an adnexal mass suspicious for ectopic pregnancy

13.2.1 Pain and Bleeding

13.2.a. Algorithm: Triage of Client Who Presents with Pain and/or Bleeding



13.2.b. Table: Medical Screening and Evaluation of Pain and Bleeding

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Must include ▪ Screening to identify risk factors for ectopic pregnancy ▪ Possible special conditions and/or contraindications to specific management options	**Must** include ▪ Temperature, if symptomatic of infection ▪ Pulse, BP ▪ Speculum, bimanual, and abdominal exams, as indicated	Laboratory tests **must** include ▪ Pregnancy test — unless ultrasound has documented an intrauterine pregnancy ▪ Hgb or Hct, as indicated ▪ Rh typing, unless client reports she is Rh-negative or written documentation of Rh status is available.

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
▪ Special attention **must** be given to allergies to medications, antiseptic solutions, and latex ▪ Medications or herbal preparations See Important Information – Ingested Medication to Induce Abortion, below.	▪ Additional examination as indicated by history or laboratory findings	▪ GC/CT evaluation per CDC STD Treatment Guidelines ✓ CDC STD Treatment Guidelines ▪ hCG, as indicated* ✓ FYI — hCG in Early Pregnancy and the Discriminatory Zone ▪ Other tests, as indicated Diagnostic imaging **must** include ▪ ultrasound**
*Results **must** be available as soon as possible and within 48 hours. **Imaging and interpretation of results **must** be available within 24 hours, either on-site or by referral.		

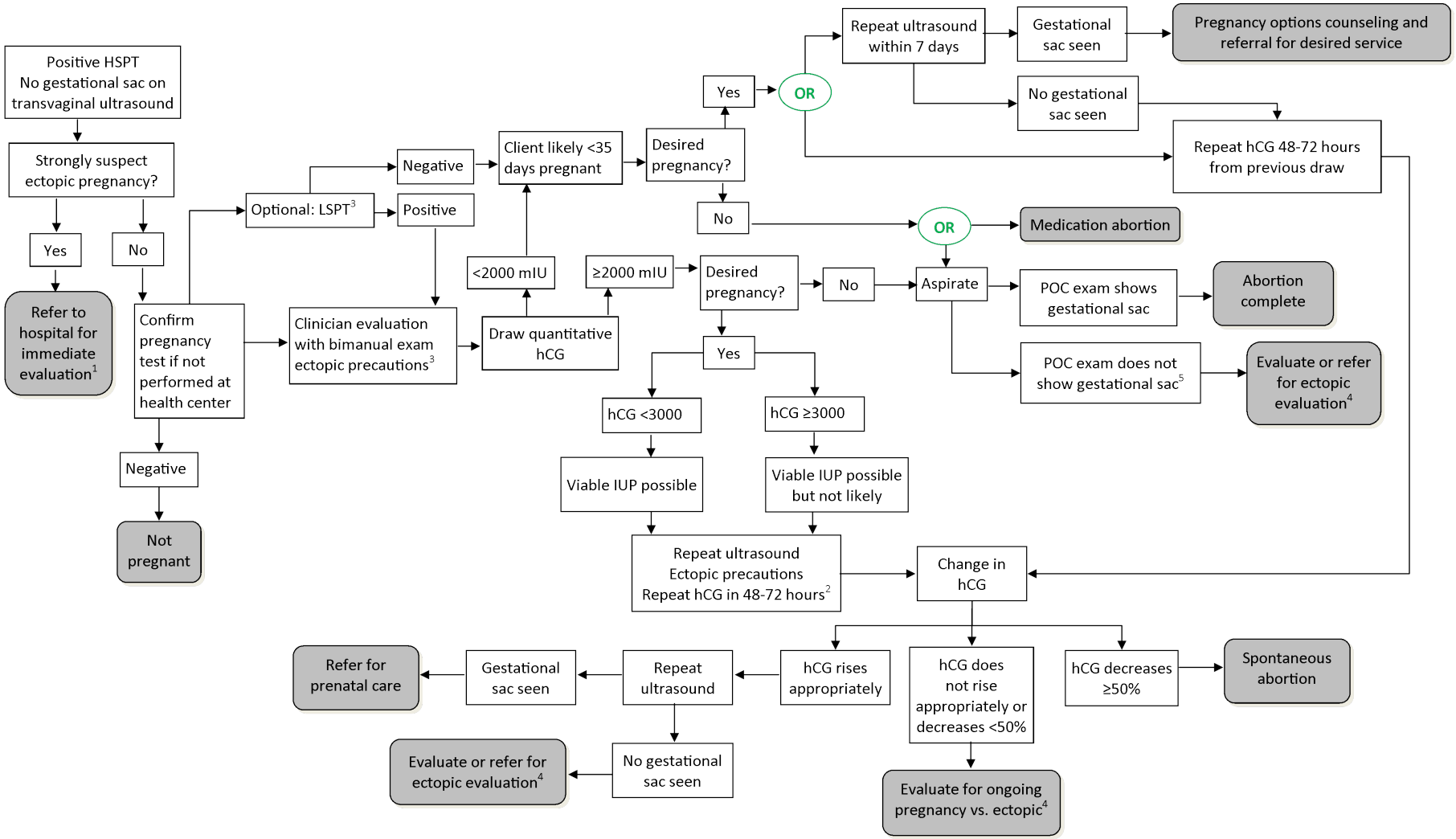
Important Information - Ingested Medication to Induce Abortion
Clients may report using various medications or herbal preparations to induce abortion. Misoprostol can be obtained from multiple sources. Methotrexate is available without a prescription in Mexico. The potency and ingredients of these drugs is often unknown.

While there are no reports that these abortifacients contain toxic substances, clinicians should be alert to that possibility when evaluating these clients. Management of these clients should be based on clinical findings. If the client wishes to continue the pregnancy, she **must** be informed of possible teratogenic effects, and genetic counseling **must** be recommended.

13.2.2 Pregnancy of Unknown Location (PUL)

- ✓ See Chapter 19.5 FYI – Pregnancy of Unknown Location (PUL)
- ✓ FYI — Heterotopic Pregnancy
- ✓ FYI — Common Symptoms of Ectopic Pregnancy
- ✓ FYI — hCG in Early Pregnancy and the Discriminatory Zone
- ✓ FYI — Evaluation for Ongoing Pregnancy vs Ectopic

13.2.c. Algorithm: Evaluation of a Client with Pregnancy of Unknown Location



[1]If Client is subsequently confirmed to have IUP, may return to affiliate for further care.

[2]If normal IUP, hCG should rise by 50% in 48 hours or 100% in 72 hours

[3]May also proceed directly to aspiration (if undesired pregnancy) or refer for ectopic evaluation

[4]See FYI — Evaluating for ongoing pregnancy vs. ectopic

[5]Follow hCG +/- send tissue to pathology. Refer out for ectopic if 2nd hCG does not increase by ≥50%.

13.3 HYDATIDIFORM MOLE

13.3.1 Diagnosis, Management, and Referral

I. Definition — abnormal proliferation of placental tissue.
II. Diagnosis made based on ultrasound findings or tissue examination.
III. Management
   A. If uterus < 14 week size, client may have a suction procedure at affiliate or be referred out for management.
      1. Manage per Chapter 1.2 Surgical Abortion
      2. If follow-up is provided at the affiliate, the medical director or physician program director **must** directly supervise client care.
      3. Follow-up care requires serial serum quantitative hCGs at 1 to 2 week intervals until hCG <5mIU/ml, then monthly for 6 to 12 months.
      4. A reliable method of contraception **must** be offered.

✓ FYI — Contraception for Women with Gestational Trophoblastic Disease

      5. Clients **must** be referred to a specialist in gynecologic oncology if either of the following hCG patterns is seen:
         a. hCG levels plateau or rise
         b. hCG does not drop to <5mIU/ml within 6 months of uterine evacuation
   B. If uterus ≥ 14 week size, client **must** be referred out of affiliate for management and follow up. The referral **must** include information on the need for follow-up hCG.

13.4 MISCARRIAGE

13.4.1 Diagnosis and Management of Miscarriage

✓ FYI - Miscarriage

13.4.a. Table: Diagnosis and Management of Miscarriage

Diagnosis	Diagnostic Criteria	Management
Complete abortion	▪ Prior confirmation of IUP ▪ All pregnancy tissue has passed from uterus (empty uterus on ultrasound with passage of tissue by history)	No treatment indicated unless client has persistent bleeding. If persistent bleeding is light or moderate and no signs of anemia or instability, may follow expectantly or treat with uterotonic

Diagnosis	Diagnostic Criteria	Management
		medications as needed. ▪ If persistent bleeding is heavy and/or client is anemic, **must** aspirate ASAP in affiliate or by referral. ▪ If signs of hemodynamic instability, refer to hospital for management.
Early Pregnancy Failure (EPF)	▪ See Table 13.4.b. ▪ Clients with a desired pregnancy and findings suspicious for EPF should be offered a follow-up visit for confirmation of diagnosis.	Treat per Table 13.4.c.
Incomplete abortion	Cervix is dilated, some pregnancy tissue remains in uterus	▪ Remove tissue from vagina or cervix, if present. ▪ Examine tissue for products of conception (POC). (See Chapter 1.4.a. FYI – Examination of Products of Conception After Surgical Abortion) ▪ If no POC are identified, should send tissue to pathology. ▪ Treat per Table 13.4.c. ▪ If persistent bleeding is heavy and/or client is anemic, **must** aspirate ASAP in house or by referral. ▪ If signs of hemodynamic instability, refer to hospital for management. ▪ If bleeding is heavy and/or client is anemic, **must** aspirate ASAP in house or by referral.
Inevitable abortion	Dilated cervix, with or without bleeding and uterine cramps or contractions	
Threatened abortion	Uterine bleeding with a closed cervix and without passage of tissue	▪ If abortion desired, treat per protocol. (See Chapter 1 Abortion) ▪ If desired pregnancy, no treatment indicated unless client has persistent or heavy bleeding. ▪ If bleeding gets worse or persists beyond 14 days return for further assessment; if bleeding stops, start or continue prenatal care.

13.4.b. Table: New Diagnostic Criteria for EPF

In 2013, Doubilet et al published a review article in the New England Journal of Medicine evaluating hCG values in use in the investigation of pregnancies of unknown location (PUL). Incorrectly diagnosing pregnancy failure in a client with a PUL can prompt interventions that damage a pregnancy that might have had a normal outcome. The criteria below are the new criteria to be used in the evaluation of a client for potential EPF. Clients with suspicious findings should be advised that a normal IUP is not likely, but should be given the option to continue evaluation until a true diagnosis can be made.

Findings diagnostic of pregnancy failure	**Findings suspicious for, but not diagnostic of, pregnancy failure**
▪ CRL ≥ 7 mm and no heartbeat ▪ MSD ≥ 25 mm and no embryo ▪ Absence of embryo with heartbeat ≥ 2 weeks after an ultrasound that showed a gestational sac without a yolk sac ▪ Absence of embryo ~~without~~ heartbeat ≥ 11 days after an ultrasound that showed a gestational sac with a yolk sac	▪ CRL < 7 mm and no heartbeat ▪ MSD 16-24 mm and no embryo ▪ Absence of embryo with heartbeat 7 to 13 days after an ultrasound that showed a gestational sac without a yolk sac ▪ Absence of embryo with heartbeat 7 to 10 days after an ultrasound that showed a gestational sac with a yolk sac ▪ Absence of embryo ≥ 6 weeks after LMP ▪ Small gestational sac in relation to the size of the embryo (< 5 mm difference between MSD and CRL)

13.4.c. Table: Miscarriage Treatment Options and Regimens

✓ FYI — Success Rates for Miscarriage Management Treatment Options

	EPF – Symptomatic	EPF – Asymptomatic	Threatened Abortion	Incomplete / Inevitable Abortion	Management
Expectant Management*	Yes	Yes	Yes	Yes	▪ Clients may wait up to 4 weeks from initial diagnosis. ▪ Clients should be seen weekly and counseled on all treatment options at each visit. ▪ If intact pregnancy is still present after 4 weeks, evacuation with suction **must** be offered.

	EPF – Symptomatic	EPF – Asymptomatic	Threatened Abortion	Incomplete / Inevitable Abortion	Management
Misoprostol Alone	Yes	Yes	No	Yes	▪ Misoprostol only regimens (800 mcg vaginally or buccally, 600 mcg sublingually) can be used up to 12 weeks gestation. ▪ Prescribe or dispense antiemetics as indicated.
Mifepristone + Misoprostol	No**	Yes	If client requests abortion	No	▪ See Chapter 1.1 Medication Abortion
Aspiration	Yes	Yes	If client requests abortion	Yes	▪ See Chapter 1.2 Surgical Abortion
*Clients managed expectantly may be treated with uterotonic medications as needed. Acceptable regimens include methergine 0.2 mg PO QID OR misoprostol 600 mcg orally or 400 mcg buccally. Repeat in 12 to 24 hours, if needed. There are generally more side effects with the oral route. Prescribe or dispense antiemetics as indicated. **In clients with EPF and significant symptoms heralding the onset of miscarriage, the addition of mifepristone does not add clinical efficacy, but does add expense. For a client with minimal symptoms, the mifepristone option may offer increased clinical efficacy, and may be offered.					

13.4.2 Contraindications and Special Conditions

I. Table 13.4.d. **must** be followed when making decisions about client selection for expectant management or treatment with misoprostol alone. **Must** refer to Chapter 1 tables 1.1.b. Contraindications and Special Conditions - Medication Abortion and 1.2.b. Contraindications and Special Conditions – Surgical Abortion when making decisions about client selection for treatment with medication abortion and surgical abortion regimens.

13.4.d. Table: Contraindications to/Special Conditions for Expectant Management of Miscarriage or Treatment with Misoprostol Alone

Legend	
A	**Musts/**Shoulds
B	Contraindications — **must not** be managed at affiliate
C	Special Conditions Requiring Special Evaluation and Management — Conditions that may complicate treatment and require management by affiliate protocols or consultation with affiliate physician or program director.

Condition	A	B	C
Anemia — hct < 30% or hgb < 10 gm/dl	▪ **Must** evaluate and determine the appropriate management or referral		●
Cervicitis – mucopurulent	▪ Assume GC/CT. ▪ Initiate treatment per CDC STD Treatment Guidelines prior to or concurrent with management of pregnancy complication. ✓ CDC STD Treatment Guidelines		●
Client Factors ▪ Cannot follow up to confirm diagnosis ▪ Does not have access to a telephone, emergency medical care (emergency treatment of incomplete abortion, blood transfusion or emergency resuscitation), and transportation		●	
Ectopic pregnancy, known or strongly suspected	▪ Unless affiliate is approved for Level III GYN	●	
Fetal demise – second trimester ✓ See Chapter 1.4 FYI - Interpretation of Laboratory Results for Evaluation of Second Trimester Fetal Demise	▪ If indicated, a DIC panel should consist of CBC with platelet count, PT/PTT, fibrinogen and D-dimers		●
Hemorrhagic disorder		●	
Hydatidiform mole		●	
Infection, intrauterine	▪ **Must** aspirate if retained tissue is suspected. ▪ Antibiotics **must** be provided per CDC STD Treatment Guidelines for PID before, or concurrent with, suction procedure ✓ CDC STD Treatment Guidelines ▪ Clients with signs of sepsis or peritonitis or who require IV antibiotics **must** be referred immediately to a hospital.	●	

Condition	A	B	C
IUC in situ	▪ Pregnancy should be considered ectopic until proven otherwise. ▪ If IUP is confirmed with IUC in situ, IUC should be removed regardless of pregnancy intention. ▪ If the string is not visible or the IUC cannot be withdrawn easily, termination of pregnancy should be offered.		●
Medications			
▪ Anticoagulants		●	
Uterine size ≥ 12 weeks		●	

13.4.3 Rho(D) Immune Globulin

I. If Rh-negative, and there is vaginal bleeding or client chooses an abortion procedure for management, give Rho(D) immune globulin.
   A. Up to 12 6/7 weeks gestation: 50 micrograms IM
   B. ≥ 13.0 weeks gestation: 300 micrograms IM

13.4.4 Follow-up

I. A follow-up visit **must** be offered and should be scheduled within 2 to 3 weeks of completion of treatment. The purpose of the follow-up visit is to
   A. Establish that the client is well.
   B. Establish that pregnancy signs and symptoms have resolved.
   C. Review contraceptive options, if not already done.
   D. Perform pelvic exam and/or other tests as clinically indicated.
      1. The visit does not require either bimanual or speculum exam if a continuing pregnancy is not suspected and there is no other clinical indication.
      2. A low-sensitivity urine pregnancy test may be used at the time of the follow-up visit for the purpose of identifying a continuing pregnancy. The test should be negative within 3 weeks of passage of the pregnancy.
   E. A client with a suspected ongoing pregnancy or persistent bleeding warrants further evaluation with ultrasound and possibly aspiration.

13.5 ADDITIONAL INFORMATION

13.5.a. Table: For Your Information

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>13.4.1</td><td>Miscarriage[R2]</td><td>Historically, miscarriage has been considered a lay term that includes several specific conditions — early pregnancy failure (EPF), incomplete abortion, inevitable abortion, and complete abortion. EPF is further divided into anembryonic gestation and intrauterine embryonic or fetal demise. An understanding of the specific diagnosis has been useful for counseling the client and selecting the best treatment option(s). As of the publication of this manual, ACOG has proposed the following terms be used
▪ Miscarriage/Intrauterine Pregnancy Loss Prior to 20 Weeks

This term can be further subdivided into
▪ Early miscarriage: Loss of a documented IUP prior to 10 weeks' gestational age
▪ Late miscarriage: Loss of a documented IUP from 10 weeks' to 19 weeks, 6 days' gestational age

While the medically accepted terminology may be in flux, older terminology may still be required when performing billing and coding for clients evaluated and/or treated for miscarriage.</td></tr>
<tr><td>13.2</td><td>Common Symptoms of Ectopic Pregnancy</td><td>▪ Abdominal or pelvic pain
▪ Vaginal bleeding with or without clots
▪ Dizziness, fainting, or syncope
▪ Shoulder pain</td></tr>
<tr><td>13.4.c.</td><td>Success Rates for Miscarriage Management Treatment Options[R1]</td><td>Success varies based upon diagnosis and follow-up period. The following table may be useful when presenting treatment options to a client.
<table>
<tr><th>Treatment</th><th>Advantages</th><th>Disadvantages</th><th>Relative Efficacy</th></tr>
<tr><td>Expectant management</td><td>▪ Noninvasive
▪ May avoid anesthesia and surgery risks</td><td>▪ Unpredictable outcome and timescale</td><td>▪ EPL: 16-75%
▪ Incomplete abortion: 82-96%</td></tr>
<tr><td>Expectant management</td><td>▪ Allows for privacy and continuity of care</td><td>▪ Process can last days to weeks
▪ Can have prolonged bleeding and cramping
▪ May still need aspiration</td><td></td></tr>
</table></td></tr>
</table>

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>Misoprostol only</td><td>▪ Noninvasive
▪ May avoid anesthesia and surgery risks
▪ Cost effective
▪ Allows for privacy and continuity of care</td><td>▪ May cause heavier or longer bleeding
▪ May cause short-term gastrointestinal and other side effects
▪ May still need aspiration</td><td>▪ EPL: 77-89%
▪ Incomplete abortion: 61-100%</td></tr>
<tr><td>Aspiration</td><td>▪ Predictable
▪ Offers fastest resolution
▪ Shortest duration of bleeding (compared to expectant management or misoprostol)</td><td>▪ Rare risks of invasive procedure</td><td>95-100%</td></tr>
</table>
</td></tr>
<tr><td>13.2</td><td>hCG in Early Pregnancy and the Discriminatory Zone</td><td>
High sensitivity pregnancy tests (HSPT) are positive at approximately 25 mIU/ml. Because these tests are so sensitive, they are often positive before the client has even missed her period, and can remain positive long after a pregnancy ends.

hCG doubling times
The earlier the pregnancy, the faster the hCG doubling time. Before hCG levels reach the discriminatory zone (1,500-2,000 mIU/ml), hCG doubles about every 1.5 days. Once hCG approaches 2,000 mIU/ml, it doubles about every 48 hours.

The Discriminatory Zone
An hCG level of 1500-2000 mIU/ml is called the discriminatory zone, because at that level of hCG a gestational sac should be visible with transvaginal ultrasound.

Discriminatory Zone = hCG 1500–2000 mIU/ml = approx 35 days LMP = gestational sac on transvaginal ultrasound.

The gestational sac is usually visualized by 35 days LMP. If hCG ≥ 2000 mIU/ml and gestational sac is not seen on transvaginal ultrasound, ectopic pregnancy must be ruled out in accordance with Algorithm 13.2.c.
</td></tr>
</table>

Section	Topic	Detail
		Evaluation of a Client with Pregnancy of Unknown Location. In stable clients with a pregnancy of unknown location, the decision to intervene should not be based solely on a single hCG level and as described in Algorithm 13.2.c. a less stringent cutoff is acceptable. **Use of Low Sensitivity Pregnancy Tests (LSPT) as a Screening Tool** LSPT can be a helpful and relatively inexpensive way to gauge whether an intrauterine pregnancy should be seen on transvaginal ultrasound. LSPTs are positive at an hCG of approximately 1500-2000 mIU/ml. LSPT **must not** be used to initially determine whether the client is pregnant or not. Important limitations of LSPT tests: ▪ There is no published data correlating urine and serum hCG levels. ▪ One cannot assume that an LSPT with a 1500-2000 mIU cut off correlates to a serum hCG of 1500-2000 mIU (the discriminatory zone at which you would expect to see a gestational sac in the uterus) ▪ LSPT test results may be affected by urine concentration. *Take home messages* ▪ *You cannot rely solely on a LSPT. The entire clinical picture **must** be considered when providing client care.* ▪ *If the hCG is ≥ 2000 mIU/ml and a gestational sac is not seen on transvaginal ultrasound, ectopic pregnancy must be ruled out*
13.3	Contraception for Women with Gestational Trophoblastic Disease[R3]	The US MEC for Contraceptive Use lists combined hormonal contraception, progestin-only pills, injections, and implants as Category 1 methods for women with a diagnosis of gestational trophoblastic disease, regardless of the pattern of response. Both the LNG-IUS and Copper-IUD are listed as a Category 3 for women with decreasing or undetectable hCG levels, and Category 4 for women with persistently elevated hCG levels or malignant disease.
13.2	Evaluating for Ongoing Pregnancy vs. Ectopic	If a client is being followed with hCG to determine pregnancy status and the hCG rises, plateaus, or does not fall appropriately, the goal of the clinician is to rule out conditions which need immediate intervention namely ectopic pregnancy and ongoing pregnancy. There are 3 ways that this may be accomplished:

Section	Topic	Detail
		▪ Immediate referral (internally or externally) to rule out ectopic pregnancy. ▪ Aspiration and examination of the tissue to identify a gestational sac and determine whether pregnancy was intrauterine, if the pregnancy is not desired. ▪ Continue to follow with hCG for asymptomatic clients. Consultation with an affiliate physician is required.
13.2.2	Heterotopic pregnancy	Should be considered if signs of ectopic pregnancy are present, even if an intrauterine pregnancy is confirmed. This rare event is more common in pregnancies resulting from in vitro fertilization.

13.5.b. Table: References

Section	R#	Reference
13.5	R2	ACOG Revitalize Initiative www.acog.org/revitalize
13.2		Barnhart K, Van Mello NM, Bourne T, et al Pregnancy of unknown location: A consensus statement of nomenclature, definitions and outcome. Fertil Steril. 2011 March 1; 95(3): 857–866.
13.4		Carey MJ and Rodgers GM. Disseminated Intravascular Coagulation: Clinical and Laboratory Aspects. American Journal of Hematology 1998;59:65–73
13.4		Carr et al. Diagnosis of Disseminated Intravascular Coagulation: Role of D-Dimer. Am J Clinical Pathol 1989;91:280-287
13.5	R3	CDC Department of Health and Human Services. U.S. Medical Eligibility Criteria for Contraceptive Use 2010. May 28, 2010.
13.4		Doubilet PM, Benson CB, Bourne T, et al. Diagnostic criteria for nonviable pregnancy early in the first trimester. NEJM. 369;15:1443-1451.
13.2		Ko JK and VT Cheung. Time to revisit the human chorionic gonadotropin discriminatory level in the management of pregnancy of unknown location. J Ultrasound Med. 2014;33:465-471
13.2		Lurie S. Feinstein M. Mamet Y. Disseminated intravascular coagulopathy in pregnancy: thorough comprehension of etiology and management reduces obstetricians' stress. Arch Gynecol Obstet 2000;263:126–130
13.4		National Institute for Health and Clinical Excellence (NICE) Clinical Guideline 154, December 2012. Ectopic Pregnancy and miscarriage: Diagnosis and management in early pregnancy of ectopic pregnancy and miscarriage.
13.5	R1	Wallace R et al. Counseling women with early pregnancy failure: Utilizing evidence, preserving preference. Patient Education and Counseling 81 (2010) 454–461

13.5.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIIC	CI Ectopic Pregnancy CI Miscarriage CI Molar Pregnancy CI Positive Pregnancy Test - No Pregnancy Seen on Ultrasound CI Taking care of Yourself - Miscarriage CIIC Treatment of Miscarriage: The Abortion Pill CIIC Treatment of Miscarriage: Medication (Misoprostol) CIIC Treatment of Miscarriage: Suction Procedure CIIC Treatment of Miscarriage: Doing Nothing or "Wait and See"	Part 3, Chapter 02_13
	CI Rho(D) Immune Globulin	Part 3, Chapter 02_01

13.5.d. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	Decline in hCG in Spontaneous Abortion hCG in Various Clinical Situations	Part 3, Chapter 02_13

CHAPTER 14: PREGNANCY TESTING AND OPTIONS COUNSELING

Revised June 2014

Chapter 14 Table of Contents

CHAPTER 14: PREGNANCY TESTING AND OPTIONS COUNSELING

Revised June 2014

14.1 PREGNANCY TESTING AND OPTIONS COUNSELING

14.1.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

14.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give
CI Early Pregnancy Symptoms			To women with positive results
CI Preconception			To women with negative results
Release When Test/Service/Consultation Will Not Be Obtained As Recommended		Once	
Written information about any medication dispensed (package insert may be used)			●
Written information on all available contraceptive methods			To women with negative results who wish to prevent pregnancy

14.1.2 Screening and Evaluation

I. Perform according to Table 14.1.b.

14.1.b. Table: Screening and Evaluation

History	Physical Examination	Laboratory Tests/Diagnostic Imaging
Must include ▪ Age ▪ LMP ▪ Current contraceptive method ▪ Last unprotected intercourse	Not routinely needed but may be indicated for the following reasons, within an appropriate timeframe: ▪ Signs and symptoms of ectopic pregnancy ▪ Signs and symptoms of spontaneous abortion ▪ Pelvic sizing	**Must** include ▪ Pregnancy confirmation via pregnancy test and/or ultrasound

14.1.3 Options Counseling

I. Provide according to table 14.1.c.

14.1.c. Table: Options Counseling

Results	Action
Positive Results ✓ FYI – Making Major Life-Altering Decisions	Guidance **must** include ▪ Discussion of risks, benefits and alternatives of continuing (parenting or adoption) or terminating the pregnancy, including ○ Signs and symptoms of an abnormal pregnancy ○ General information about how/where/when to obtain necessary care (e.g., fees, insurance coverage, etc) ○ Information about avoiding hazards of pregnancy (cigarette smoking, alcohol and drug use, etc.) for clients who are undecided or plan to continue the pregnancy ▪ Information about the importance of folic acid for the prevention of birth defects Offer or refer for more intensive intervention and information about adoption when appropriate. ✓ FYI – Adoption Today
Negative Results	Guidance should include ▪ Reproductive life planning – see Chapter 21.3 FYI – Reproductive Life Planning ▪ Recommendation to have preconception care visit, if indicated - see Chapter 21.2 Preconception Care ▪ Discussion of risks, benefits and alternatives of appropriate contraceptive methods if client wants to prevent pregnancy ▪ Provision of emergency contraception, if indicated - see Chapter 7 Emergency Contraception ▪ Information about the importance of folic acid for the prevention of birth defects

14.1.4 Follow-up and Referral

I. Recommend the following care (within or outside affiliate), as needed, including but not limited to
   A. For clients with negative results
      1. Reproductive life planning
      2. Preconception care
      3. Contraceptive visit, immediately or as soon as possible

B. For clients with positive results
   1. Prenatal care
   2. Abortion services
   3. Adoption services

✓ FYI – Screening Potential Adoption Referral Sources

✓ See Part 3: Required Documents and Other Resources - Pro-Choice Adoption Agencies

II. All clients with a positive pregnancy test and signs or symptoms of
   A. Ectopic pregnancy **must** be immediately referred out for evaluation and management (unless the affiliate provides Level III GYN services and can manage this condition in-house).
   B. Early pregnancy failure **must** be immediately referred (within or outside affiliate) for evaluation and management as appropriate.

14.2 ADDITIONAL INFORMATION

14.2.a. Table: For Your Information

Section	Topic	Detail
14.1.c	Making Major Life-Altering Decisions	For any visit that involves a major life decision (i.e., adoption, carrying a pregnancy to term, abortion), the follow up discussion should include a discussion of the client's anticipation of coping after the visit and an assessment of the client's coping strengths and style, including ▪ Feelings about the pregnancy and the circumstances surrounding the pregnancy ▪ Support for her decision ▪ Relationship with significant other ▪ Any feelings of stigma associated with her chosen option ▪ Expectation of coping ▪ Mental health prior to the pregnancy ▪ History of sexual abuse ▪ Other major factors in her life and/or medical history that may affect her feelings about her decision The client should also be advised of any warning signs of poor coping following her decision including ▪ Not getting back to old self

Section	Topic	Detail
		▪ Feeling worse, not better, over time ▪ Having major problems during normal life activities Clients experiencing warning signs should be advised to follow up for further care.
14.1.c	Adoption Today: Incidence and Practice	One reason that women's health and family planning providers face challenges in effectively integrating the adoption option into their everyday practice is that the recent history of adoption in the United States is so dark. It is difficult for many to embrace or trust the newer, brighter reality. Throughout much of the 20th century, adoption was cloaked in shame and secrecy. The popular and accepted wisdom was that it would be less painful and traumatic for all parties if there was a "clean break" between the birth mother and child after the birth of the infant. Women who placed their children during this period frequently reported a lifetime of chronic and unresolved grief. Many adult adoptees spoke of an ongoing sense of loss, and many had unanswered questions about their origins and why they were placed. Today, cultural norms have shifted. Abortion is legal, and the use of contraceptives has increased dramatically. The cultural stigma associated with single parenthood has been reduced significantly — some would even argue that it is non-existent. As a result, the prevalence of domestic adoption placements has gone down dramatically, from a peak of approximately 89,000 in 1970 to 13–14,000 today. (Livingston Smith 2007) The best practice standards in adoption today centers on autonomy and empowerment for the birth mother and adopting family throughout the process. It most often includes varying degrees of openness in the adoption following the birth of the baby and the adoptive placement. ▪ Women who place their children for adoption in the 21st century are very diverse and differ from those of previous generations. They are no longer primarily teenagers; in fact, only about one out of four is a teen. The predominant profile is a young woman in her 20s who has graduated from high school. She may have other children. (Livingston Smith 2007) ▪ The vast majority of adoption agencies, as well as independent practitioners, offer open adoptions, in

Section	Topic	Detail
		which identifying information is exchanged. (Livingston Smith 2007) ▪ The overwhelming majority of contemporary birth mothers have met the adoptive parents of their children — probably 90 percent or more — and nearly all of the remaining birthmothers helped to choose the new parents by evaluating their application profiles. Contrary to the stereotypes we may have about them, hardly any woman choosing adoption today seeks anonymity or expresses a desire for no ongoing information or contact. (Livingston Smith 2007)
14.1.4	Screening Potential Adoption Referral Sources	Questions for screening an adoption agency ▪ Is the agency licensed and accredited to facilitate adoptions? ▪ Does the agency practice open adoption? ▪ Are birth parents able to have a legally enforceable open adoption? ▪ Does the agency provide unbiased, non-directive options counseling? ▪ Will it refer for abortion services if a client is interested in that option? ▪ Is there a racially, religiously, and socioeconomically diverse pool of adoptive families available for birth parents to choose from? ▪ Are there single and/or same-sex prospective adoptive families in the pool? ▪ Does the agency allow the birth parent(s) control in choosing the adoptive family, or does it limit their choices? ▪ Do birth parents determine the level and kind of contact (e.g., number of visits and how many pictures and letters exchanged per year) they will be able to maintain with the adoptee and adoptive family? ▪ Is interim care available for the infant after it is discharged from the hospital while the birth parent continues to receive options counseling? ▪ Does the agency provide post-adoption services? ▪ Are post-adoption services free for the birth parent(s)? ▪ Are the prospective adoptive families educated about open adoption and the importance of birth family involvement? ▪ Is there a fee for services for birth parents? ▪ Are there birth parents who chose adoption available to talk with women considering adoption?

14.2.b. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIIC	CI Early Pregnancy Symptoms	Part 3, Chapter 02_14
	CI Preconception	Part 3, Chapter 02_21

14.2.c. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	Pro-Choice Adoption Agencies	Part 3, Chapter 02_14
Training	**CAL Courses** Healthcare Assistant Training for Abortion Services Series Orientation to Family Planning Providing and Documenting Pregnancy Test Results Talking About Abortion Series	

CHAPTER 15: PRENATAL AND POSTPARTUM CARE

Revised June 2014

Chapter 15 Table of Contents

15.1 PRENATAL CARE

15.1.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

15.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	Should give	**Must** offer
CI Breast Engorgement and Mastitis				●	
CI Early Pregnancy Symptoms				●	
CI Rho(D) Immune Globulin			●		
CIIC Genetic Counseling and Diagnostic Testing*		●	●		
CIIC Prenatal Care		●	●		
CIIC Screening for Birth Defects*, **		●	●		
Release When Test/Service/Consultation Will Not Be Obtained As Recommended[+]		once			
Request for Surgery or Special Procedure		●			●
Written information about any medication dispensed (package insert may be used)			●		

*__Must__ use forms provided by PPFA unless state laws/regulations or delivery provider(s) require the use of other forms.

** If other aneuploidy screening tests are available (other than those covered in CIIC Screening for Birth Defects), appropriate written materials **must** be offered to and signed by each prenatal client.

[†]The requirement to have the release form signed includes, but is not limited to, the following: screening test(s) for aneuploidy, neural tube defects, and/or fetal anatomy ultrasound at 18 to 20 weeks; screening tests for gestational diabetes (GDM); Rh(O)D when it is indicated; recommended genetic counseling; screening and treatment of STIs and HIV; recommended third-trimester fetal surveillance testing

II. Additionally, **must** give information on

A. The general plan for hospital admission, labor and delivery, postpartum care and family planning care, and neonatal care to all clients.

B. Managing diet-controlled GDM to clients diagnosed with the condition (if affiliate is managing these clients)

15.1.2 Medical Screening and Evaluation

15.1.b. Table: Screening and Evaluation

History – comprehensive prenatal history **must** address, document, and include	Physical Exam – at initial visit, **must** include	Laboratory and Ultrasound – **must** include

▪ Medications — current and immediate past including OTC and herbals
▪ Allergies — seasonal, drug, contact/latex
▪ Social history
  ○ Occupation
  ○ Work and living environments — with attention to exposure to toxins such as radiation, chemicals, and infections
✓ FYI – Exposures to Teratogens
  ○ Educational background
  ○ Intimate partner violence — current and/or previous, including reproductive coercion
  ○ Religious beliefs precluding or mandating Certain types of therapy
  ○ Tobacco use — past and/or current
  ○ Alcohol use — past and/or current
  ○ Illicit/recreational drug use — past and/or current
  ○ Sexual risk (multiple partners, partner(s) with other partner(s))
  ○ Nutritional status
  ○ Exercise patterns
  ○ Psychosocial concerns
▪ Family history
  ○ Congenital abnormalities with attention to neural tube defects, congenital heart disease, mental retardation, autism, or Fragile X Syndrome
	▪ Height
	▪ Weight
	▪ BMI
	▪ BP
	▪ Nutritional status
	▪ Head and neck (including dental)
	▪ Heart and lungs
	▪ Breast
	▪ Abdominal palpation
	▪ Pelvis, including
	  ○ Inspection of the perineum, vulva, vagina, and cervix
	  ○ Bimanual exam, with attention to the size of the uterus in relation to the presumed duration of pregnancy
	  ○ Configuration and capacity of the bony pelvis
	▪ Inspection and examination of the extremities
		First Trimester
		▪ Pap test, as indicated
		▪ Chlamydia test
		▪ Gonorrhea test, as indicated per CDC Guidelines
		✓ FYI – Risk Factors for Gonorrhea
		▪ Urinalysis, including screening for glycosuria, ketonuria, and proteinuria (by dipstick)
		▪ Urine culture
		▪ CBC
		▪ Blood group and Rh type determination
		▪ Blood group antibody screen
		▪ Rubella antibody screen
		▪ Hepatitis B antigen screening
		▪ Syphilis screen (RPR or VDRL)
		▪ Type 2 diabetes screening for clients who have BMI ≥ 25 plus any of the following risk factors
		✓ FYI – Screening for Diabetes
		  ○ Physical inactivity
		  ○ First-degree relative with diabetes
		  ○ High risk ethnic group (e.g. African American, Latino, Native American, Asian American, Pacific Islander)
		  ○ Glucosuria at first prenatal visit
		  ○ Prior GDM
		  ○ Previous stillborn
		  ○ Previous infant >9lbs
		  ○ History of hypertension or cardiovascular disease

History – comprehensive prenatal history **must** address, document, and include	Physical Exam – at initial visit, **must** include	Laboratory and Ultrasound – **must** include
○ History of genetic, chromosomal, and/or familial disorders ○ Hematologic abnormalities, including hemoglobinopathies, clotting disorders ○ Metabolic disorders with attention to first-degree relatives with diabetes mellitus, phenylketonuria ○ Multiple births ○ Recurrent pregnancy loss ○ Early-onset cardiovascular disease ○ Maternal DES use ▪ Previous pregnancy history ○ Length of each gestation ○ Outcome of pregnancy — early pregnancy failure, spontaneous abortion, ectopic ○ Route of delivery and length of labor ○ Sex and weight of newborn ○ Complications, including those resulting in fetal or neonatal death ○ Preterm labor, prolonged labor ○ Previous administration of Rh immune globulin ○ Previous blood transfusion ▪ Review of systems ○ Eye/nose/throat ○ Breast ○ Pulmonary — asthma ○ Cardiovascular — hypertension, valvular, DVT/thrombophlebitis ○ Gastrointestinal — liver, gall bladder ○ Urinary — uterine anomalies, UTIs, kidney stones		○ polycystic ovarian syndrome ○ A1C ≥ 5.7%, IGT, or impaired fasting glucose on previous testing ▪ HIV — unless mandated otherwise by state laws/regulations, client **must** be notified she will be screened unless she declines ▪ Additional laboratory evaluations as indicated, depending upon the prevalence of risk factors in the population served. If not done routinely, these tests should be done as indicated: ○ TB screening ○ Hemoglobinopathy screening (e.g., sickle cell testing, thalassemia) ✓ FYI - Hemoglobinopathies ○ HSV antibody screening ○ Varicella-zoster antibody screening (See Table 15.1.f.) ○ Hepatitis C antibody screening for women with unknown status and CDC-recognized risk factor (See Chapter 9) ○ Thyroid disease screening if • Symptomatic • History of thyroid disease • Medical condition associated with thyroid disease ▪ Clients **must** be educated and offered screening and/or diagnostic tests including ○ Cystic fibrosis carrier screening (in first trimester, if possible) ○ Carrier screening for inborn errors of metabolism such as Tay-Sachs, Gaucher, Canavan, etc.

History – comprehensive prenatal history **must** address, document, and include	Physical Exam – at initial visit, **must** include	Laboratory and Ultrasound – **must** include
○ Gynecologic • Menarche • Menstrual history • Contraceptive history ○ Neurologic — seizure disorder, migraine headache ○ Anemia/hematologic/transfusion ○ Endocrine — diabetes including gestational, thyroid ○ Autoimmune disorder ○ Infectious/communicable disease/immunizations • Rubella • Varicella zoster and HSV • STIs • HIV • HBV, HCV • TB ○ Psychiatric — postpartum depression ▪ Current pregnancy history ○ Intimate partner violence ○ Vaginal bleeding ○ Exposure to environmental toxins ○ Use of illicit/recreational drugs and/or alcohol ○ Tobacco use ○ Nutritional status evaluation ○ Exercise patterns ○ Psychosocial concerns		○ Aneuploidy screening ✓ FYI – Aneuploidy Screening ○ Genetic counseling and testing including chorionic villus sampling and genetic amniocentesis for clients • Who desire aneuploidy testing without screening • With positive aneuploidy screening • With history of infant with chromosomal abnormality (including Fragile X), neural tube defect, or other detectable genetic disorders • With family history of known or suspected chromosomal abnormality or genetic disorder If nuchal translucency* is part of aneuploidy screening, clients **must** be referred out of the affiliate for first trimester ultrasound. **Second Trimester** ▪ Any screening test above, which has not been completed or includes second trimester component ▪ Maternal serum aneuploidy screening (MSAFP) at 15 to 20 weeks. Discuss optimal testing with referral provider if client has had other testing (first trimester testing — CVS or nuchal translucency). ▪ **Must** be referred out of affiliate for 18 to 20 week ultrasound to assess fetal anatomy.

History – comprehensive prenatal history **must** address, document, and include	Physical Exam – at initial visit, **must** include	Laboratory and Ultrasound – **must** include
		Third Trimester ▪ Early (24 to 28 weeks) ○ Hgb/Hct ○ Rh(D) antibody testing for all unsensitized Rh(D)-negative women ○ Screening for Gestational Diabetes Mellitus (GDM) • Clients who did not need or had normal diabetes screening at initial prenatal visit **must** be screened • One Step or Two Step approach may be used. ✓ FYI - Defining Class-A_2 GDM ✓ FYI - Screening for and Diagnosis of GDM ▪ late (28 weeks to term) ○ Hgb/Hct ○ Repeat syphilis serology for clients • At high risk for syphilis, • In areas of high syphilis morbidity ○ Chlamydia retesting for clients • Aged ≤25 years • At increased risk for chlamydia • Positive for chlamydia earlier in pregnancy ○ Gonorrhea retesting for clients • Positive for gonorrhea earlier in pregnancy • Who continue to be at high risk ○ Group B Strep VPR culture (vaginal/perineal/rectal) • **Must** be performed for all clients

History – comprehensive prenatal history **must** address, document, and include	Physical Exam – at initial visit, **must** include	Laboratory and Ultrasound – **must** include
		between 35-37 weeks unless client has been previously identified as a Group B Strep carrier on urine culture. • Clients who previously delivered newborn with GBS sepsis should not be cultured, treatment will be given regardless of result. **Must** ensure that the delivery provider is aware of history. ○ Genital herpes testing for suspected overt lesions is strongly recommended. ○ Repeat HIV testing may be considered in • May be considered in ◊ Areas with high HIV prevalence (5 per 1,000 or 0.5 percent or greater) in women of childbearing age ◊ Clients with risk factors ✓ CDC Risk Factors • Should be done before 36 weeks
*Ultrasound for nuchal translucency **must** only be performed by NTQR-specially-trained experts/centers (https://www.ntqr.org/SM/default.aspx) using appropriate equipment and specific guidelines for measuring.		

15.1.3 Prenatal Risk Assessment

I. Affiliates may only provide prenatal care to non-high-risk pregnant women. Risk factors **must** be evaluated initially and reevaluated throughout the pregnancy during the 3 windows of risk, identified in Table 15.1.a. All risk assessments **must** be documented.

15.1.c. Table: Prenatal Risk Assessment - Maternal Conditions, Current or History of

Risk Factor	Action			Continuation of Care at Prenatal Affiliate?
	<24 weeks	24-35 weeks	>35 weeks	
Age, < 15 years at time of delivery	▪ Provide special counseling addressing possible rape or incest, drug abuse, client's home situation, and diet. ▪ Refer as indicated.	Same	Same	Yes
Anemia, refractory (Hgb < 9.0 mg/d on 2 separate occasions)	▪ RBC indices, Fe/TIBC, other tests as indicated	Same	Same	Yes, if ▪ problem inactive or well-controlled ▪ no negative effect on pregnancy ▪ and pregnancy has no negative effect on disease
	▪ If iron deficiency, give 1 month iron therapy; refer to HROB if no response. ▪ If macrocytic anemia, 1 month therapy with folic acid; refer to HROB if no response. ▪ If other refractory anemia, refer to HROB.			
BMI, pre-pregnancy <18.5	▪ Screen for eating disorder. ▪ Consider nutritional counseling.	Follow for increased risk of growth restriction, preterm labor	Follow for increased risk of growth restriction, preterm labor	Yes, unless suspected negative impact on pregnancy outcome.
BMI, pre-pregnancy ≥ 25	▪ Consider nutritional counseling ▪ Early screening for GDM as indicated.	Same	Same	Yes, unless suspected negative impact on pregnancy outcome.

Risk Factor	Action			Continuation of Care at Prenatal Affiliate?
	<24 weeks	24-35 weeks	>35 weeks	
Diabetes, pre-existing — diet-controlled or insulin-dependent	▪ Refer to HROB or manage per Diet- Controlled GDM (See Table 15.1.g.)	Same	Same	See Diet-Controlled GDM (See Table 15.1.g.)
Genetic disease or abnormal screening test for birth defects, personal or family history of	▪ Offer referral for genetic testing/counseling ASAP. ▪ Give attention to possible maternal medical diseases.	N/A	N/A	If referral refused, document and release **must** be signed. Yes, if screening is negative.
HIV-positive, without medical compromise	▪ Refer for concurrent medical surveillance. ▪ Carefully document that fetal risk and options were discussed. ▪ Refer to HROB if there is medical compromise, or as indicated.	same	same	Yes, if approved by concurrent medical provider and PPOB. Physician **must** be involved in management.
Illness, chronic, e.g. cardio-vascular, thromboembolic, chronic pulmonary, metabolic, endocrinological, upper urinary tract, connective tissue or neurological disease, cancer	▪ Refer to PPOB ▪ Refer to HROB and/or medical specialist as indicated.	Same	Same	Yes, if ▪ Problem is inactive, resolved or well-controlled ▪ No negative effect on preg-nancy ▪ And pregnancy has no negative effect on disease.
Nutritional disorder, e.g., bulimia or excessive dieting (with evidence of iron or protein deficiency)	Refer to PPOB and nutritionist; to HROB as indicated.	Same	Same	Yes, unless suspected negative impact on pregnancy outcome.

Risk Factor	Action			Continuation of Care at Prenatal Affiliate?
	<24 weeks	24-35 weeks	>35 weeks	
Pap test, abnormal or visible abnormal cervical lesion	See Chapter 4 Cervical Cancer Screening	Same	Same	Yes, unless the physician colposcopist indicates need for cone biopsy or other surgical treatment.
Reproductive tract, anatomic abnormalities of	Consult with or refer to PPOB and/or HROB, as indicated.	Same	Same	Yes, unless suspected negative impact on pregnancy outcome.
STIs, risk for	Educate client about dangers of STIs during pregnancy, including health effects on fetus and neonate.	Same	Same	Yes
Substance use -- tobacco, alcohol, or street drug	▪ Educate client about dangers of continued tobacco, alcohol, and street drug use. ▪ Refer to substance abuse programs as appropriate. ▪ Clearly document non-compliance with care/recommendations.	Same	Same	Yes, unless suspected negative impact on pregnancy outcome.
Teratogen exposure, possible — environmental, drugs, x-ray, or infections	▪ Offer counseling by OTIS office ✓ http://www.otispregnancy.org/ ▪ If question of teratogenicity of specific agent exists, evaluation by PPOB or consultation with HROB may suffice. ▪ If using Rx medicine, advise client to continue unless advised otherwise by PPOB or HROB.	Same	Same	Yes, develop care plan in consultation with PPOB and referral provider (High Risk OB, Genetics or Teratology service.) If client using Rx medication, PPOB or HROB also **must** provide management plan.

15.1.d. Table: Prenatal Risk Assessment - Obstetrical History

Risk Factor	Action			Continuation of Prenatal Care at Affiliate?
	<24 weeks	24-35 weeks	>35 weeks	
Abnormal pregnancy, history of (ectopic or molar gestation)	▪ Provide early ultrasound to document IUP. ▪ Consult with or refer to PPOB or HROB. ▪ If condition confirmed, refer for appropriate treatment (in or out of affiliate)	N/A	N/A	Yes, if normal intrauterine pregnancy.
Abortion, recurrent -- history of ≥ 2 sequential spontaneous abortions in the absence of a subsequent term delivery	▪ Obtain hospital records, if possible, and determine gestational age at time of SABs. ▪ If client at gestational age earlier than previous abortions, refer to PPOB or HROB.	N/A	N/A	Yes, if approved by referral physician. Yes, if GDM is excluded or client is managed per Diet-Controlled G0DM (See Table 15.1.g)
Bleeding, vaginal	▪ If suspected, threatened or missed SAB, mole, or ectopic, refer to PPOB or HROB. ▪ If IUP, Rh negative, and negative Rh antibody screen, give RhIG.	If minimal bleeding, consult with PPOB or HROB. If moderate or heavy bleeding, refer to hospital immediately	Same	Yes, if ultrasound documented viable IUP and no evidence of placental abruption or previa.
Cesarean section or uterine surgery, prior	▪ If possible, obtain and evaluate copies of operative reports. ▪ Consult with or refer to PPOB or delivery provider.	Same	Refer for care and delivery at gestational age specified by delivery physician.	Yes, if approved by delivery provider.

Risk Factor	Action			Continuation of Prenatal Care at Affiliate?
	<24 weeks	24-35 weeks	>35 weeks	
Congenital abnormalities, previous offspring with	▪ Offer referral for genetic counseling ASAP. ▪ Give attention to possible maternal medical disease.	N/A	N/A	If referral refused, document same. Yes, if GDM is excluded or client is managed per Diet-Controlled GDM (See Table 15.1.g)
Gestational diabetes, risk factors for (history of prior GDM, macrosomia, or stillbirth)	▪ Screen for diabetes per protocol. ▪ If gestational diabetes, refer to HROB or manage per Table 15.1.g.	Same	Same	Yes, if GDM is excluded or client is managed per Table 15.1.g.
Grand multiparity (parity ≥ 5)	▪ Discuss diet and iron/vitamin intake. ▪ Address client's desire for future fertility. ▪ Offer education for female and male sterilization.	Same	Same Monitor third-trimester hemoglobin.	Yes
Hematological disease, neonatal, history of -- isoimmunization (Rh disease), fetal hydrops, neonatal transfusion, or other neonatal hematological disease)	If antibody screen abnormal, refer to HROB.	Same	Same	Yes, unless risk of fetal erythroblastosis.

Risk Factor	Action			Continuation of Prenatal Care at Affiliate?
	<24 weeks	24-35 weeks	>35 weeks	
Incompetent cervix, history of known, or suggested	▪ Assess obstetrical history. ▪ Consult with or refer to PPOB or HROB.	Same	Same	Yes, if no evidence of history of incompetent cervix.
Preeclampsia, history of	N/A	▪ Monitor BP, urine protein, weight, and any other signs of preeclampsia. ▪ Refer to HROB or delivery provider as indicated in Table 15.1.e.	Refer to Problems in Current Pregnancy — Elevated blood pressure, proteinuria, or symptoms of preeclampsia, in Table 15.1.e.	Preeclampsia, history of
Prior low birth weight infant (less than 2,500 gm), preterm delivery, preterm rupture of membranes, stillbirth, intrauterine growth retardation	▪ Consultation with PPOB or HROB with referral for cervical length, if needed ▪ Careful history (antecedent drug use, trauma, etc.) ▪ Obtain autopsy report, if possible, if stillbirth ▪ early baseline ultrasound	Same Refer to HROB at 25 weeks, or continue affiliate care with a specific approved protocol for prevention of preterm labor.	Same	Yes, if no evidence of IUGR in current pregnancy.

15.1.e. Table: Prenatal Risk Assessment - Problems in Current Pregnancy

Risk Factor	Action			Retention/Reacceptance
	<24 weeks	24-35 weeks	>35 weeks	
Amniotic fluid abnormality, clinical (polyhydramnios or oligohydramnios)	Refer to PPOB or HROB.	Same	Transfer care to HROB or delivery provider.	Yes, if no fetal abnormalities that require fetal surveillance or other specialized care.
Aneuploidy or MSAFP screening test, abnormal	▪ Confirm dates by ultra-sound. ▪ If indicated, refer to HROB or for genetic counseling.	If fetal abnormality present, develop plan for delivery with HROB or delivery provider.	Same	Yes, if no abnormality; if abnormality present, e.g., trisomy, may co-manage with delivery provider to provide routine prenatal care only.
Antibody screen, positive blood group	Refer to PPOB or HROB.	Same	Same	Yes, unless isoimmunization diagnosed and specialized surveillance or intervention is specified by HROB.
Condyloma accuminata, vulvar or vaginal	▪ May treat minimal geni-tal disease with TCA or freezing. ▪ If large lesions, refer for specialized treatment.	same	same	Yes, if not deemed to have negative effect on pregnancy.
Dilation, cervical or effacement -- beyond expected for gestational age	▪ Evaluation by PPOB ▪ Refer to HROB if indi-cated.	Same If delivery impending, transfer to delivery hospital immediately.	Same If delivery impending, transfer to delivery hospital immediately.	Yes, if degree of cervical dilation is acceptable for gestational age.

Risk Factor	Action			Retention/Reacceptance
	<24 weeks	24-35 weeks	>35 weeks	
Fetal movement, decreased	N/A	Consult with, or refer to, PPOB or HROB.	Same Assessment also may be performed by delivery provider.	Yes, if normal fetal surveillance testing, and further follow-up testing is not recommended
Gestational diabetes	Manage per diet-controlled GDM management in Table 15.1.g or refer to HROB.	Same	Same	Yes, if diet-controlled (class A-1). See GDM management in Table 15.1.g.
Gestational trophoblastic disease, suspected	Refer to PPOB or HROB.	N/A	N/A	Yes, if not a molar pregnancy
Hyperemesis gravidarum	▪ If mild, encourage small, frequent, bland meals and fluids. ▪ Ultrasound if indicated to rule out molar pregnancy or multiple gestation. ▪ If no improvement or if moderate to large urine ketones or excessive weight loss, refer to PPOB or HROB.	Same	Same	Yes, if controlled/resolved.
Intrauterine fetal demise, known or suspected	Refer to PPOB to document demise. May evacuate on site, per Abortion MS&Gs, or refer.	If fetal demise, refer.	Same	Yes, if viable fetus.

Risk Factor	Action			Retention/Reacceptance
	<24 weeks	24-35 weeks	>35 weeks	
Intrauterine growth retardation, signs of (failure to gain weight, poor fundal height growth, size < gestational age)	Obtain ultrasound and refer to PPOB or HROB for assessment if indicated.	Same	Same	Yes, if no evidence of IUGR.
Labor, preterm	Refer to hospital. Notify delivery provider or HROB.	Same	Same	Yes, if client not found to be in labor, if preterm labor is not recurrent, or if preterm labor is resolved and the client is not using tocolytics.
Macrosomia, on clinical exam	N/A	N/A	Obtain ultrasound and refer to delivery provider (before labor onset) for evaluation	Yes, if no evidence of macrosomia.
Malpresentation (non-vertex lie)	N/A	N/A	Refer at 36 weeks (for possible version).	Yes, if fetus is in a vertex lie.
Multiple gestation, suspected or known	Refer to HROB, or continue affiliate care with approved protocol for twin pregnancy.	Same	Transfer care to HROB or delivery provider.	Yes, if twins managed by PPOB. Triplets and other multiple gestations **must** be referred to HROB.
Post-term (287 days of gestation or 41 completed weeks)	N/A	N/A	Preferable to refer by 40 completed weeks. **Must** be referred by 41 completed weeks or as stipulated by delivery provider.	No

Risk Factor	Action			Retention/Reacceptance
	<24 weeks	24-35 weeks	>35 weeks	
Preeclampsia, suspected (elevated blood pressure, elevated proteinuria; or symptoms of preeclampsia)	▪ Monitor BP, urine protein, weight, and any other signs or symptoms of preeclampsia. ▪ Refer to PPOB or HROB if ○ BP ≥ 140 systolic or ≥ 90 diastolic; ○ Or if there is persistent, unex-plained proteinuria > trace; ○ Or if there are symptoms of preeclampsia, e.g., edema, headaches, visual scotomata, epigastric or right upper quadrant pain.	Same	Same	Yes, if preeclampsia excluded. No, if ▪ Uncontrolled hypertension ▪ Preeclampsia ▪ Previously diagnosed hypertension
Rupture of membranes	▪ Perform sterile speculum exam only. ▪ If positive for rupture of membranes, refer to HROB or delivery hospital.	If positive for rupture of membranes, refer to delivery hospital.	same	Yes, if membranes not ruptured.

Risk Factor	Action			Retention/Reacceptance
	<24 weeks	24-35 weeks	>35 weeks	
STI -- chlamydia, gonorrhea, and/or trichomoniasis	▪ Provide appropriate treatment, partner management and follow-up ▪ Refer to PPOB or HROB if indicated.	Same	Same Retest for STIs to detect repeat infection.	Yes, if successful treatment (negative test of cure), if not deemed to have negative effect on pregnancy.
Ulcer, genital	▪ Perform syphilis serology and culture lesions for HSV to confirm diagnosis. ▪ If lesion does not clear within 2 weeks, refer to r/o immunosuppressed status.	Same If ruptured membranes or labor, transfer to hospital ASAP.	Same	Yes, except with a visible lesion at time of labor.
Uterine size/ gestational age discrepancy	▪ Provide ultrasound evaluation. ▪ Consult with or refer to PPOB or HROB.	Same	Same	Yes, if no evidence of IUGR or other abnormalities.

15.1.4 Management

I. Visits
   A. Frequency
      1. First visit on or before 12 weeks
      2. Every 4 to 6 weeks for the first 28 to 32 weeks including visits at 16 and 18 weeks and on or near 28 weeks
      3. After 28th week every 2 to 3 weeks until 37 weeks
      4. After 37th week, weekly

B. Content -- Each follow-up visit **must** include
   1. History update to assess status and identify possible risk factors
   2. BP
   3. weight
   4. Evaluation of fundal height, measured after 20 weeks
   5. Leopold's maneuvers — as soon as appropriate
   6. Fetal heart rate — as soon as possible
   7. Urinalysis for protein and glucose as appropriate
   8. Appropriate and indicated laboratory testing for intercurrent conditions
   9. Plans for hospital admission, labor, and delivery to be reviewed with client near term
   10. Opportunity for client to ask questions, discuss the results of any laboratory tests, comment on changes, and receive information appropriate to gestational age

15.1.f. Table: Infection, Vaccination and Pregnancy

Condition	Screening, Prevention, and Management
Cytomegalovirus (CMV)	▪ Routine serologic screening of pregnant clients for CMV is of little value. ▪ Testing should be limited to clients in whom CMV infection is clinically suspected, e.g., work up of suspected IUGR ▪ If client tests positive, **must** refer to PPOB/HROB.
Hepatitis B	Women at high risk for HBV infection should be vaccinated for HBV after HBSAg is drawn in first trimester
Herpes simplex virus (HSV)	▪ Offer clients with known prior genital infection antiviral prophylaxis from 36 weeks to delivery in the form of ○ Acyclovir 400 mg orally, twice daily ○ Valacyclovir 500 mg orally, once daily ○ Famcyclovir 250 mg orally, twice daily ▪ Clients with a history suspicious for genital HSV-2 infection or with no history but with a partner with known HSV infection should be offered serologic testing for type-specific HSV antibodies. ▪ Clients with partners who have known HSV infection should be counseled on safe sex practices to prevent transmission during pregnancy. ▪ Consider suppressive therapy for HSV-2 seropositive partners of seronegative clients. ✓ See CDC Guidelines

Condition	Screening, Prevention, and Management
Influenza	▪ All clients **must** be offered influenza vaccine or referral for vaccination. ▪ Intramuscular, inactivated vaccine can be used throughout pregnancy. ▪ Intranasal vaccine [which contains live attenuated virus] **must not** be used during pregnancy. ▪ Breastfeeding is not a contraindication to influenza vaccination.
Parvovirus, human B-19 (Fifth disease)	▪ Clients with documented exposure should be offered serologic diagnosis as soon as possible after such exposure: o Blood should be drawn to identify immune status with evidence of antiparvovirus IgG. o If non-immune, the test should be repeated in 3 to 4 weeks; if seroconversion does not occur, fetus is not at risk for in-utero infection. ▪ Clients who are seronegative for Fifth Disease and who seroconvert **must** be referred to HROB ▪ Clients who are seronegative for Fifth Disease may be co-managed with HROB if there is no evidence of fetal involvement (fetal hydrops, placentomegaly and/or fetal growth disturbances).
Tetanus, Diphtheria and Pertussis (Tdap)[R1]	▪ All pregnant women should receive a dose of Tdap regardless of prior history of receiving Tdap. ▪ Optimal timing for Tdap administration is between 27 and 36 weeks of gestation, although may be given at any time during pregnancy. ▪ Special circumstances o Due for tetanus booster: If it has been more than 10 years since previous Td, should give Tdap between 27 and 36 weeks gestation. o Wound management: If it has been more than 5 years since previous Td and a booster is recommended, consider Tdap. o Unknown or incomplete tetanus vaccination: If never vaccinated against tetanus, client should receive 3 vaccinations containing tetanus and reduced diphtheria toxoids. The recommended schedule is 0, 4 weeks, and 6 to 12 months. Tdap should replace 1 dose of Td, preferably between 27 and 36 weeks gestation.
Toxoplasmosis	▪ Routine screening of pregnant clients is not indicated, except in the presence of HIV. ▪ Testing for the presence of antibodies indicative of previous infection in clients at risk is best accomplished before conception. ▪ Demonstration of seroconversion by a rise in IgG titer in paired samples taken 2 to 4 weeks apart and tested simultaneously requires referral to PPOB/HROB.
Varicella zoster virus (VZV)	▪ A known prior history of VZV infection should be documented in the record. ▪ Clients with unknown previous VZV exposure should be offered VZV serologic evaluation (IgG) as early in the pregnancy as possible.

Condition	Screening, Prevention, and Management
	▪ Clients whose serologic status is unknown and who are exposed to VZV should be offered serologic evaluation as soon as possible after suspected exposure. ▪ Clients known to be serologically negative for VZV and who are exposed to VZV in pregnancy should be offered treatment with varicella-zoster immune globulin (VZIG) as soon as possible after suspected exposure and **must** be referred to HROB.

II. Management of Diet-Controlled GDM (Class A1)

A. All clients diagnosed with gestational diabetes **must** be discussed with the PPOB and care **must** be initiated per table 15.1.g, Diet- Controlled GDM (Class A_1) Care, below.

15.1.g. Table: Diet-Controlled GDM (Class A_1) Care

<table>
<tr><th>Visit Schedule*</th><th>Diet</th><th>Exercise</th><th>Glucose Monitoring</th></tr>
<tr>
<td>Weekly to
▪ Review diet
▪ Review home glucose monitoring
▪ Check urine for ketones
▪ Discuss any problems encountered by client</td>
<td>Licensed nutritionist must perform initial diet instruction and follow-up of dietary problems.

Total number of calories per day is based on true pregnancy weight:
▪ If normal weight — 30 calories (kcal) per kg/day (13.6 calories per lb.)
▪ If obese (>120 percent of ideal body weight when not pregnant) — 25 calories per kg/day (11.4 calories per lb.)

Daily calorie intake should be allocated as follows:
<table>
<tr><td>Breakfast</td><td>15%</td><td>Afternoon snack</td><td>10%</td></tr>
<tr><td>Morning snack</td><td>10%</td><td>Dinner</td><td>30%</td></tr>
<tr><td>Lunch</td><td>25%</td><td>Bedtime snack</td><td>10%</td></tr>
</table>
</td>
<td>Daily walking (especially after meals) should be encouraged</td>
<td>Home glucose monitoring to check
▪ Fasting level
▪ 1 hour postprandial level</td>
</tr>
<tr><td colspan="4">*Must transfer all clients with diet-controlled GDM (Class A1) to delivery provider no later than 37 completed weeks of gestation (or sooner if normal fasting glucose levels have not been maintained)</td></tr>
</table>

15.1.5 Transfer of Care and Referral

I. Transfer for delivery
   A. A copy or abstract of the medical record to date **must** be available in the labor and delivery area of the hospital by the estimated 36th week of pregnancy.
   B. If the client is transferred for high risk management or early delivery prior to the 36th week, the record **must** be available to the referral physician.
   C. In order to facilitate continuity of care, each client **must**, at a minimum, have an opportunity to arrange a visit with the delivery provider by 37 weeks.

II. Referral – Indicated for
   A. Diet-controlled GDM if not managed at affiliate or at discretion of PPOB
   B. Diet-controlled GDM managed by affiliate
      1. If ketonuria is detected at any visit **must** refer to PPOB/HROB for evaluation.
      2. **Must** refer to HROB if
         a. Serum fasting glucose ≥ than 105 mg/dl,
         b. Persistent postprandial blood sugars > 140mg/dl
         c. Development of secondary problem requiring high-risk assessment
   C. Any condition as directed in 15.1.3 Prenatal Risk Assessment

15.2 POSTPARTUM CARE

15.2.1 Providing Care

I. The provider who performed the delivery should initiate postpartum care if the client was delivered by cesarean or there was some delivery complication.
II. Clients should be instructed to contact the affiliate after an uncomplicated delivery to schedule a postpartum follow-up visit.

15.2.a. Table: Indicated Postpartum Tests and Treatments

Client Condition	Management
Rh negative	If client anti-D antibody negative and infant Rh-positive, **must** give a full dose of RhIG if not provided by delivery provider within 72 hours of delivery

Client Condition	Management
Rubella seronegative	If not immunized in hospital or postpartum, refer for or provide immunization.
No prior vaccination with Tdap	If Tdap not given during pregnancy, 1 dose of Tdap should be given immediately postpartum
GDM in most recent pregnancy	▪ 75 gm glucose tolerance test (OGTT) 6 to 12 weeks after delivery ▪ Annual evaluation with OGTT or fasting glucose ▪ Refer for management (in or out of affiliate) if any testing consistent with diabetes or impaired glucose tolerance

15.2.2 Contraceptive Care

I. **Must** follow Table 6.1.a. Choosing a Method when initiating contraception postpartum. Refer to specific sections regarding need for back-up or other questions.
   A. CHC
   B. Contraceptive Implants
   C. DMPA
   D. Intrauterine Contraceptives
   E. Prescription Barriers
   F. Progestin Only Pills
   G. Non-Prescription Contraception Methods
   H. Fertility Awareness-Based Methods
   I. Emergency Contraception

II. Lactational amenorrhea method (LAM) — A postpartum woman **mus**t meet the following conditions to ensure the highest effectiveness of LAM
   A. Exclusive or near-exclusive breastfeeding
   B. Amenorrhea
   C. First 6 months postpartum only

15.3 ADDITIONAL INFORMATION

15.3.a. Table: For Your Information

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>15.1.b.</td><td>Exposures to Teratogens</td><td>Clients who are concerned about exposures to teratogens (substances or infections that create concern for fetal risk) such as prescription or OTC medications, drugs of abuse, environmental toxins, and infectious agents should be referred to the local Teratogen Information Service (TIS). For more information about TIS go to http://www.otispregnancy.org/.</td></tr>
<tr><td>15.1.b.</td><td>Risk Factors for Gonorrhea[R2]</td><td>▪ Age <25 years
▪ Previous gonorrhea infection
▪ Other STDs
▪ New or multiple sex partners
▪ Inconsistent condom use
▪ Commercial sex work
▪ Drug use</td></tr>
<tr><td>15.1.b.</td><td>Screening for Type 2 Diabetes[R3]</td><td>Any of the following screening tests may be used for clients at risk for Type 2 Diabetes:
<table>
<tr><th>Test</th><th>Cut Off</th></tr>
<tr><td>A1C</td><td>≥ 6.5%</td></tr>
<tr><td>Fasting* Plasma Glucose (FPG)</td><td>≥ 126 mg/dl (7.0 mmol/l)</td></tr>
<tr><td>2-hr plasma glucose</td><td>≥ 200 mg/dl (11.1 mmol/l) during a 75 gm OGTT</td></tr>
<tr><td>Random plasma glucose</td><td>≥ 200 mg/dl (11.1 mmol/l) in a client with classic symptoms of hyperglycemia or hyperglycemic crisis</td></tr>
</table>
*Fasting is defined as no caloric intake for at least 8 hours.</td></tr>
<tr><td>15.1.b.</td><td>Hemoglobinopathies</td><td>Hemoglobinopathies, including sickle cell disease and thalassemia, are among the most common genetic diseases. Prenatal care providers should have a comprehensive approach to recognizing and screening clients in higher risk groups. Hemoglobin electrophoresis is the preferred test for at risk parents. Abnormal results should be referred to a genetic counseling center or high risk obstetric care provider for further follow up. Consider sending Hemoglobin electrophoresis in parents who
▪ are of African, Southeast Asian or Mediterranean ancestry
▪ have an MCV <80fL, unless associated with known iron deficiency
▪ have a family history hemoglobinopathy or thalassemia</td></tr>
</table>

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>15.1.b.</td><td>Aneuploidy Screening Tests</td><td>
<table>
<tr><th>Screening Test</th><th>Down Syndrome Detection Rate (%)</th></tr>
<tr><td>Combined First Trimester
▪ Nuchal translucency measurement, PAPP-A, and hCG</td><td>
82-87</td></tr>
<tr><td>Second Trimester
▪ Triple Screen (MSAFP, hCG, unconjugated estriol)
▪ Quadruple Screen (MSAFP, hCG, unconjugated estriol, inhibin A)</td><td>
69
81</td></tr>
<tr><td>First Plus Second Trimester
▪ Integrated (NT, PAPP-A, quad screen)
▪ Serum integrated (PAPP-A, quad screen)
▪ Stepwise sequential
○ First-trimester result:
• Positive: diagnostic test offered
• Negative: second trimester test offered
• Final: risk assessment incorporates first and second results
▪ Contingent Sequential (proposed as a model but large clinical trials using this approach have not been published):
○ First-trimester result:
• Positive: diagnostic test offered
• Negative: no further testing
• Intermediate: second trimester test offered
• Final: risk assessment incorporates first and second results</td><td>
94-96
85-88
95

88-94</td></tr>
</table>
</td></tr>
<tr><td>15.1.b.</td><td>Defining Class-A_2 GDM</td><td>Serum fasting glucose equal to or higher than 105 mg/dl defines Class-A_2 GDM. Women with a fasting hyperglycemia (>104 mg/dl) substantially are at a greater risk of stillbirth and pregnancy complications. They require insulin therapy and antepartum fetal surveillance.</td></tr>
</table>

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>15.1.b.</td><td>Screening for and Diagnosis of Gestational Diabetes Mellitus (GDM)[R3]</td><td>Screening for GDM may be performed using either a one-step or two-step approach as outlined below.

One-Step Approach
Perform a 75-gm OGTT in the morning after an overnight fast of at least 8 hours. Blood sugar values should be checked at fasting, 1 hour, and 2 hours. The diagnosis of GDM is made when any of the following plasma glucose values are:
▪ Fasting ≥ 92 mg/dl (5.1 mmol/l)
▪ 1 hr ≥ 180 mg/dl (10.0 mmol/l)
▪ 2 hr ≥ 153 mg/dl (8.5 mmol/l)

Two-Step Approach
Perform a 50-g GLT (nonfasting), with plasma glucose measurement at 1 hour (Step 1), at 24–28 weeks of gestation in women not previously diagnosed with overt diabetes. If the plasma glucose level measured 1 hour after the load is ≥140 mg/dL* (7.8 mmol/L), proceed to 100-g OGTT (Step 2). The 100-g OGTT should be performed when the patient is fasting. The diagnosis of GDM is made when at least 2 of the following 4 plasma glucose levels (measured fasting, 1 h, 2 h, 3 h after the OGTT) are met or exceeded (using either Carpenter/Coustan or NDDG):
<table>
<tr><th></th><th>Carpenter/Coustan</th><th>NDDG</th></tr>
<tr><td>Fasting</td><td>95 mg/dL (5.3 mmol/L)</td><td>105 mg/dL (5.8 mmol/L)</td></tr>
<tr><td>1 hour</td><td>180 mg/dL (10.0 mmol/L)</td><td>190 mg/dL (10.6 mmol/L)</td></tr>
<tr><td>2 hour</td><td>155 mg/dL (8.6 mmol/L)</td><td>165 mg/dL (9.2 mmol/L)</td></tr>
<tr><td>3 hour</td><td>140 mg/dL (7.8 mmol/L)</td><td>145 mg/dL (8.0 mmol/L)</td></tr>
</table></td></tr>
</table>

15.3.b. Table: References

Section	R#	Reference
FYI – Type 2 FYI - GDM	R3	American Diabetes Association. Standards of medical care in diabetes – 2014. Diabetes Care 2014;37(Suppl. 1). http://care.diabetesjournals.org/content/37/Supplement_1/S14.full.pdf+html Accessed May 27, 2014
Table 15.1.f	R1	Centers for Disease Control and Prevention. Updated recommendations for use of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) in pregnant women – advisory committee on immunization practices (ACIP), 2012. MMWR 2012; 62:131-135. http://www.cdc.gov/mmwr/pdf/wk/mm6207.pdf Accessed May 27, 2014.
FYI	R2	Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2010. MMWR 2010;59(No. RR-12). http://www.cdc.gov/std/treatment/2010/default.htm Accessed May 27, 2014.

15.3.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIIC	CIIC Genetic Counseling and Diagnostic Testing CIIC Prenatal Care CIIC Screening for Birth Defects	Part 3, Chapter 02_15
	CI Breast Engorgement and Mastitis	Part 3, Chapter 02_03
	Items to Add to Request for Surgery Comprehensive Prenatal Care Clients	Part 3, Chapter 01_04

CHAPTER 16: PRIMARY CARE

Revised June 2014

Chapter 16 Table of Contents

16.1 ASTHMA

16.1.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

16.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	Should give
Asthma Action Plan			●
Release When Test/Service/Consultation Will Not Be Obtained		Once	
Written information as appropriate			●

16.1.2 Initial Evaluation

16.1.b. Table: Initial Evaluation for Asthma

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Should include review of the following key indicators ▪ History of any of the following ○ Wheezing / recurrent wheezing ○ Breathlessness ○ Chest tightness ○ Cough, worse particularly at night and/or persistent ○ Recurrent pneumonia ○ Recurrent bronchitis ○ Recurrent chest tightness ○ Recurrent difficulty breathing ▪ Symptoms occur or worsen in the presence of triggers: ○ Exercise ○ Viral infection	Should include ▪ Vital signs, including temperature, pulse and respirations ▪ upper respiratory tract examination, with particular attention to the following key findings: ○ Increased nasal secretion, nasal polyps, or mucosal swelling ○ Sinus tenderness ▪ Chest examination, with particular attention to the following: ○ Quality and ease of respiration	May include ▪ Baseline peak flow ▪ Spirometry ✓ FYI — Spirometry ▪ Pulse oximetry, if indicated ▪ Chest x-ray (CXR), if indicated ▪ Full pulmonary function tests (PFTs) with diffusion capacity, if indicated ▪ Allergen skin tests

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
○ Animals with fur or hair ○ House-dust mites (in mattresses, pillows, upholstered furniture, carpets) ○ Cockroaches ○ Mold ○ Smoke (tobacco, wood) ○ Pollen ○ Changes in weather ○ Strong emotional expression (i.e., laughing or crying hard) ○ Occupational irritants ○ Airborne chemicals or dusts ○ Drugs such as aspirin and beta blockers ○ Menstrual cycles ○ Particular seasons ▪ Symptoms occur or worsen at night, awakening the client Should include review of additional key historical features: ○ symptoms • Consider the pattern of symptoms and their onset, duration, frequency, and intensity ○ Psychosocial history ○ Previous and current asthma medication use including type, frequency, and efficacy ○ Common co-morbidities • GERD, allergic rhinitis, sinusitis, and obesity ○ Prior steroid use, hospitalizations, ICU admissions, and/or intubations	○ Tachypnea ○ Wheezing during normal breathing or a prolonged phase of forced exhalation ○ Use of accessory muscles ○ Chest deformity ○ Hyperexpansion of the chest ▪ Skin ○ Atopic dermatitis/eczema or any other manifestation of an allergic skin condition ▪ Attention to critical signs ○ Pulsus paradoxus ✓ FYI — Impending Respiratory Failure ○ Quiet chest ○ Mental status changes ○ Difficulty speaking	

16.1.3 Diagnosis of Asthma

I. May be established with any of the following
   A. History that is suggestive of episodic symptoms
      1. Consider a diagnosis of asthma with presence of any key indicators (See Table 16.1.b.). While these indicators are not diagnostic by themselves, the presence of multiple key indicators increases the probability of a diagnosis of asthma.
   B. Lack of history or exam findings that would support alternative diagnoses
   C. Empiric, short-term treatment that shows clinical improvement of symptoms (reversibility). (See Table 16.1.g.) Quick Relief Medications.

II. Measurement of lung function may be used to confirm the diagnosis.

III. Upon diagnosis of asthma, proceed with classification of asthma severity according to Table 16.1.c.

16.1.c. Table: Classifying Asthma Severity (In Clients Not Taking Long-term Control Medications)

Components of Severity		Classification of Asthma Severity			
		Intermittent	Persistent: Mild	Persistent: Moderate	Persistent: Severe
Impairment	Symptoms	≤2 days/wk	>2 days/wk, but not daily	Daily	Throughout the day
	Nighttime awakenings	≤2x/month	3 to 4x/month	>1X/wk but not nightly	Often 7x/wk
	Short-acting beta agonist use for sx control (not prevention of EIB)	≤2 days/wk	>2 days/wk, but not >1x/day	Daily	Several times per day
	Interference with normal activity	None	Minor limitation	Some limitation	Extremely limited
	Lung function	Normal FEV_1 between exacerbations FEV_1 >80% predicted FEV_1/FVC normal	FEV_1 ≥80% predicted FEV_1/FVC normal	FEV_1>60%, but <80% predicted FEV_1/FVC reduced 5%	FEV_1<60% FEV_1/FVC reduced >5%
Risk	Exacerbations requiring oral systemic corticosteroids	0 to 1/year	≥ 2/year		
		Consider severity and interval since last exacerbation. Frequency and severity may fluctuate over time for clients in any severity category.			
		Relative annual risk of exacerbations may be related to FEV_1			

Components of Severity	Classification of Asthma Severity			
	Intermittent	Persistent: Mild	Persistent: Moderate	Persistent: Severe
▪ Level of severity is determined by assessment of both impairment and risk. Assess impairment by client recall of previous 2 to 4 weeks and spirometry. Assign severity to the most severe category in which any feature occurs. ▪ For treatment purposes, clients who had ≥2 exacerbations requiring oral systemic corticosteroids in the past year may be considered the same as clients who have persistent asthma, even in the absence of impairment levels consistent with persistent asthma.				

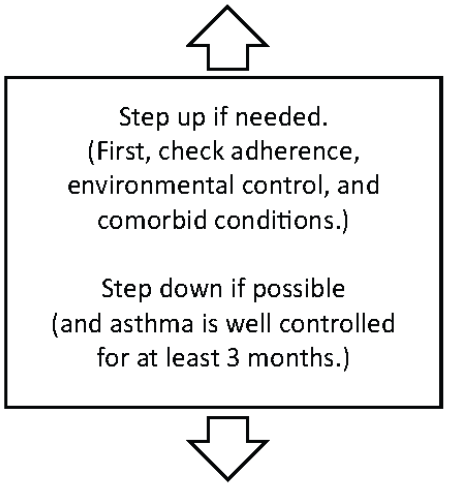
✓ FYI – Differential Diagnosis of Asthma

16.1.4 Management

I. Stepwise Management – initiate management per Table 16.1.d.
   A. The stepwise approach is meant to assist, not replace, the clinical decision-making required to meet individual client needs.
   B. Some circumstances, such as client contraindications, history of inadequate response to a preferred therapy, or prior, successful use of an alternative regimen, may support initiating alternative therapy in lieu of preferred. If alternative treatment is used and response is inadequate, discontinue it and use the preferred treatment, if possible, before stepping up.
   C. Check baseline ALT and AST for clients using LTRA, then periodically as indicated.

16.1.d. Table: Stepwise Approach for Managing Asthma in Clients ≥ 12-years-old

Intermittent asthma	Persistent Asthma: Daily Medication **Must** refer to asthma specialist if step 4 care or higher is required. Consider consultation at step 3.		
			STEP 4 **MUST REFER** **Severe persistent** Preferred: Medium-dose ICS + LABA Alternative: Medium-dose ICS + LTRA
		STEP 3 **Moderate persistent** Preferred: Medium-dose ICS + LABA Alternative: Medium-dose ICS + LTRA	
	STEP 2 **Mild persistent** Preferred: Low-dose ICS Alternative: LTRA		
STEP 1 Preferred: SABA prn			
Each step: Client education, environmental control, and management of comorbidities. **Steps 2-4:** Consider referral for allergen immunotherapy for clients who have allergic asthma			
Quick-relief medication for all clients: • SABA as needed for symptoms. Intensity of treatment depends on severity of symptoms: up to three treatments at 20-minute intervals as needed. Short course of oral systemic corticosteroids may be needed. • Use of SABA >2 days/week for symptom relief (not prevention of EIB) generally indicates inadequate control and the need to step up treatment.			



Key: SABA = short-acting beta agonist; ICS = inhaled corticosteroid; LTRA = leukotriene receptor antagonist; LABA = long-acting beta2 agonist; EIB = exercise-induced bronchoconstriction

II. Acute Asthma – manage according to Table 16.1.e.

✓ FYI —Signs of Impending Respiratory Failure

16.1.e. Table: Management of Acute Asthma

Level of Severity	Management
Acute exacerbation of severe asthma	**Must** refer client to emergency department immediately
Acute exacerbation of intermittent, mild or moderate asthma	Initiate the following as appropriate: ▪ Auick relief medications - see Table 16.1.g Quick-Relief Medications. ○ Short-acting beta agonists (SABA) ○ Anticholinergics ○ Combination beta-agonists/anticholinergics ▪ Steroids – see Table 16.1.h. Systemic Corticosteroids ○ For short-course systemic use with moderate to severe exacerbations ○ Dosing: 1 mg/kg every 6 hours (max 180 mg/day) for 48 hours, then 1 mg/kg/day PO for 5 to 7 days ○ May use for up to 14 days ○ No tapering necessary ○ Initiate simultaneous inhaled corticosteroid (ICS), follow up quickly to establish chronic disease management plan (see Table 16.1.f.), and initiate stepwise therapy as appropriate.

16.1.f. Table: Management of Chronic Asthma

Component of Management	Details
Assessment and monitoring	▪ Assess severity at each visit – see Table 16.1.c. Classifying Asthma Severity. ▪ Assess control and responsiveness at each visit. ▪ Assess risk of asthma exacerbations, progressive decline in lung function, or adverse effects from medication(s) as indicated. ▪ Monitor client's use of rescue medication. ▪ Assess client's technique for use of inhaler. ▪ Assess for smoking or smoke exposure.

Component of Management	Details
	▪ Identify allergen and irritant triggers. ▪ Consider testing lung function with spirometry annually and as indicated. ▪ Measure peak flow to compare to the client's own previous best measurement.
Self-management by client	▪ Encourage self-management by using recommended client resources and tools - see Associated Resources page for Chapter 3 ▪ Teach and reinforce at each opportunity ○ Basic facts about asthma ○ Definition of well-controlled asthma and client's current level of control ○ Roles of medication • Ensure client understands the difference between "controller" and "rescue" medications. ○ Skills, e.g. inhaler technique, use of spacer, and self-monitoring ○ When and how to handle signs and symptoms of worsening asthma ○ Reduction of environmental exposures
Asthma action plan ✓ FYI — Asthma Action Plan	Develop and review plan with client.
Stepwise management	Initiate according to Table 16.1.d.
Long-term control therapy See Table 16.1.i.	Consider, if not already initiated: ▪ Initiate drug therapy with ICS according to Stepwise Approach, with possible inclusion of LTRAs or LABAs. See Table 16.1.d. ▪ Use spacer or holding chamber for medication administration when possible.
Control of environmental factors and comorbidities that affect asthma	▪ Provide smoking cessation counseling if applicable – See 16.8 Smoking Cessation ▪ Refer for allergy testing ○ Consider referral for allergen immunotherapy, which may be accomplished by concurrent management with an allergist. ▪ Manage comorbidities within affiliate or concurrent management with an outside provider. ▪ Recommend and/or provide flu and pneumococcal vaccines - see Chapter 20 Vaccination Services.

16.1.5 Follow-up

I. Clients seen for initial evaluation of asthma **must** be advised to return for follow-up evaluation within 2 weeks.
II. When initiating therapy, monitor client with visits at 2 to 6 week intervals until asthma control is achieved (Evidence D).
III. Recommend regular follow-up visits at 1 to 6 month intervals, depending on level of control.
IV. Consider follow-up at 3 months if a step down in therapy is anticipated (Evidence D).
V. Consider monitoring ALT and AST in clients using LTRAs, as indicated.

✓ For more detail on evidence rankings, see NIH Guidelines for the Diagnosis and Management of Asthma

16.1.6 Referral

I. **Must** refer clients who
   A. Are age < 12 years old or ≥ 65 years old
   B. Have comorbidities COPD, CHF
   C. Develop severe, persistent asthma or management requiring Step 4 or higher
   D. Show no improvement in symptoms of mild, intermittent or mild to moderate, persistent asthma following 6 months of management at the affiliate. These clients may be referred for consultation and may return to the affiliate for on-going management if their status is stable and their care meets parameters outlined earlier in this section.
   E. Are pregnant and not planning termination, unless the affiliate provides prenatal care - see Chapter 15 Prenatal and Postpartum Care.
II. At the time of referral to a specialist, affiliate may continue therapy ONLY after consultation with the program director. Only program director may authorize additional medication refills.

16.1.7 Asthma Medication Tables

16.1.g. Table: Quick-relief Medications

Quick-relief Medications			
Medication	Indication	Considerations	Adverse Effects
Short-acting beta agonists (SABA) Inhaled SABA	▪ Relief of acute symptoms ▪ Prevention of EIB	▪ Drugs of choice for acute bronchospasm ▪ Regularly scheduled daily use is not recommended	Tachycardia, skeletal muscle tremor, hypokalemia, increased lactic acid, headache, hyperglycemia

Quick-relief Medications			
Medication	Indication	Considerations	Adverse Effects
▪ Albuterol ▪ Levalbuterol ▪ Pirbuterol		▪ Regular use >2 days/week for symptom control, increasing use, or lack of expected effect indicates inadequate asthma control ▪ For clients frequently using SABA, anti-inflammatory medications should be initiated or intensified.	
Anticholinergics ▪ Ipratropium bromide	Relief of acute bronchospasm	▪ Alternative for clients who cannot tolerate SABA ▪ Treatment of choice for bronchospasm due to beta-blocker use ▪ Not proven to be efficacious as long-term control therapy for asthma	Drying of mouth and respiratory secretions, increased wheezing in some users, and blurred vision if sprayed in the eyes

16.1.h. Table: Systemic Corticosteroids

Systemic Corticosteroids			
Medication	Indication	Considerations	Adverse Effects
Corticosteroids (glucocorticoids) Systemic ▪ Methylprednisolone ▪ Prednisolone ▪ Prednisone	▪ For short-term (3 to 10 day) burst (to gain control promptly of inadequately controlled persistent asthma) ▪ For moderate or severe exacerbations to prevent progression of exacerbation, reverse inflammation, speed recovery, and reduce rate of relapse	▪ Use at lowest effective dose. ▪ Consider co-existing conditions that may be worsened with systemic corticosteroid use, i.e., HSV, varicella, tuberculosis, hypertension, peptic ulcer, diabetes mellitus, osteoporosis, and *Strongyloides.*	Short-term use — increased appetite, fluid retention, weight gain, mood alteration, hypertension, reversible abnormalities in glucose metabolism, peptic ulcer, and aseptic necrosis (rare)
Theophylline/ aminophylline provide no additional benefit in the acute setting and should not be used.			

16.1.i. Table: Medications for Long-term Control

Medications for Long-term Control			
Medication	Indication	Considerations	Adverse Effects
Corticosteroids (Glucocorticoids) Inhaled (ICS) ▪ Beclomethasone dipropionate ▪ Budesonide ▪ Flunisolide ▪ Fluticasone proprionate ▪ Mometasone furoate ▪ Triamcinolone acetonide	▪ Long-term prevention of symptoms ▪ Suppression, control, and reversal of inflammation ▪ Reduces need for oral corticosteroid	▪ Spacer/holding chamber devices with non-breath-activated MDIs and mouth washing after inhalation may decrease local side effects. ▪ Preparations are not interchangeable on a mcg or per puff basis. ▪ Weigh risks of uncontrolled asthma against limited risks of ICS therapy. ▪ Include adjustable dosing for management of exacerbations within asthma action plan.	▪ Cough, dysphonia, oral thrush ▪ In high doses, systemic effects may occur, though clinical significance of these effects is not established.
Leukotriene Receptor Antagonists (LTRAs) ▪ Montelukast tablets and granules ▪ Zafirlukast tablets	▪ Long-term control and prevention of symptoms in mild persistent asthma. ▪ Can be used in combination with ICS in moderate persistent asthma	▪ Will have a flat dose-response curve, without further benefit, if dose is increased beyond recommended. ▪ Take at least 1 hour before or 2 hours after meals: administration with meals. ▪ Decreases bioavailability and inhibits metabolism of warfarin; should monitor INRs during administration. ▪ Advise clients to discontinue use with signs and symptoms of liver dysfunction; should monitor client's ALTs.	Postmarketing reports of reversible hepatitis and irreversible hepatic failure (rare)

Medications for Long-term Control			
Medication	Indication	Considerations	Adverse Effects
Long-acting Beta$_2$ Agonists (LABAs) Inhaled ▪ Formoterol ▪ Salmeterol	▪ Long-term prevention of symptoms, added to ICS ▪ Prevention of EIB	▪ Not to be used to treat acute symptoms or exacerbations. ▪ Should not be used as monotherapy for long-term control of asthma or as anti-inflammatory therapy. ▪ May provide more effective symptom control when added to ICS rather than increasing ICS dose. ▪ Decreased duration of protection against EIB may occur with regular use. ▪ Inhaled route is preferred because LABAs are longer acting and have fewer side effects than oral sustained-release agents.	▪ Tachycardia, skeletal muscle tremor, hypokalemia, and prolonged QTc interval in overdose ▪ Diminished bronchoprotective effect within one week of chronic therapy, though clinical significance has not been established ▪ Potential risk of uncommon, severe, life-threatening or fatal exacerbation

16.2 DEPRESSION AND ANXIETY

16.2.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

16.2.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give
Release When Test/Service/Consultation Will Not Be Obtained		Once	
Suicide Prevention Resources*			●
Written information as appropriate			●
*Should include contact numbers and procedures to use if suicidal ideation worsens.			

16.2.2 Depression

I. Screening – should screen annually with the Patient Health Questionnaire-2 (PHQ-2). If positive, proceed with evaluation.

✓ FYI — Patient Health Questionnaire-2

✓ FYI — Routine Screening for Depression

II. Evaluation - **must** be performed when depression is suspected. Suspicion of depression is based on any of the following:
   A. Positive PHQ-2
   B. Presence of risk factors
   C. Symptoms

✓ FYI – Common Presenting Symptoms for Depression

✓ FYI — Risk Factors for Major Depression

16.2.b. Table: Evaluation for Depression

History- should include		Laboratory Testing and Diagnostic Imaging
History of Present Illness ▪ Symptoms of major depressive episode (MDE) ✓ FYI — Common Symptoms of MDE ○ Onset of symptoms, degree of functional impairment and severity ○ May be facilitated by using PHQ-9, or SIGECAPS ✓ Patient Questionnaire Screeners • **S**leep disorder (increased or decreased) • **I**nterest deficit (anhedonia) • **G**uilt (worthlessness, hopelessness, regret) • **E**nergy deficit • **C**oncentration deficit • **A**ppetite disorder (increased or decreased)	**Medical History** ▪ Prior diagnosis of mental illness ▪ Past hospitalizations for mental illness ▪ Prior suicide attempts ▪ Eating disorders including anorexia nervosa (AN), bulimia nervosa (BN), eating disorder not otherwise specified (EDNOS) ▪ Medical disorders that could cause or mimic depression, such as anemia, cancer, diabetes, hypothyroidism, multiple sclerosis, Parkinsonism, stroke, dementia, and connective tissue disorders ▪ Current or past medications ○ OTC and herbal medications, including potential	May include ▪ TSH ▪ Comprehensive metabolic panel ▪ CBC

History- should include		Laboratory Testing and Diagnostic Imaging
• **P**sychomotor agitation or retardation • **S**uicidality ▪ Symptoms of other psychological dysfunction (presence or absence) ○ History suggestive of mania or hypomania • Past episodes of high energy, feeling revved up • Irritability or uncontrollable anger • periods when less sleep was needed ○ History suggestive of psychotic disorder • Disorganized thoughts • Feeling of being controlled by outside forces • Seeing or hearing things that others cannot ○ Medically unexplained symptoms suggestive of anxiety disorder or somatoform disorder, with or without depression (see 16.2.3 Anxiety) • Chest pain or palpitations (**Must** distinguish cardiac from non-cardiac chest pain prior to considering psychological disorder as a cause.) • GI complaints such as bloating, epigastric distress • Headaches or vague neurological complaints • Sexual or reproductive symptoms • Panic attacks	self-treatment regimens (i.e., St. John's wort) ○ Those that could cause depressive symptoms [i.e., antihypertensives, GnRH analogues, isotretinoin, hormones, steroids, varenicline (Chantix)] ○ Prescription medications for pain management or sleep disorders **Social History** ▪ History of domestic abuse ▪ Recent psychosocial stressors ▪ Relationship status ▪ Support system ▪ Cultural or financial factors that might influence client's acceptance of treatment ▪ Substance abuse, with special attention to active use and/or abuse of alcohol, hypnotics, cocaine, anxiolytics, and amphetamines. **Family History** ▪ Mental health disorders	

III. Diagnosis– Apply DSM-V criteria to evaluation findings to diagnose the following types of depression

A. Major Depressive Episode (MDE)

✓ FYI — DSM-5 Criteria for Major Depressive Episode

B. Persistent Depressive Disorder (PDD)

✓ FYI — DSM-5 Criteria for Diagnosis of Other Depressive Disorders

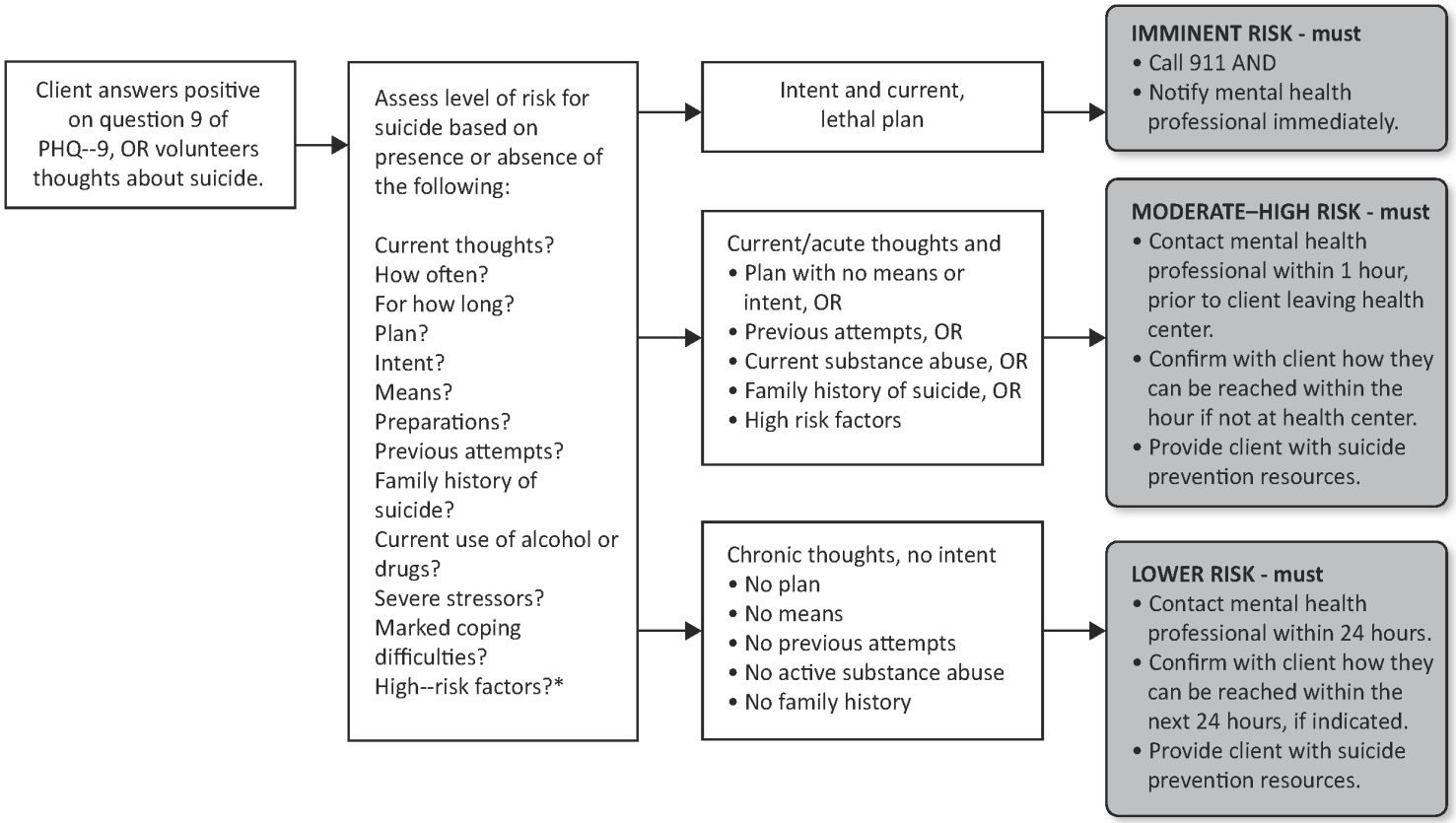
IV. Management - prior to initiation of therapy, **must**

A. Determine suicidality

B. Perform severity classification for MDE – see Table 16.2.d.

16.2.c. Algorithm: Suicidality Determination

✓ FYI – Risk Factors for Suicide



* High-risk factors for suicide include psychosis, agitation, history of aggressive or impulsive behavior, hopelessness, high anxiety, comorbid physical illness, and high-risk demographics (male sex, advanced age, divorced or separated, Caucasian or Asian race).

16.2.d. Table: Management of Depression

Depressive Disorder	Severity Classification for MDE	Criteria	Management
Major Depressive Episode	Any classification of MDE	N/A	In all clients ▪ Establish treatment plan, using collaborative care model where appropriate. ✓ FYI — Collaborative Care Model ▪ Provide client education, to include ○ Pathophysiology of MDE ○ Treatment options ○ What to expect during treatment, including • Symptoms and side effects • Follow-up visits • Length of treatment • Risk of relapse, how to recognize and how to avoid • How to communicate with clinician and care manager ▪ Enable client engagement by encouraging ○ Self-management responsibilities (e.g. taking medications appropriately, reading about the disease, keeping a journal) ○ Behavioral activation (i.e., scheduling pleasant activities throughout the treatment period) ○ Routine physical activity – 30 minutes of moderate intensity aerobic exercise 3 to 5 times a week is ideal, but individualize goals according to what is realistic for the client to avoid worsening of symptoms
	Mild, single or recurrent episode	Symptoms are distressing but manageable and cause minimal functional disturbance	▪ Consider referral for psychotherapy ▪ Pharmacotherapy is not routinely indicated, but may be considered when: ○ Past history moderate or severe depression, **OR** ○ Initial presentation of subthreshold depressive symptoms that have been present for ≥2 years, **OR**

Depressive Disorder	Severity Classification for MDE	Criteria	Management
			○ Subthreshold depressive symptoms or mild depression that persists after other interventions
	Moderate, single or recurrent episode	Functional impairment and symptoms are more pronounced	▪ Initiate pharmacotherapy - see Table 16.2.e. ▪ Refer for psychotherapy.
	Severe, single or recurrent episode	Unmanageable symptoms that markedly interfere with social and occupational functioning	**MUST r**efer to mental health provider for management. May prescribe antidepressant while client is being worked into specialist setting. Once goals of therapy achieved, client may return to affiliate for ongoing management as appropriate.
Persistent Depressive Disorder	N/A	N/A	**Must** refer to mental health provider for initial management. Once goals of therapy achieved, client may return to affiliate for ongoing management as appropriate.
Other Specified Depressive Disorder	N/A	N/A	**Must** refer to mental health provider for management.
Unspecified Depressive Disorder	N/A	N/A	**Must** refer to mental health provider for management.

16.2.e. Table: Pharmacotherapy for Major Depressive Episode

✓ FYI – Considerations for Pharmacotherapy in Depression

I. General Principles

A. Initiate pharmacotherapy using first-line agents such as SSRIs, SNRIs, bupropion, trazodone, or mirtazapine.
   1. Limit use of TCAs to adjunctive use for sleep or chronic pain at lower doses only.

B. Select antidepressant based on factors such as family history of response to a certain drug or class, side effect profile, cost, client preference, and presence of comorbid conditions or symptom profile:
   1. Tobacco abuse, contemplating cessation – consider bupropion.
   2. Anxiety – consider SSRIs and SNRIs.
   3. Insomnia – consider a sedating antidepressant such as a TCA at a lower dose as an adjunct or mirtazapine or advise taking at a different time of day.
   4. Chronic pain syndromes, such as headaches or fibromyalgia – SNRIs or TCAs may be more effective than SSRIs, though all have been shown to have benefit in these types of syndromes.
   5. Low libido - starting with bupropion may be more effective.

C. Initiate the medication at a lower-than-effective dose for 1 week in order to combat side effects.

D. Side effect management
   1. Early side effects, especially GI disturbances, can often be managed by encouraging client to continue the medicine until the symptoms dissipate, usually in 2 to 4 weeks.
   2. Decrease in libido or other sexual dysfunction in SSRIs and SNRIs can be managed by adding a small dose of bupropion. Clarify whether the symptoms arose before or after initiation of the anti-depressant.

Medication Class	Considerations	Side Effects	Precautions/Contraindications
Serotonin Selective Reuptake Inhibitors (SSRIs)	▪ Taper dose gradually to discontinue. ▪ Consider starting with half the lowest dose and tapering up after 1 week (except in escitalopram)	▪ GI disturbance (usually goes away over 1 to 2 weeks) ▪ Sexual dysfunction (erectile and loss of libido) ▪ Sleep disturbance (can be improved by changing time of day of administration in some cases). ▪ Withdrawal symptoms if abrupt	**Precautions** ▪ Paroxetine: Pregnancy Category D ▪ Others: Pregnancy Category C. Sertraline and citalopram have the most positive profile for use in pregnancy. ▪ Lactation: Sertraline and Paroxetine safe in lactation, safety unknown for others.

Medication Class	Considerations	Side Effects	Precautions/Contraindications
		cessation	**Contraindications** ▪ Hypomania ▪ Bipolar disorder ▪ Use of other serotonin-enhancing medications
Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)	▪ Approved for management of neuropathic pain, fibromyalgia, chronic musculoskeletal pain ▪ Indicated for migraine prophylaxis ▪ Take with food	▪ Same as SSRIs ▪ HTN ▪ Hyperlipidemia	**Precautions** ▪ Pregnancy Category C ▪ Lactation safety unknown
Bupropion – inhibits uptake of norepinephrine and dopamine	▪ No sexual dysfunction ▪ Can sometimes improve sexual dysfunction and fatigue associated with SSRIs and SNRIs ▪ Used for smoking cessation	▪ Agitation ▪ Insomnia ▪ Decreased appetite, anorexia ▪ GI distress	**Precautions** ▪ Caution in eating disorders ▪ Pregnancy category C ▪ Lactation – possibly unsafe
Tricyclic Antidepressants (TCAs)	▪ Secondary TCAs cause less orthostatic hypotension and sedation than do tertiary TCAs ▪ Secondary TCAs may be used in combination with nicotine replacement ▪ Taper when discontinuing ▪ Due to potential for death following overdose, use of these medications at full antidepressant dosing should be left to mental health professionals.	▪ Drowsiness ▪ Dry mouth ▪ Constipation ▪ Nausea ▪ Orthostatic hypotension ▪ Dizziness ▪ Confusion ▪ Urinary retention ▪ Sexual dysfunction	**Precautions** ▪ Pregnancy Category D ▪ Amitriptyline: not safe in lactation ▪ Nortriptyline: safe in lactation ▪ Monitor closely in client with heart problems, or in clients with potential for drug interactions **Contraindications** ▪ Concomitant use with MAOIs

Medication Class	Considerations	Side Effects	Precautions/Contraindications
Mirtazapine	May be used alone or with an SSRI	▪ Drowsiness ▪ Increased appetite ▪ Weight gain ▪ Dizziness ▪ Dry mouth ▪ Constipation	**Precautions** ▪ Pregnancy Category C ▪ Lactation safety unknown **Contraindications** ▪ Concomitant use with MAOIs
Trazodone	▪ Give on empty stomach ▪ Taper dose gradually to discontinue		▪ Pregnancy Category C. ▪ Probably safe in lactation.

16.2.f. Table: Pharmacotherapy Treatment Duration and Discontinuation[R1,R2]

✓ FYI – Relapse Prevention

Indication	Treatment Duration – treat to remission
MDE - 1st episode (single episode)	Continue treatment for 4 to 9 months once remission is reached* Total duration should be 6 to 12 months
MDE - 2nd episode (recurrent)	Consider continuing medication treatment for 3 years once remission is reached. Withdraw gradually* ✓ FYI – Continuing Pharmacotherapy in Recurrent MDE
Anxiety disorder	Pharmacotherapy may be needed for 1 to 2 years or longer*
* When discontinuing pharmacotherapy, dose should be tapered over several weeks to months in order to avoid withdrawal symptoms. (Note that this is only feasible when starting dose is lower than the therapeutic dose.)	

16.2.3 Anxiety

I. Screening — routine screening for anxiety is not recommended
II. Evaluation — **must** be performed per Table 16.2.g. when anxiety disorder is suspected. Suspicion for anxiety disorder is based on presence of risk factors and/or symptoms.

✓ FYI — Risk Factors for Anxiety

✓ FYI — Identifying Anxiety Disorders

16.2.g. Table: Evaluation of Anxiety

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Should include **History of Present Illness** ▪ Key features of anxiety such as excessive anxiety, fear, worry, avoidance, and compulsive rituals ▪ Stress, sleeplessness, vague pains, headache, dizziness, stomach upset, loss of concentration, fatigue, reduced effectiveness in routine tasks **Past Medical History** ▪ Conditions that may mimic anxiety disorder ✓ FYI — Conditions that May Aggravate or Mimic Anxiety Symptoms ▪ Psychiatric history that includes depression, somatoform disorders, or psychotic disorders, anxiety in childhood or adolescence (including marked shyness) ▪ Current and past medications **Social History** ▪ Substance abuse ▪ Caffeine intake ▪ Stressful and/or traumatic life event, including abuse or neglect **Family History** ▪ Anxiety or other mental disorder	Should focus on areas of symptomatology, as indicated	May include ▪ CBC ▪ Basic metabolic panel (BMP) ▪ Fasting glucose ▪ Fasting lipid profile ▪ Prolactin ▪ TSH ▪ Urine pregnancy test

III. Diagnosis

✓ FYI – DSM-V Diagnostic Criteria for Anxiety Disorders

A. Identify anxiety disorder using DSM-V Criteria and evaluation findings

1. Social Anxiety Disorder (SAD)

2. Generalized Anxiety Disorder (GAD)
3. Obsessive Compulsive Disorder (OCD)
4. Post-traumatic stress disorder (PTSD)
5. Panic Disorder (PD)
6. Agoraphobia

B. Determine whether anxiety symptoms are concurrent with depression – see 16.2.2 Depression

IV. Management

A. Suicidality – **must** assess prior to initiation of management - see Algorithm 16.2.c. Suicidality Determination

B. If depression present, manage depression first with selection of medication that is also effective for anxiety disorder.

C. For all types of anxiety disorder managed within affiliate

1. Consider client preference and motivation
2. Establish a treatment plan, using collaborative care model where appropriate.

✓ FYI — Collaborative Care Model

3. Provide client education, to include
   a. A description of the disorder and pathophysiology where appropriate
   b. Treatment options
   c. What to expect during the course of treatment, including
      i. Symptoms and side effects,
      ii. Follow-up visits
      iii. Length of treatment
      iv. Risk of relapse, how to recognize and how to avoid
      v. How to communicate with the clinician and care manager
4. Enable client engagement by encouraging
   a. Self-management responsibilities (e.g. taking medications appropriately, reading about the disease, keeping a journal)
   b. Self-help literature

16.2.h. Table: Management of Anxiety Disorders

Anxiety Disorder	Pharmacotherapy – **must** use first-line agents only. Limit to single medication, SSRI or SNRI only. See Table 16.2.e.	Psychotherapy	Other
Generalized anxiety disorder	▪ Paroxetine, escitalopram, and sertraline of the SSRIs ▪ venlafaxine XR of the SNRIs NOTE: Paroxetine, sertraline and venlafaxine have been shown to decrease relapse when used for longer term.	Consider referral for cognitive behavioral therapy (CBT) alone.	May consider combined pharmacotherapy and CBT, though evidence of added benefit is limited.
Obsessive-Compulsive disorder	Fluoxetine, fluvoxamine, sertraline and paroxetine	May refer for exposure therapy with response prevention (ERP) or CBT.	▪ Advise self-help literature. ▪ May consider combined CBT and pharmacotherapy.
Specific phobias	Not recommended.	Consider referral for exposure therapy.	Advise self-help literature in milder cases.
Social anxiety disorder	▪ All SSRIs ▪ venlafaxine XR (also effective in preventing relapse)	Consider referral for CBT.	▪ Advise self-help literature. ▪ May consider combined CBT and pharmacotherapy.
Post-traumatic Stress disorder	▪ Fluoxetine, paroxetine, sertraline ▪ Venlafaxine XR NOTE: Continuing for > 1 year is associated with a lower rate of relapse.	Consider referral for CBT.	May consider combined CBT and pharmacotherapy.
Agoraphobia	**MUST** refer out to primary care or mental health professional for management.		
Panic disorder	**MUST** refer out to primary care or mental health professional for management.		

16.2.4 Follow-up for Depression and Anxiety

I. All follow-up encounters should address the following
   A. Relapse prevention and encouraging clients to return if symptoms return
   B. Client education points as listed above
   C. Adherence to treatment plan – see Administrative Chapter 2 Client Centered Communications

II. Frequency – individualize according to symptom severity.
   A. Consider follow-up contact, either face-to-face or by phone as appropriate, within the first 3 weeks to address
      1. Medication side effects
      2. Review of client education points
   B. Consider advising 3 or more follow-up visits within the first 3 months of initiating treatment.

III. In clients on pharmacotherapy be alert to
   A. Increased symptoms, especially suicidality
   B. Side effects, especially those that may lead to discontinuation
   C. Inadequate response to medication as measured with a standard instrument such as the PHQ-9. If adequate response does not occur in the first 6 weeks, consideration should be given to possibility of
      1. Incorrect diagnosis
      2. Need for adjuvant therapy, such as a second medication or the need to adjust dosage
      3. Switching medication

✓ Patient Questionnaire Screeners

IV. Referral for depression and anxiety
   A. **Must** call 911 and notify mental health professional immediately for clients who
      1. Are unable to care for self/family
      2. Are psychotic
      3. Are a danger to others
      4. Are at immediate risk for suicide
   B. **Must** refer clients who
      1. Are <18 years old or ≥ 65 years old
      2. Have co-morbidities that complicate management and are not managed within the affiliate
      3. Do not respond to treatment

4. Are pregnant and not planning termination, unless affiliate provides prenatal care

✓ FYI — Postpartum Depression

5. Have Severe MDE
6. Have new diagnosis or relapse of Persistent Depressive Disorder
7. Have Other Specified Depressive Disorder, Unspecified Depressive Disorder or when diagnosis of depression is unclear
8. Have panic disorder, agoraphobia or any severe anxiety disorder non-responsive to treatment

C. Clients choosing psychotherapy for monotreatment or adjuvant therapy should be referred to a mental health professional for evidence-based therapies, including cognitive behavioral therapy (CBT), interpersonal therapy (IPT), or dialectical behavioral therapy (DBT).

D. At the time of referral to mental health professional, affiliate may continue to provide treatment ONLY after consultation with program director.

16.3 DIABETES MELLITUS (DM), TYPE 2

16.3.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

16.3.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	Should give
Release When Test/Service/Consultation Will Not Be Obtained		Once	
Written information as appropriate			●

16.3.2 Screening

I. Any of the following tests are acceptable for screening

A. A1C test

B. Fasting plasma glucose (FPG) (no caloric intake for at least 8 hours prior to test)

C. 75 gm two-hour oral glucose tolerance test (OGTT)

16.3.b. Table: Screening Criteria for Diabetes

Criteria	Frequency
All clients ≥ 45 years and older	At least every 3 years ▪ Consider more frequent testing depending on initial results and risk status
At any age in asymptomatic client with sustained BP (either treated or untreated) ≥135/80	At least every 3 years
At any age if client has BMI ≥ 25 AND any of the following additional risk factors: ▪ Physically inactive ▪ Diabetes in first degree relative (parent, sibling, or child) ▪ Latina/o, African American, Native American, Asian, or Pacific Islander ▪ Hypertension (HTN) — BP ≥ 140/90 or on therapy for HTN ▪ HDL < 35 mg/dL and/or triglyceride > 250 mg/dL ▪ History of gestational diabetes mellitus or newborn ≥ 9 lbs ▪ History of CVD ▪ Condition associated with insulin resistance such as acanthosis nigricans ▪ PCOS	At least every 3 years
All clients with prediabetes per previous testing (A1C 5.7-6.4 or FPG 100-125 or OGTT 140-199)	Annually

16.3.3 Diagnosis and Management of Prediabetes

16.3.c. Table: Diagnosis and Management of Prediabetes — made on the basis of screening test

Type	Criteria for Diagnosis	Management
Prediabetes	▪ A1C 5.7 to 6.4%, OR ▪ FPG 100-125 mg/dL (impaired fasting glucose [IFG]), OR ▪ OGTT 140-199 mg/dL (impaired glucose tolerance [IGT])	▪ Recommend lifestyle interventions to address the following goals: o 7% weight loss. o Minimum of 150 minutes exercise per week. ▪ Consider referral for Medical Nutrition Therapy (MNT) with a registered dietician or diabetes educator or a referral to a structured support program with follow-up counseling. ✓ FYI — Nutrition Recommendations for Prediabetes ▪ Identify and treat, or refer for treatment, other modifiable CVD risk factors.

Type	Criteria for Diagnosis	Management
		▪ Medication — consider initiating metformin therapy (see Table 16.3.f.) for clients with ≥1 of the following high risk factors ○ Under 60 years old with BMI ≥ 35 ○ Impaired fasting glycemia ○ IGT ○ A1C of 5.7 - 6.4% ○ Low HDL, or elevated cholesterol ○ Diabetes in first degree relative ○ History GDM ▪ Perform annual screening test for diabetes.

16.3.4 Diagnosis and Management of Type 2 DM

I. Diagnostic Criteria
   A. A1C ≥ 6.5%* OR
   B. FPG ≥ 126 mg/dL* OR
   C. OGTT ≥ 200 mg/dL* OR
   D. Random plasma glucose ≥ 200 with classic symptoms of hyperglycemia or hyperglycemic crisis

   *In the absence of unequivocal hyperglycemia, the criteria should be confirmed by repeating with the same test.

II. Evaluation - perform according to Table 16.3.d.

16.3.d. Table: Evaluation of Type 2 DM

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Should include ▪ Presence or absence of fatigue, unintentional weight loss, urinary frequency, polydipsia, polyphagia, blurred vision, itchy skin, numbness in hands, legs, or feet, slow healing of wounds and sores, frequent vulvovaginal	May include ▪ Height, weight, waist circumference, BMI, BP ▪ HEENT: fundoscopic exam, assess mouth for gum disease, fungal infections, or lesions ▪ Neck: assess thyroid for enlargement or nodules; auscultate neck for carotid bruits and	**Must** include, if not measured in past 3 months ▪ A1C **Must** include, if not performed or available in past year

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
candidiasis or UTIs ▪ Symptoms, risk factors and history of depression - see 16.2.2 Depression ▪ History of HTN, dyslipidemia, CVD, cerebrovascular disease, peripheral vascular disease, dental disease ▪ Medications, including supplements and herbal remedies ▪ Tobacco, alcohol, street drug use ▪ Diet and exercise ▪ Family history	evaluate for vein distension ▪ Cardiovascular: assess rate, rhythm, murmurs, clicks, extra heart sounds ▪ Abdomen: assess for hepatomegaly, abdominal bruits, aortic pulsations ▪ Neuro: check fingers and toes for vibratory and proprioceptive sensation ▪ Feet: inspect for ulcers, bony deformity, calluses, and loss of hair or atrophic skin; palpate dorsalis pedis and posterior tibial pulses; assess for 10 mg monofilament sensation	▪ Urine albumin/creatinine ratio (UACR) ○ At least 2 specimens, preferably first morning void, should be collected in a 3 to 6 month period. ○ Test is positive if UACR is > 30 mg/g on 2 separate occasions. ▪ ALT, AST, serum electrolytes, BUN, creatinine ▪ Total cholesterol, HDL, LDL, triglycerides Consider TSH.

III. Management of Type 2 DM – manage per Table 16.3.e

✓ FYI — Goals of Type 2 Diabetes Management

16.3.e. Table: Management of Type 2 DM

✓ For client resources, see Associated Resources for Chapter 16

Intervention	Details
Lifestyle interventions	▪ Diet — recommend 7 to 10% weight loss for obese clients – see 16.9 Weight Management. ✓ FYI — Nutritional Recommendations for Management of Type 2 Diabetes ▪ Exercise — recommend ○ Moderate intensity exercise 4 to 7 days/week for at least 150 minutes per week ○ Resistance training at least twice a week
Smoking cessation	Include smoking cessation interventions as routine part of care, as indicated - see 16.8 Smoking Cessation
Diabetes Self-Management Education (DSME)	Refer client for initial support and as needed thereafter.
Self-monitoring of blood glucose (SMBG)	Consider, as appropriate.

Intervention	Details
Medication management	Initiate pharmacotherapy with metformin or a sulfonylurea according to Table 16.3.f.
Aspirin Therapy	Recommend 81 mg/day. ✓ FYI — Aspirin Therapy
Vaccinations	Recommend pneumococcal vaccine and annual influenza. See Chapter 20 Vaccination Services
Bariatric surgery referral	Offer bariatric surgery referral for clients with type 2 DM and BMI ≥ 35. ✓ FYI — Bariatric Surgery

16.3.f. Table: Medication Management of Type 2 DM

	Metformin (first-line agent)	Sulfonylureas (second-line agent)
Indications	▪ A1C > 0.5 above goal and/or SMBG > 20 mg/dL above goal ▪ Prediabetes ▪ PCOS	▪ Should be added to metformin if ○ Initial A1C is > 10, symptomatic, and declines referral/insulin, or ○ A1C > 7 after 3 months of metformin treatment, or FBG > 130 after 6 wks on metformin ▪ Can be used initially if there is a contraindication to metformin.
Contraindications	▪ Clinically significant liver disease ▪ Renal impairment ▪ Hypersensitivity to metformin ▪ Current heavy alcohol use (> 3 drinks/day) ▪ Past history of lactic acidosis	▪ Renal failure ▪ Hypersensitivity to the drug class ▪ Pregnancy near term ▪ Diabetic ketoacidosis
Considerations	▪ **Must** consult physician if client taking antiviral medications that may cause lactic acidosis: abacavir, didanosine, emtricitabine, entecavir, lamivudine, tenofivir, zalcitabine, zidovudine ▪ Treatment may result in resumption of ovulation in anovulatory women - contraception **must** be considered See Chapter 6 Contraception - Reversible	▪ Typical use associated with weight gain ▪ Associated with hypoglycemia ✓ FYI — Hypoglycemia ○ Advise clients on how to prevent and manage episodes of low blood sugar. ○ Consider potential medication adjustment if client experiences multiple episodes in 1 week.

	Metformin (first-line agent)	Sulfonylureas (second-line agent)
Regimen	▪ Start 500 mg qd with largest meal x 1 to 2 weeks. ▪ Increase to 500 mg BID if tolerated. ▪ Discuss GI side effects and review for symptoms when increasing dosage.	▪ Glipizide o Start 5 mg qd o Take 30 minutes before meals ▪ Glyburide o Start 2.5 mg qd o Take with breakfast or first meal. ▪ Glimepiride o Start 1 to 2 mg qd o Give with first main meal
Titration and Monitoring	▪ If not at SMBG goals after 1 to 2 weeks, increase dose as follows — o 500 mg BID for 1 to 2 weeks, then increase to o 1000 mg q am and 500 mg q pm with food for 1 week, then increase to o 1000 mg BID with food ▪ If SMBG not possible or client not willing, check A1C after 3 months and adjust medication according to regimens above. ▪ Monitor ALT and AST at baseline and periodically thereafter. ▪ Monitor creatinine at baseline and every 6 months. ▪ **Must** discontinue metformin and refer if o ALT or AST > 2.5 times ULN o Creatinine > 1.4 mg/dL for women, > 1.5 mg/dL for men or abnormal creatinine clearance (< 70 ml/minute) o Client develops ketosis or severe diarrhea (≥ 5 times per day)	Obtain creatinine at baseline. Titration of ▪ Glipizide o Increase in 6 to 12 wk intervals up to 40 mg per day o Divide to BID above 15 mg ▪ Glyburide o increase in 6 to 12-wk intervals up to 20 mg per day ▪ Glimepride o increase by 1 to 2 mg/day every 1 to 2 wks up to 8 mg/day

IV. Follow-up Type 2 DM
- A. Schedule of visits
  1. Weekly, while glucose is being controlled
  2. Then, every 3 months until treatment goals have been achieved
  3. Every 6 months, once diabetes is well controlled
- B. Check A1C every 3 months, or every 6 months if very stable.
- C. If on metformin
  1. Monitor ALT and AST periodically.
  2. Monitor creatinine every 6 months
- D. Perform or recommend/refer annually for
  1. Dilated eye exam
  2. Urine albumin to creatinine ratio (UACR)
  3. Lipid panel, manage LDL >100 – see 16.7 Lipid Disorders
  4. Comprehensive foot exam, with neuropathy testing as above
  5. Influenza vaccine
  6. reproductive life planning (RLP) as appropriate — See Chapter 21.3 FYI — Reproductive Life Planning
- E. Advise or refer as needed for concurrent management
  1. DSME
  2. Registered dietitian for MNT
  3. Mental health professional
  4. Dentist for comprehensive periodontal examination

V. Referral - **must** refer clients to either primary care provider or specialist who
- A. Are <18 years old or ≥ 65 years old
- B. Have diabetes and
  1. Hypertension (stage I or II) requiring management outside the affiliate

  OR
  2. LDL >160 requiring management outside the affiliate
- C. Have or develop contraindication(s) to metformin or sulfonylurea use
- D. Have albuminuria
- E. Develop other microvascular or macrovascular complications

F. Have glucose that is not controlled with diet, exercise, and metformin/sulfonylureas
G. Are pregnant and not planning termination, unless affiliate will be providing prenatal care

16.4 GASTROESPOPHAGEAL REFLUX DISEASE (GERD)

16.4.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

16.4.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	Should give
Release when test/service/consultation will not be obtained		Once	
Written information as appropriate			●

16.4.2 Evaluation

✓ FYI — Classification of GERD

16.4.b. Table: Evaluation for GERD – **must** be performed when GERD is suspected

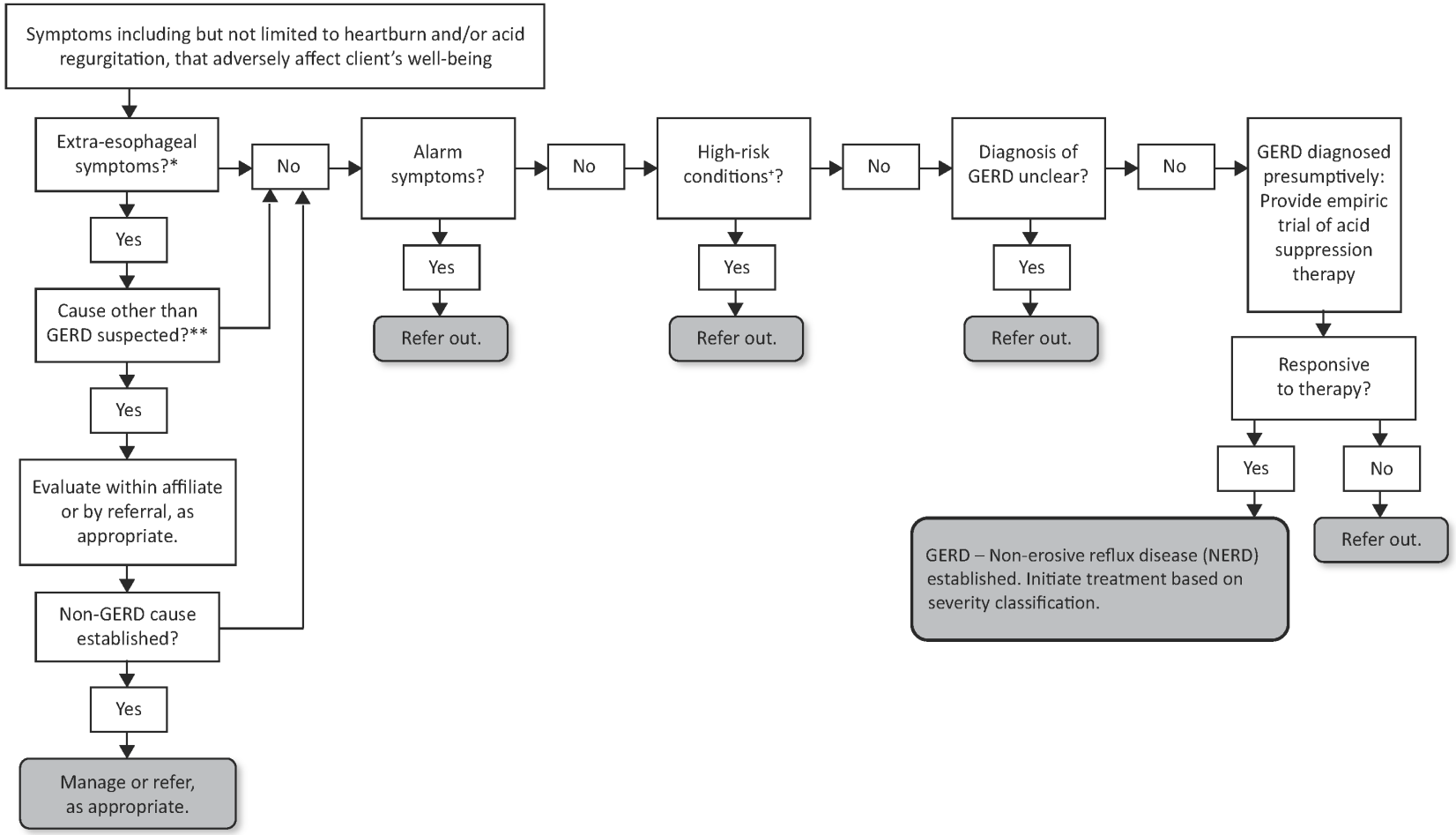
History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Should include review of the following key indicators ▪ **Typical symptoms**: heartburn, regurgitation, indigestion; aggravated by meals (especially fatty meals), lying down, bending, or physical exertion ▪ **Atypical symptoms**: non-cardiac chest pain, dyspepsia, epigastric pain, nausea, bloating, and belching ▪ **Extra-esophageal symptoms**: wheezing, chronic cough, shortness of breath, chronic hoarseness/laryngitis, unexplained chest pain, globus (choking sensation), halitosis, sore throat, or a sense of needing to clear one's throat.	Should include ▪ General: temperature, weight, BP, heart rate ▪ HEENT: teeth, oropharynx ▪ Neck ▪ Cardiovascular ▪ Lungs ▪ Abdomen	No routine tests within affiliate. ✓ FYI — Use of Tests and Imaging in GERD ✓ FYI – *Helicobacter Pylori* and GERD

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
▪ **Alarm symptoms** for underlying motility disorder, stricture, ring, ulceration, or malignancy: dysphagia, odynophagia, recurrent vomiting, GI bleeding, anemia, early satiety, anorexia, weight loss, and/or choking ▪ **Medications** that can cause GERD or esophageal injury or exacerbate symptoms (e.g., theophylline, nitrates, anticholinergic agents, calcium-channel blockers, α-adrenergic antagonists, β blockers, α, β agonists, prostaglandins, sedatives, NSAIDs, caffeine) ▪ **Risk factors for complications**: tobacco use, elevated BMI, visceral fat, hiatal hernia and nocturnal reflux ▪ **Effects of symptoms on quality of life**: time off work, decrease in productivity, decrease in physical functioning, nocturnal symptoms causing sleeping disturbances		

✓ FYI – Differential Diagnosis of GERD

16.4.3 Diagnosis

16.4.c. Algorithm: Diagnosis of GERD

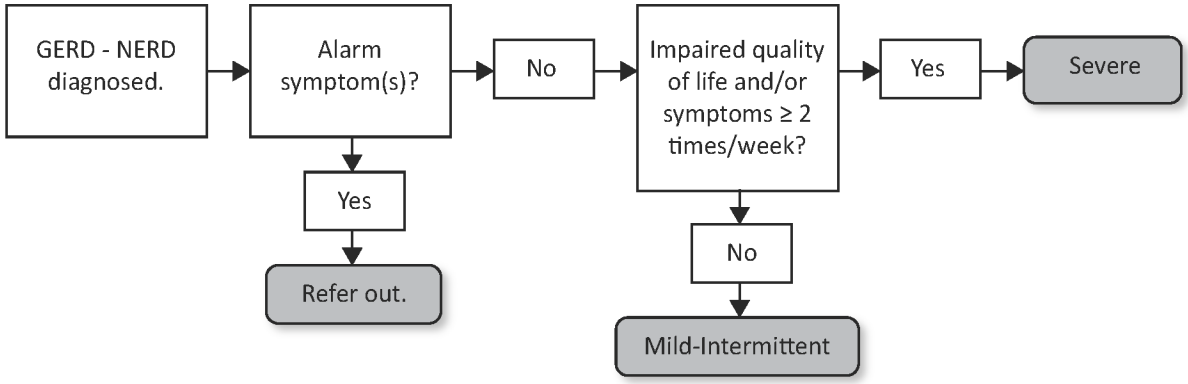


*Clients with extra-esophageal such as asthma, chronic cough, laryngitis, or chest pain as well as typical GERD symptoms should be evaluated for non-GERD causes.

In clients reporting chest pain, **must distinguish cardiac from non-cardiac cause of chest pain prior to proceeding with management. Refer as appropriate.

+Applies to males >50 years old with GERD-like symptoms for at least 5 years AND additional risk factors for Barrett's esophagus and esophageal adenocarcinoma (e.g. white race, nocturnal reflux symptoms, hiatal hernia, elevated BMI, tobacco use, intra-abdominal distribution of fat).

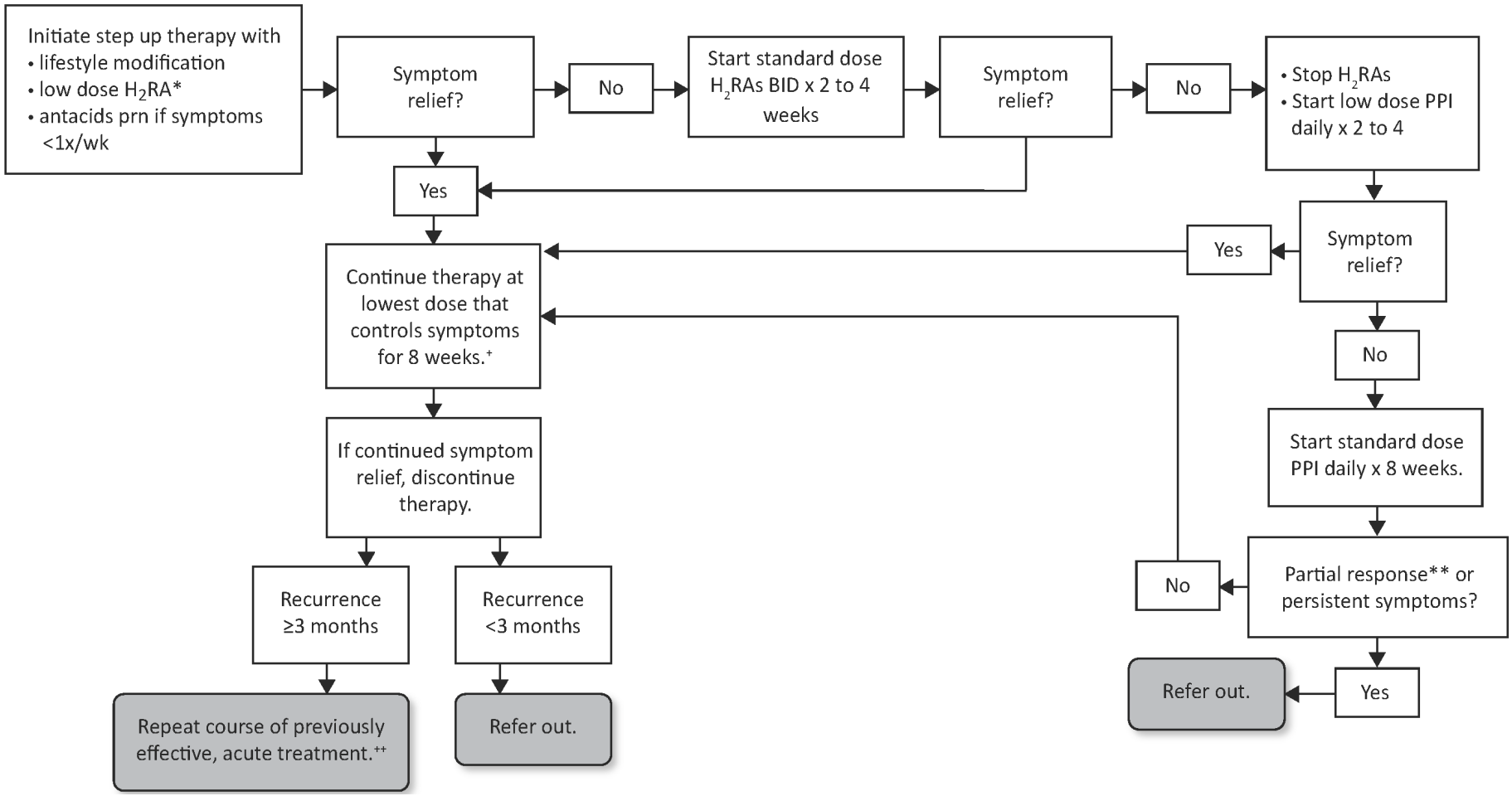
16.4.d. Algorithm: Classification of GERD-NERD



16.4.4 Management

I. For clients not previously diagnosed - proceed with step therapy appropriate to GERD-NERD classification.
II. For clients diagnosed outside of affiliate and already on pharmacotherapy who desire to continue management with affiliate
   A. Perform GERD-NERD classification – see Algorithm 16.4.d.
   B. Proceed with management appropriate to classification

16.4.e. Algorithm: Step-up Therapy for Management of GERD-NERD – Mild-Intermittent



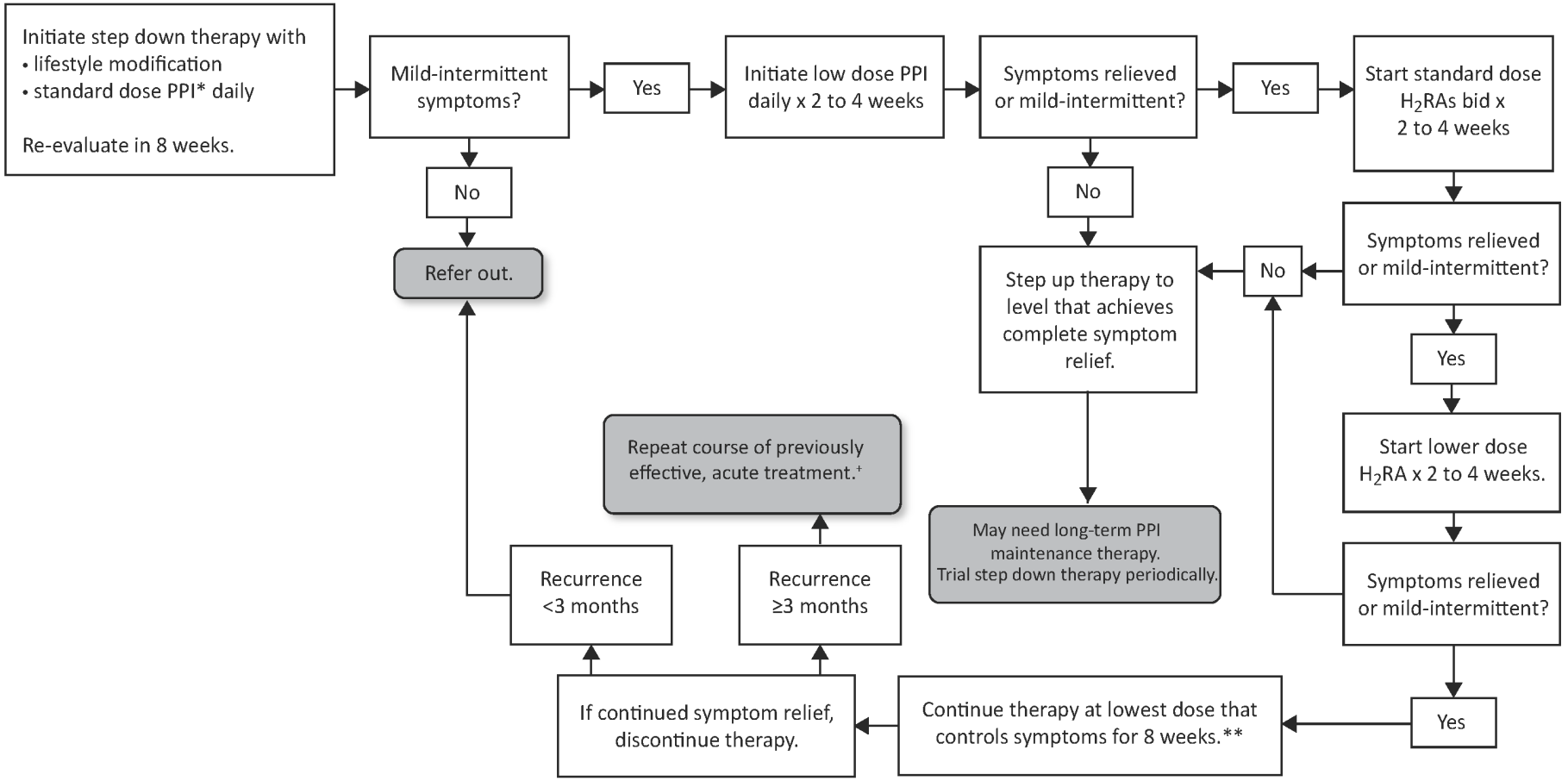
*Selection of acid suppression agent should be based on the least expensive agent at the lowest effective dose for the minimum duration needed to manage symptoms and prevent complications.

**At the time of referral to a specialist in clients with partial response to therapy, affiliate may continue therapy with either a dose increase to twice daily or initiation of a different PPI ONLY after consultation with the program director. Only the program director may authorize additional refills.

+If symptoms resume during the 8-week course, step-up therapy to dose that relieves symptoms and continue for 8 weeks; then discontinue as appropriate.

++Initiate dose that controlled symptoms, then proceed with titrating medications according to appropriate step up or down algorithm.

16.4.f. Algorithm: Step-down Therapy for Management of GERD-NERD – Severe



*Selection of acid suppression agent should be based on the least expensive agent at the lowest effective dose for the minimum duration needed to manage symptoms and prevent complications.

**If symptoms resume during the 8-week course, step-up therapy to dose that relieves symptoms and continue for 8 weeks; then discontinue as appropriate.

+Initiate dose that controlled symptoms, then proceed with titrating medications according to appropriate step up or down algorithm.

16.4.g. Table: Lifestyle Modifications in the Management of GERD-NERD

Type of modification	Clients should be advised to
Dietary	▪ Lose weight, if overweight (BMI ≥25) or recent weight gain – see 16.9 Weight Management ▪ Avoid large meals ▪ Selectively eliminate dietary triggers of GERD symptoms (e.g. chocolate, peppermint, onions, garlic, alcohol, carbonated beverages, citrus fruits/juices, tomato products, fatty foods, spicy foods) ○ Modifications should only be recommended for clients who note correlation with GERD symptoms and improvement with selective elimination.
Behavioral	▪ In clients with night time and/or laryngeal symptoms: ○ Elevate head of bed while sleeping by using blocks under the legs of the head of the bed or foam wedges ○ Avoid recumbency for 2 to 3 hours after meals, especially those with high fat content ▪ Sleep in left lateral position ▪ Tobacco cessation – see 16.8 Smoking Cessation ▪ Avoid alcohol ▪ Avoid tight fitting garments ▪ Avoid medications that may exacerbate GERD - see Table 16.4.b.

16.4.h. Table: Pharmacologic Therapy for GERD-NERD

I. General principles

A. Therapy for GERD other than acid suppression (e.g., pro-kinetic therapy, sucralfate, and/or baclofen) should not be used in GERD clients without diagnostic evaluation.

B. Selection of acid-suppression agent should be based on the least-expensive agent at the lowest effective dose for the minimum duration needed to manage symptoms and prevent complications.

✓ FYI — Intermittent vs. Continuous Dosing

Drug Class	Indication	Considerations	Side Effects	Cautions
Antacids	Temporary relief of individual heartburn episodes	▪ Onset of action within 15 to 30 minutes ▪ Duration of action 90 minutes ▪ Inexpensive	▪ Diarrhea ▪ Constipation	

Drug Class	Indication	Considerations	Side Effects	Cautions
		▪ Inadequate for prophylaxis		
Histamine-2 Receptor Antagonists (H_2RA)	First line therapy for uncomplicated GERD-NERD mild-intermittent	▪ OTC doses are ½ the standard prescription dose ▪ No difference in clinical efficacy or adverse effect profiles among agents when using standard dose ▪ Onset of action within 1 to 2.5 hours ▪ Duration of action up to 10 hours	▪ Drug interactions with cimetidine ▪ Theophylline ▪ Phenytoin ▪ Warfarin	▪ Delay in effect ▪ Tolerance may develop ▪ Not appropriate for maintenance therapy of severe GERD due to development of tachyphylaxis
Proton pump inhibitors (PPIs)	First line therapy for GERD-NERD severe, provides symptomatic relief and healing of esophagitis	▪ No difference in clinical efficacy or adverse effect profiles among agents when using standard dose ▪ Should take daily rather than prn as it may take 1 to 4 days to achieve full effect ▪ Should take 30 to 60 minutes before meals ▪ Initiate before the first meal of the day ▪ Consider switching to a different PPI for management of side effects	▪ Headaches ▪ Nausea ▪ Dyspepsia ▪ Constipation ▪ Diarrhea ▪ Pruritus	Possible associations with long-term use include vitamin B-12 deficiency, risk for gastroenteritis and other infections

16.4.5 Follow-up

I. Clients who discontinue therapy should be advised to return if symptoms resume.
II. Clients on maintenance therapy should return every 6 months.

16.4.6 Referral

I. **Must** refer clients who
   A. Are < 18 or ≥ 65 years old
   B. Have known erosive esophagitis or Barrett's esophagus
   C. Fail to respond to an 8 week course of once daily PPI therapy

D. Develop atypical symptoms or complications
E. Have concomitant asthma, chronic cough, and/or laryngitis that cannot be managed within the affiliate
F. Have chest pain in which a cardiac cause cannot be excluded by history
G. Cannot tolerate medication side effects
H. Are pregnant and plan to continue the pregnancy, unless the health center will be providing prenatal care

✓ FYI – GERD in Pregnancy

II. At the time of referral, affiliate may continue maintenance therapy, as indicated, ONLY after consultation with the program director. Medication refills may only be authorized by the program director.

16.5 HYPERTENSION (HTN)

16.5.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

16.5.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	Should give
CI Lower Your BP			●
CI Preconception			●
Release When Test/Service/Consultation Will Not Be Obtained		Once	
Written information as appropriate			●

16.5.2 Screening for HTN

I. Should be performed routinely in clients ≥18 years old every
A. 2 years when BP <120/80
B. Year when SBP 129-139 or DBP 80-90

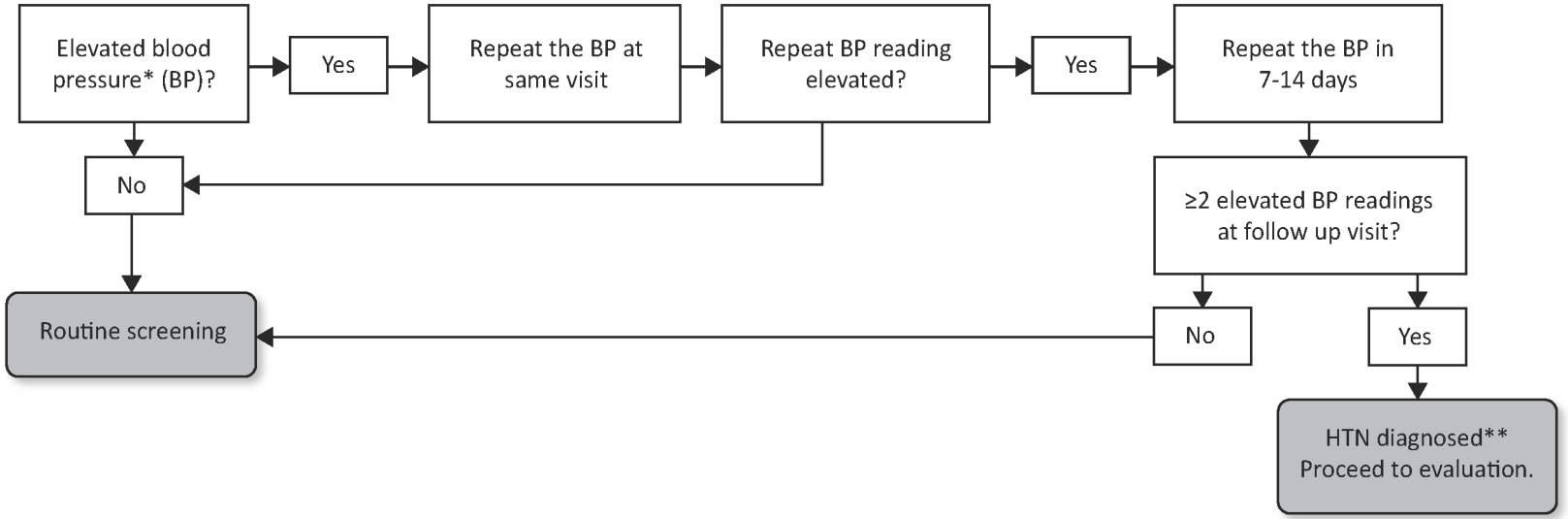
16.5.3 Diagnosis of HTN

I. After an initial elevated BP reading, proceed with Algorithm 16.5.b. Diagnosis of HTN

✓ FYI — BP Measurement Techniques

✓ FYI — Risk Factors and Secondary Causes

16.5.b. Algorithm: Diagnosis of HTN



*Elevated BP - If <60 years old: systolic ≥140 and/or diastolic ≥90. If ≥60 years old: systolic ≥150 and/or diastolic ≥90.

**HTN defined as ≥2 elevated BP readings at ≥2 visits.

16.5.4 Evaluation - **must** perform prior to initiation of HTN management

16.5.c. Table: Evaluation - HTN

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Should include ▪ Relevant review of systems ▪ History of CVD, such as myocardial infarction, stroke, CHF, peripheral vascular disease, retinopathy, or renal disease ▪ History of diabetes ▪ Family history of early CVD (men <55 years old or women <65 years old) ▪ Social history – exercise, tobacco and alcohol use ▪ Medications - prescribed, OTC, and herbals	May include, as determined by age, risk factors, and degree of HTN ▪ General — height, weight, waist circumference, BMI ▪ HEENT — fundoscopic exam, as indicated ▪ Neck — palpate thyroid and check for bruits if age appropriate ▪ Respiratory ▪ Cardiovascular ▪ Extremities — assess lower extremities for edema and pulses ▪ Neuro — as indicated	**Must** perform ▪ Urinalysis ▪ Metabolic panel to include evaluation of renal function Should perform ▪ A1C or fasting glucose ▪ Lipid profile, if not done in past year Additional testing may include ▪ Electrocardiogram ▪ Hgb

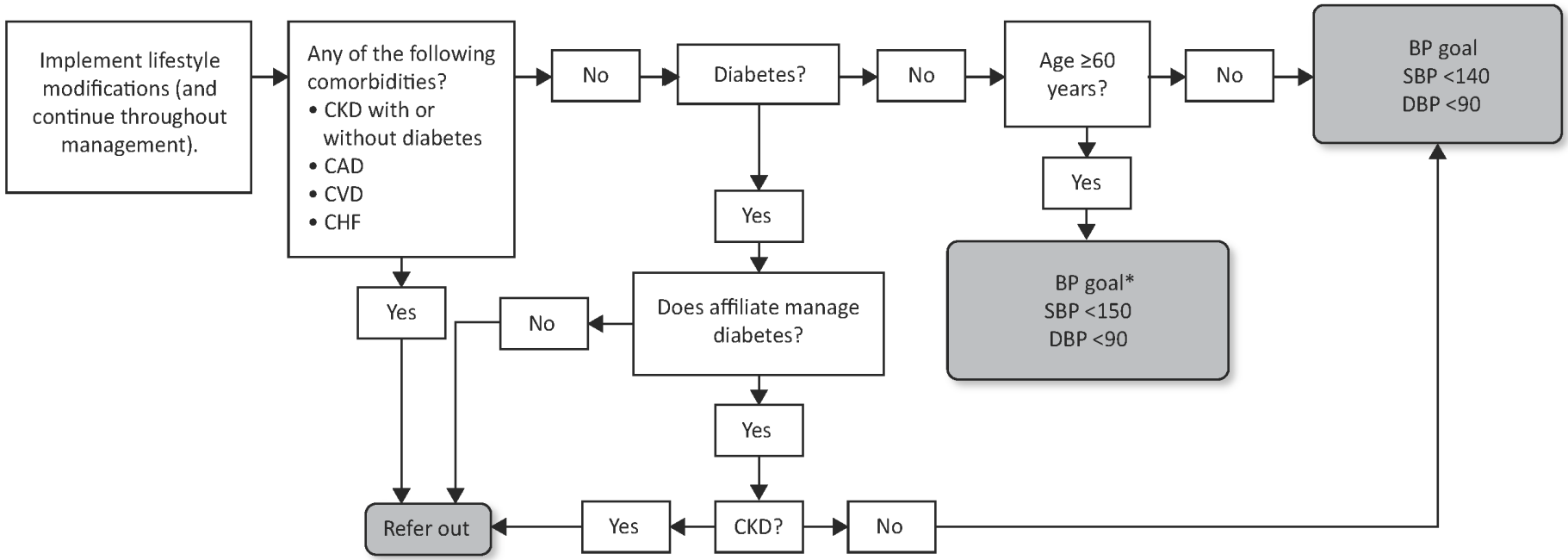
16.5.5 Management

16.5.d. Table: HTN Management According to Staging – **must** stage BP in order to guide management of HTN

BP Stage	Management
Pre-HTN (SBP 120-139 and/or DBP 80-90)	Advise lifestyle modification: ▪ Dietary modification ○ Adapt dietary modification recommendations to appropriate calorie requirements, personal and cultural food preferences, and nutrition therapy for other medical conditions (including diabetes mellitus). ○ Dietary sodium restriction ○ Recommended dietary patterns include • Dietary Approaches to Stop Hypertension (DASH) • USDA Food Pattern

BP Stage	Management
	• American Heart Association Diet ▪ Exercise recommendations ▪ Weight management, if applicable – see 16.9 Weight Management ▪ Limiting alcohol intake to no more than 1 oz of ethanol per day in men or 0.5 oz of ethanol per day for women and people of lighter weight ▪ Tobacco cessation, if applicable – see 16.8 Smoking Cessation
Stage 1 HTN (SBP 140-159 and/or DBP 90-99) Stage 2 HTN (SBP ≥160 and/or DBP ≥100)	▪ Advise lifestyle modification as above AND ▪ Set BP goal per Algorithm 16.5.e. AND ▪ Initiate pharmacotherapy accordingly per Algorithm 16.5.f.

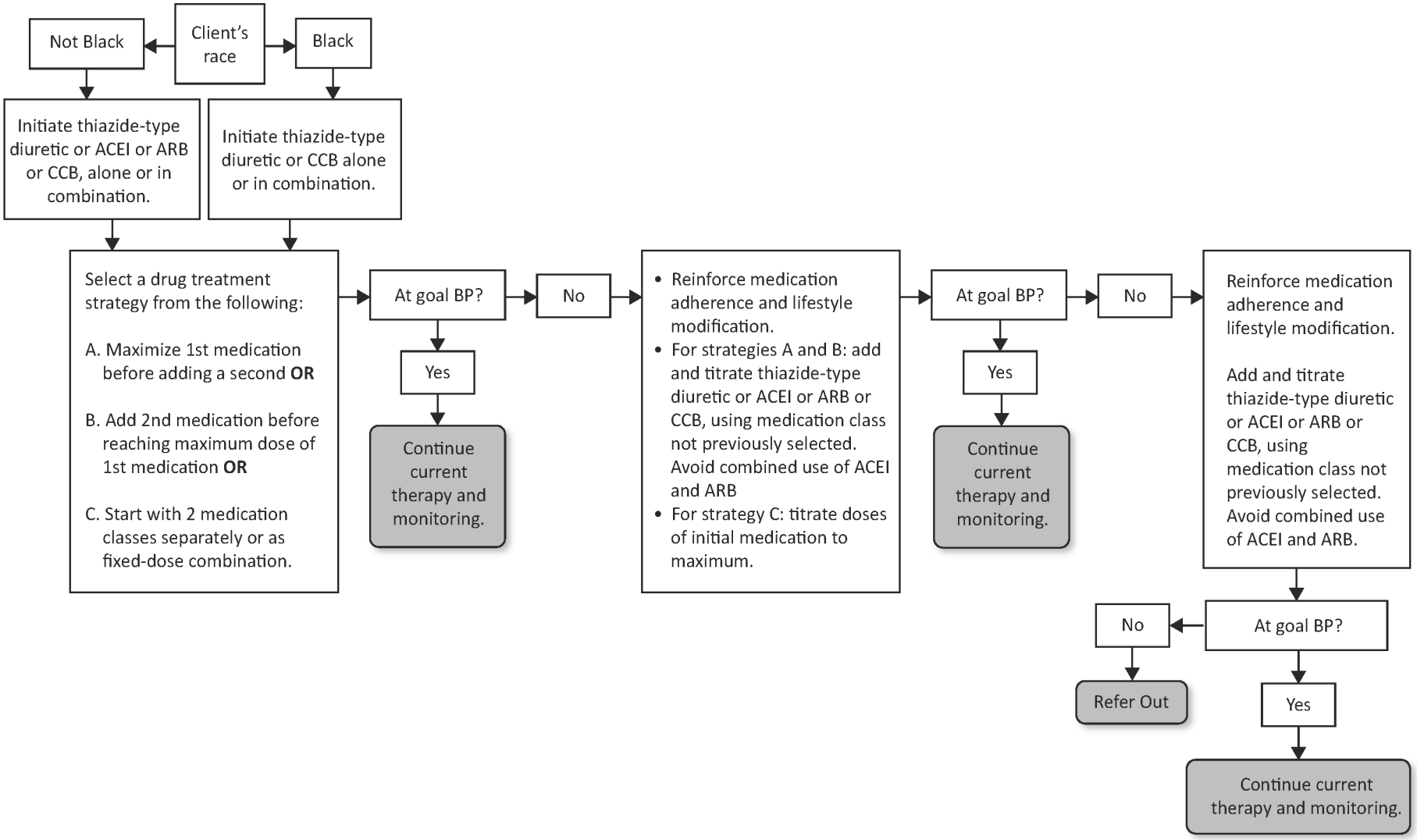
16.5.e. Algorithm: Goal BP in HTN Management



Key: CKD = chronic kidney disease; CAD = coronary artery disease; CVD = cardiovascular disease; CHF = congestive heart failure; SBP = systolic blood pressure; DBP = diastolic blood pressure

*If pharmacologic treatment for HTN results in lower achieved BP (e.g. <140 mmHg) and treatment is well-tolerated and without adverse effects on health or quality of life, treatment does not need to be adjusted.

16.5.f. Algorithm: Medication Management of HTN



Key: ACEI = angiotensin converting enzyme Inhibitor; ARB = angiotensin II receptor blocker; CCB = calcium channel blocker

16.5.g. Table: Anti-hypertensive Medications

Drug Class	Cautions and Considerations	Monitoring
Thiazide diuretics	▪ Pregnancy category C. ▪ Lactation*: chlorothiazide and hydrochlorothiazide are preferred agents, but use only in low doses. ▪ May cause renal impairment. ▪ Possible hypersensitivity in client with sulfa allergy. ▪ Co-administration with NSAIDs may reduce the thiazide diuretic's antihypertensive effects.	▪ Monitor creatinine and electrolytes 2 to 4 weeks after initiation or dose change, then annually.
ACE- Inhibitor (ACEI)	▪ Pregnancy category D. ▪ Lactation*: enalapril, benazapril, captopril, and quinapril are preferred agents. ▪ Potential for hyperkalemia	▪ Monitor creatinine and electrolytes 2 to 4 weeks after initiation or dose change, then annually.
Angiotensin II receptor blocker (ARB)	▪ Pregnancy category D. ▪ Lactation*: not compatible — prefer ACEI. ▪ Potential for hyperkalemia ▪ Coadministration of NSAIDs may decrease the ARB's antihypertensive effects.	▪ Monitor creatinine and electrolytes 2 to 4 weeks after initiation or dose change, then annually.
Calcium channel blocker (CCB)-dihydropyridines	▪ Pregnancy category C. ▪ Lactation*: nifedipine is preferred agent. ▪ May be used in asthma. ▪ Caution against intake of grapefruit products.	
Calcium channel blocker (CCB)-dihydropyridines	▪ Pregnancy category C. ▪ Lactation*: nifedipine is preferred agent. ▪ May be used in asthma. ▪ Caution against intake of grapefruit products.	
Calcium channel blocker (CCB) – non-dihydropyridines	▪ Pregnancy category C. ▪ Lactation*: verapamil and diltiazem are preferred agents, though less data exist for diltiazem. ▪ May be used in asthma.	

Drug Class	Cautions and Considerations	Monitoring
	▪ May reduce proteinuria more than CCB-dihydropyridines. ▪ Caution against intake of grapefruit products.	
Beta Blockers (BB)	▪ Pregnancy category D. ▪ Lactation*: metoprolol and propanolol are preferred agents. ▪ Avoid use of nonselective beta blockers in clients with asthma. ▪ Avoid abrupt cessation. ▪ Can mask symptoms of hypoglycemic response in clients with diabetes. ▪ Coadministration of non-dihydropyridine calcium channel blockers may increase risk of bradycardia.	
Combined alpha and beta-blocker	▪ Pregnancy category C. ▪ Lactation*: labetolol is preferred agent, but avoid when nursing a preterm infant. ▪ Avoid in asthma. ▪ Avoid abrupt cessation.	
Central alpha-2 agonists and other centrally acting drugs	▪ Pregnancy category C. ▪ Lactation*: methyldopa is preferred agent.	
*Lactation information provided is a general statement to guide care. Clinicians should investigate individual drugs for safety in lactation and consider risks and benefits prior to prescribing. For information on safety in lactation: http://www.toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT. Accessed May 2014		

16.5.6 Follow-up

I. Clients should return for monthly follow-up visits until goal BP is achieved, then every 6 months.
II. Discuss barriers to medication adherence at each visit. See Administrative Chapter 2 Client Centered Communications.
III. Lab tests should be repeated as indicated.
   A. Creatinine and electrolytes should be checked 2 to 4 weeks after initiation and dose changes, and then annually for patients taking ACEIs, ARBs, and/or diuretics.
   B. Lipid profile should be checked yearly.
IV. Reproductive life planning and preconception care should be addressed in the routine HTN visit for all women of childbearing potential, as appropriate. See Chapter 21.3 FYI — Reproductive Life Planning.

16.5.7 Referral

I. **Must** refer clients who
   A. Are <18 years old or ≥65 years old
   B. Have HTN and
      1. Diabetes requiring management outside the affiliate
      OR
      2. Elevated cholesterol requiring management outside the affiliate
   C. Have co-morbidities such as CVD, CHF, or CKD
   D. Have signs and symptoms of hypertensive emergency (**must** refer to emergency department immediately)
   E. Have not achieved goal BP after a reasonable trial
   F. Have not achieved goal BP using the 4 specified drug classes because of a contraindication or the need to use more than 3 of the drugs to control BP
   G. Are pregnant and plan to continue the pregnancy, unless the affiliate will be providing prenatal care

II. At the time of referral to a specialist, affiliate may continue therapy ONLY after consultation with program director. Only program director may authorize additional refills.

16.6 HYPOTHYROIDISM

16.6.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

16.6.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	Should give
Release When Test/Service/Consultation Will Not Be Obtained		Once	
Written information as appropriate			●

16.6.2 Evaluation

I. Should be performed if hypothyroidism suspected per Table 16.6.b.

✓ FYI — Common Causes of Hypothyroidism

✓ FYI —Screening and Diagnostic Testing for Hypothyroidism

16.6.b. Table: Evaluation

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Should include ▪ Review of symptoms ✓ FYI — Common Symptoms of Hypothyroidism ▪ Review of medications that can cause thyroid disease ✓ FYI — Medications that Can Cause Thyroid Disease ▪ Past history of endocrine disorders, thyroid surgery, and radiation to the head and neck	Should include ▪ General — temperature, weight, BP, HR ▪ HEENT — assess for facial edema ▪ Neck – assess for nodules or goiter ▪ Cardiovascular – assess for cardiomegaly, pericardial effusion (friction rub), bradycardia ▪ Neuro – assess for delayed relaxation phase of the deep tendon reflexes ▪ Skin – assess for coarseness of hair, dryness of skin, edema	**Must** include ▪ TSH — preferred initial test for evaluation of hypothyroidism. If abnormal, confirm with repeat TSH and check free T4. ▪ If repeat TSH is undetectable and free T4 is normal, should check T3. ✓ FYI — Understanding Lab Testing and the Diagnosis of Hypothyroidism

16.6.3 Diagnosis

I. Made based on lab testing in Table 16.6.c.

16.6.c. Table: Diagnosis

Laboratory Testing Results		Diagnosis	Notes
TSH	Free T4/T3		
High	Low free T4	Primary hypothyroidism	Routine measurement of serum antithyroid antibodies is NOT recommended.
Slightly elevated	Normal	Subclinical hypothyroidism	Anti-thyroid peroxidase antibody (TPOAb) measurements should be considered when evaluating patients with subclinical hypothyroidism.
Low (or inappropriately normal)	Low	Secondary or Tertiary hypothyroidism	Low (or inappropriately normal) TSH, low free T4 and T3

16.6.4 Management and Monitoring

I. Hypothyroidism usually requires lifelong treatment, unless a reversible cause can be identified, such as drug-induced hypothyroidism, or the etiology is transient (thyroiditis).

✓ FYI — Hypothyroidism and Estrogen Therapy

16.6.d. Table Management and Monitoring

Diagnosis	Management	Client Instruction	Monitoring
Primary hypothyroidism	Goals are TSH in normal range and resolution of symptoms. Initiate pharmacologic treatment with levothyroxine monotherapy ▪ Age 18 to 60 ○ Average starting dose — 75 mcg/day	▪ Take medication with water on empty stomach, either 1 hour before breakfast or at bedtime 4 hours after the last meal. ▪ Avoid medications that interfere with T4 absorption (calcium carbonate, bile acid resins, proton	▪ Monitor serum TSH every 4 to 8 weeks, increasing the dose of levothyroxine until the TSH is in the normal range. ▪ Once a stable dose is achieved, check TSH after 6 months and then annually, or more frequently

Diagnosis	Management	Client Instruction	Monitoring
	○ Increase dose by 25 mcg/day to full replacement dose of 1.6 mcg/k/d ○ Consider starting with full replacement dose in young, healthy clients ▪ age >60 ○ Consider starting at 25 to 50 mcg/day ○ Increase dose by 12.5 to 25 mcg/day every 6 to 8 weeks to full replacement dose of 1.6 mcg/k/d	pump inhibitors, ferrous sulfate).	if the clinical situation dictates otherwise. ▪ Monitoring levothyroxine therapy: ○ Consider assessment of serum free T4, in addition to TSH ○ Management of interruptions in therapy: • Clients may resume levothyroxine therapy after an interruption of less than 6 weeks at their previously employed full replacement dose if they have not had an intercurrent cardiac event or marked weight loss.
Subclinical hypothyroidism ✓ FYI — Subclinical Hypothyroidism	Base decision to treat on clinician judgment and client preference. In clients with subclinical hypothyroidism, consider initiating therapy with a daily dose of 25-75 mcg, lower than what is required for overt hypothyroidism.		Adjust dosing based on clinical response and follow up labs including TSH.
Secondary or tertiary hypothyroidism	▪ Clients with a new diagnosis of secondary or tertiary hypothyroidism **must** be referred out for management. ▪ Clients who have been previously diagnosed may continue pharmacologic management with levothyroxine at the affiliate. Manage to a goal of TSH in the normal range.		

16.6.5 Follow-up

I. Perform annual visit for labs and symptom monitoring once client is asymptomatic and on a stable dose of levothyroxine.
II. Increase frequency of monitoring if client develops symptoms or has significant weight loss or gain.

16.6.6 Referral

I. **Must** refer clients who
   A. Are <18 years old or ≥ 65 years old
   B. Have the following conditions
      1. Secondary or tertiary hypothyroidism requiring diagnostic evaluation
      2. Thyroid nodule, mass or suspected goiter
      3. Co-morbid cardiac disease
      4. Other endocrine disorders
   C. Do not respond to treatment
   D. Are planning a pregnancy
   E. Are pregnant and plan to continue the pregnancy, unless the affiliate will be providing prenatal care

✓ FYI – Hypothyroidism and Pregnancy

16.7 LIPID DISORDERS

16.7.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

16.7.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	Should give
Release When Test/Service/Consultation Will Not Be Obtained		Once	
Written information as appropriate			●

16.7.2 Screening and Risk Determination

I. Screening for lipid disorders is done in parallel with risk determination for atherosclerotic cardiovascular disease (ASCVD).

✓ 2013 Prevention Guidelines Tools – CV Risk Calculator

✓ FYI – Risk Factors for ASCVD

II. When indicated, perform screening and risk determination according to Table 16.7.b.

✓ FYI — Screening for Lipid Disorders

16.7.b. Table: Screening and Risk Determination

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Should include ▪ Personal history of ASCVD ○ Acute coronary syndrome ○ History of myocardial infarction ○ Angina ○ Coronary or other arterial revascularization ○ History of stroke ○ History of transient ischemic attack (TIA) ○ Peripheral arterial disease that is presumed to be of atherosclerotic origin ▪ History of hyperlipidemia or Type 2 DM ▪ Family history of premature ASCVD ▪ Social history including diet, physical activity, tobacco use, alcohol abuse	Should include ▪ Height ▪ Weight ▪ BP ▪ Waist circumference ▪ BMI	Initial evaluation ▪ Fasting lipid panel after 9 to 12 hour fast ✓ FYI — Fasting for Lipid Panels ○ If fasting is not possible, proceed with non-fasting lipid panel and follow-up as indicated. ▪ Consider a fasting glucose or A1C if the client is at risk for diabetes or insulin resistance syndromes, such as metabolic disorder or PCOS. If considering statin therapy, should include ▪ Baseline measurement of hepatic transaminase levels (ALT) ▪ Baseline measurement of CK for individuals at increased risk for adverse muscle events based on a personal or family history of statin intolerance or muscle disease, clinical presentation, or concomitant drug therapy that might increase the risk of myopathy NOTE: when indicated, ALT and CK measurements may be obtained either ▪ Simultaneously with initial lipid panel OR ▪ Following initial lipid panel, but prior to initiating statin therapy

16.7.3 Diagnosis

I. Based on the above screening and risk assessment

✓ FYI – Secondary Causes of Hyperlipidemia

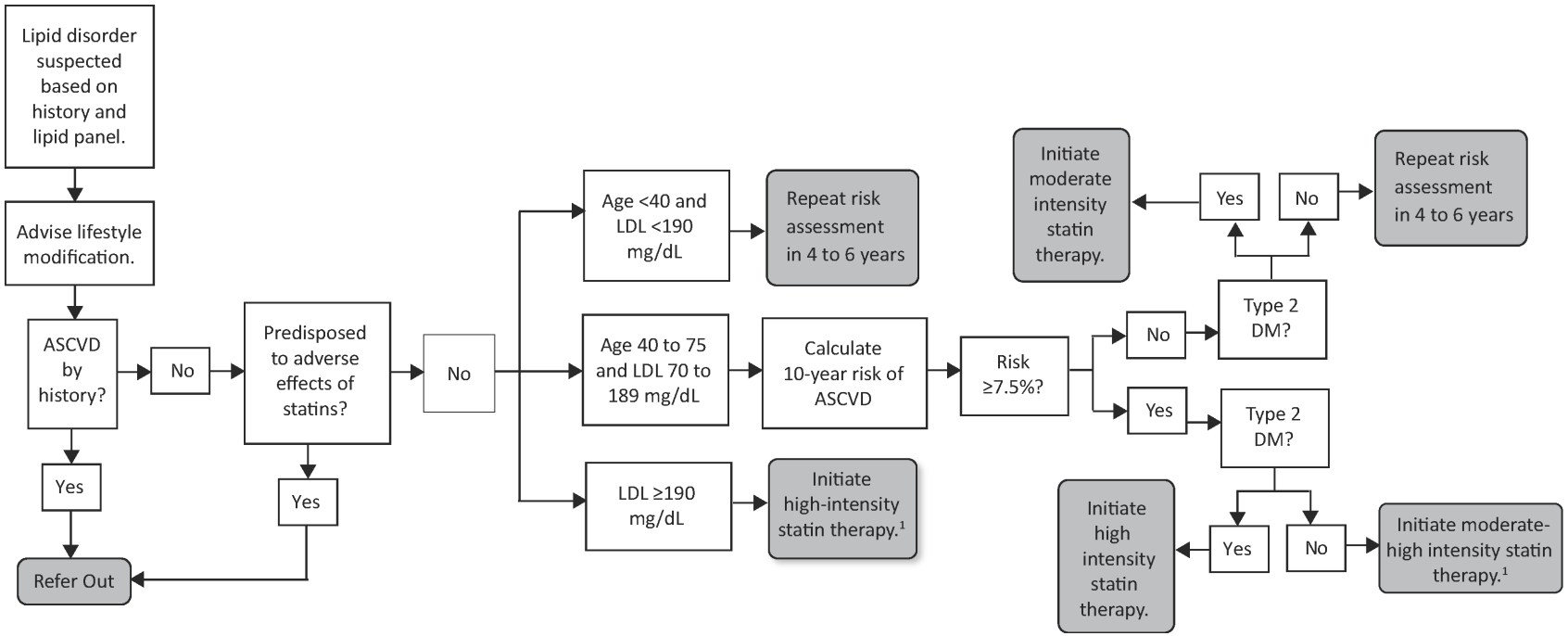
16.7.c. Table: Management

Component of Management	Details
Lifestyle Modification ✓ FYI — Lifestyle Modifications	Encourage healthy lifestyle habits in all clients prior to initiation and in conjunction with the use of lipid-lowering drug therapies. All clients who are candidates for statin therapy **must** be advised to initiate and maintain lifestyle modification efforts: ▪ Adhere to a heart healthy diet ▪ Maintain a healthy body weight – see 16.9 Weight Management ▪ Increase regular aerobic physical activity ▪ Avoid tobacco products and encourage smoking cessation – see 16.8 Smoking Cessation ▪ Control hypertension and diabetes when present
Preconception Care and Reproductive Life Planning See Chapter 21.3 FYI — Reproductive Life Planning	Address in all clients of reproductive age: ▪ Increased morbidity for mother and fetus/infant if uncontrolled hyperlipidemia ▪ Teratogenicity of statins. Statin is Category X in pregnancy. ▪ **Must** refer clients who are planning pregnancy ✓ FYI – Hyperlipidemia in Women of Reproductive Age
Evaluation of Family Members	Advise screening of client's family members.
Medication Therapy	▪ Use of specific LDL-C and/or non-HDL-C treatment targets are not recommended ▪ Consider the following prior to initiation of medication therapy ✓ FYI — Weighing Benefits and Risks of Statin Therapy ○ Factors that may influence statin use and management ○ Dietary habits, exercise type and frequency, tobacco use ○ Characteristics that predispose clients to statin adverse effects ✓ FYI — Predisposition to Adverse Events ○ Contraindications to statin therapy ○ Reliability of contraceptive method in sexually active clients of reproductive age

Component of Management	Details
	○ Client preference ▪ In eligible clients, ○ Use Algorithm 16.7.d. to determine • Clients who will benefit from lipid-lowering therapy with statin medications for secondary and primary prevention of ASCVD events. • Clients who require additional risk stratification in order to determine if they are candidates for treatment. • Appropriate intensity of statin therapy ○ Initiate statin therapy clients according to Algorithm 16.7.e. ○ Manage statin intolerance according to Algorithm 16.7.f. ○ Use Algorithm 16.7.g. to initiate statin therapy in clients already taking lipid-lowering medication.

16.7.d. Algorithm: Indications for Statin Therapy – for clients not currently taking lipid-lowering therapy

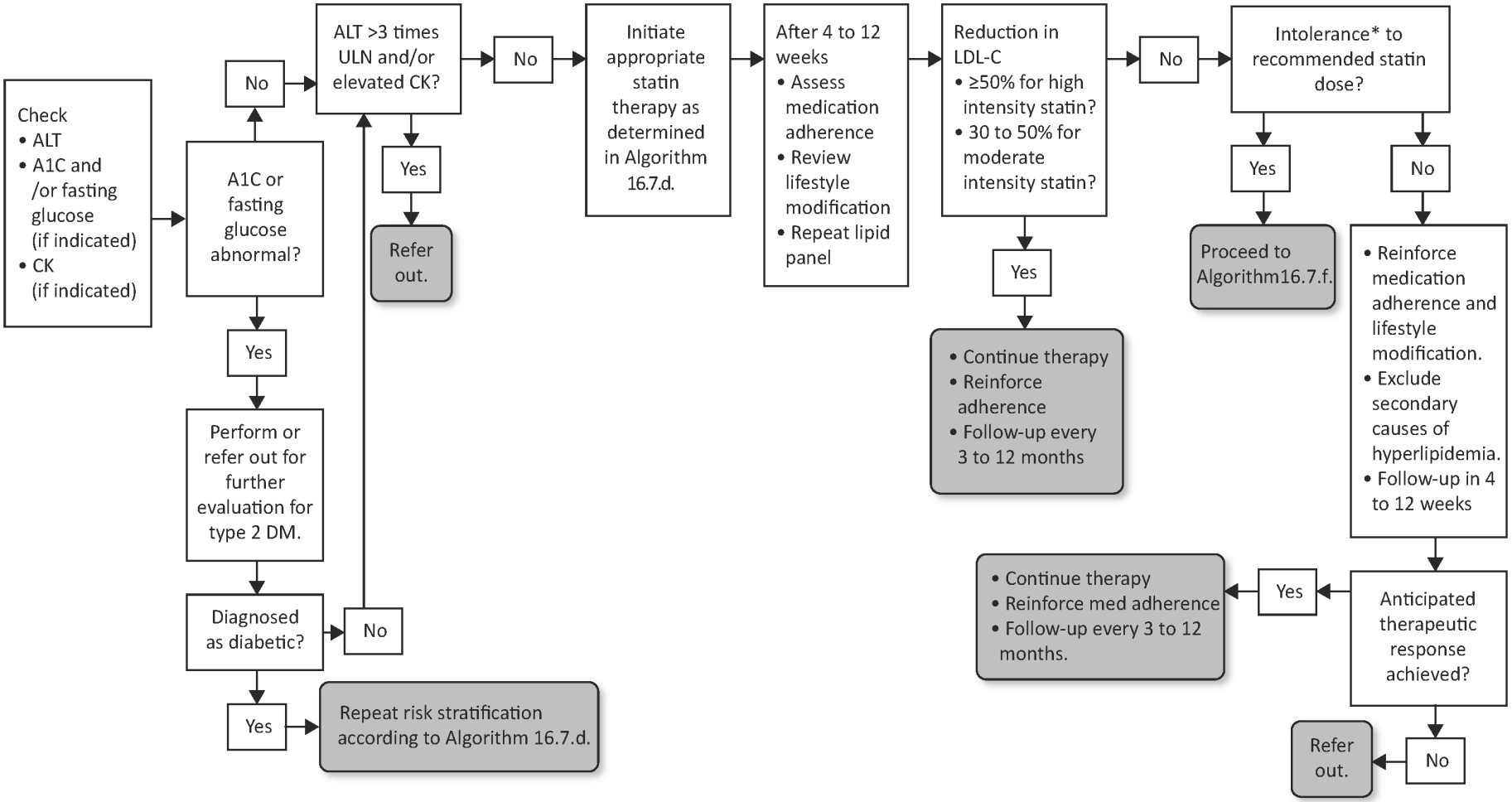
✓ FYI – Statin Drug Choices



[1]When choosing the intensity of statin therapy for primary prevention of ASCVD, consideration may be given to LDL-C ≥160 mg/dL or other e/o genetic hyper lipidemias, family history of premature ASCVD, or additional risk factors that may influence ASCVD risk.

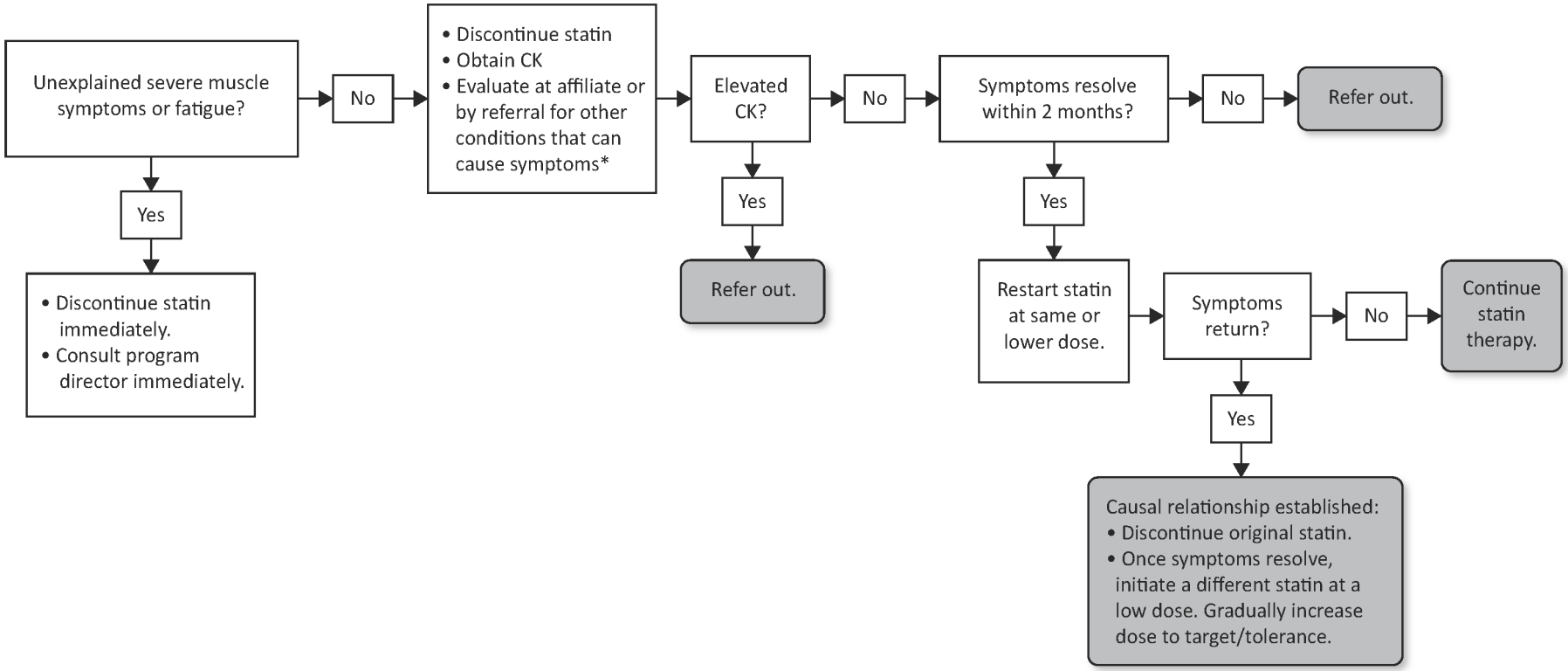
16.7.e. Algorithm: Initiating and Monitoring Statin Therapy – for clients not currently taking lipid-lowering medications

✓ FYI – Statin Drug Choices



*Symptoms of intolerance that warrant further evaluation include muscle pain, tenderness, stiffness, cramping, weakness or fatigue.

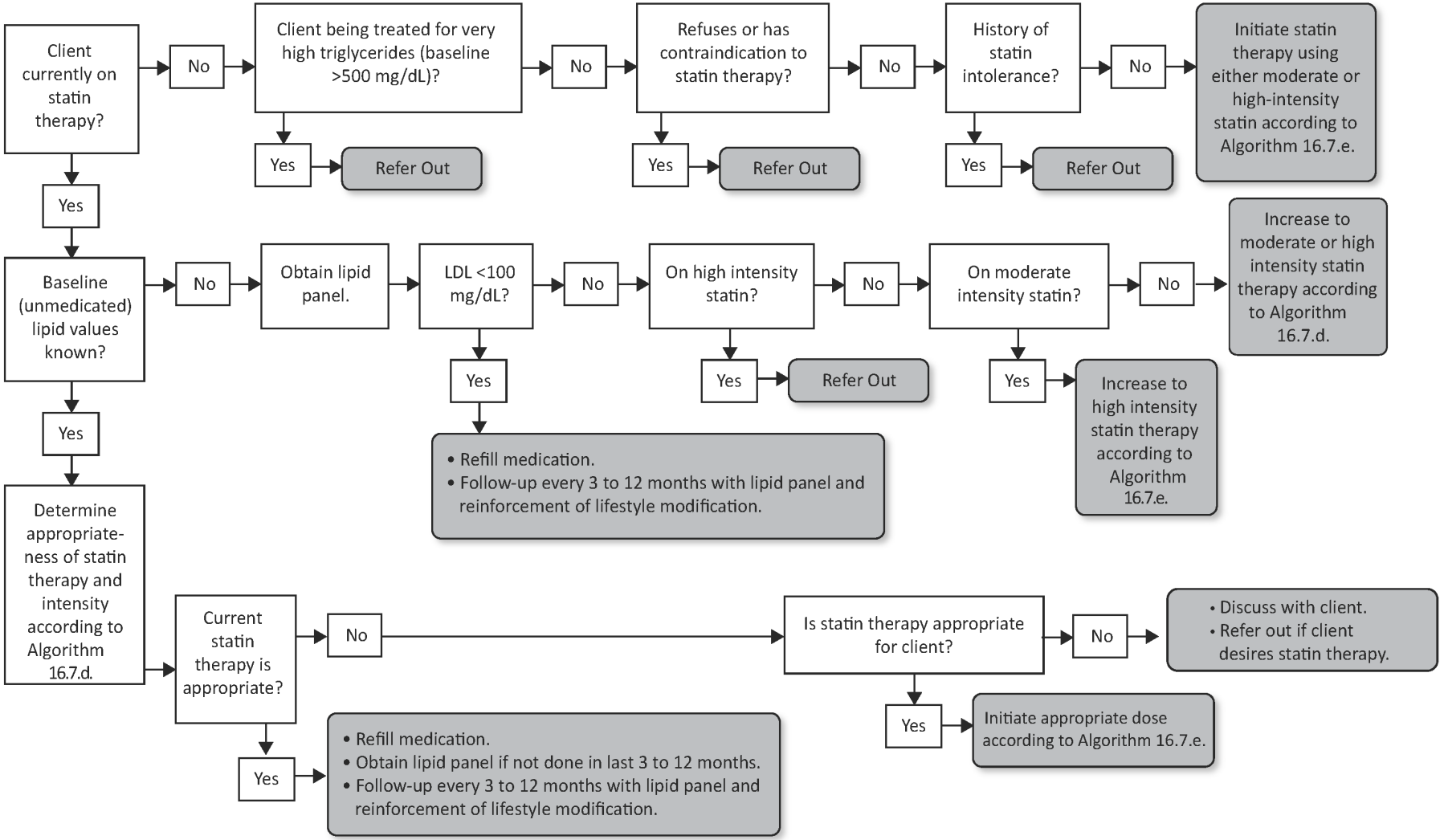
16.7.f. Algorithm: Management of Muscle Symptoms and Fatigue (Statin Intolerance)



*Other causes of muscle symptoms may include hypothyroidism, renal or hepatic disease, rheumatologic disorders, or vitamin D deficiency.

16.7.g. Algorithm: Statin Therapy - for clients currently being treated with lipid-lowering medications

✓ FYI – Statin Drug Choices



16.7.4 Follow-up

I. Periodic visits should address the following
   A. Evaluation of LDL response to therapy
   B. Cardiovascular review of systems
   C. Side effects to medications – see Algorithm 16.7.e.
   D. Medication adherence
   E. Lifestyle modification
   F. Preconception care and reproductive life planning as indicated - see Chapter 21.3 FYI — Reproductive Life Planning

II. Obtain fasting lipid panel after initiation of or changes in statin.
   A. Use percentage reductions in LDL-C level to assess and provide feedback to promote adherence to healthy lifestyle behaviors and statin therapy, not as treatment goals or performance measures.

✓ FYI — Statin Therapy

III. Check hepatic aminotransferase level and/or CK when clinically indicated by symptoms suggesting hepatotoxity or myopathy – see Algorithm 16.7.f.

16.7.5 Referral

I. **Must** refer clients who
   A. Are <21 years old or ≥ 75 years old
   B. Have LDL ≥ 160 and
      1. HTN (stage I or II) requiring management outside the affiliate
      OR
      2. Diabetes requiring management outside the affiliate
   C. Have characteristics predisposing individuals to statin adverse effects, including but not limited to
      1. Elevated baseline CK
      2. Impaired renal or hepatic function
      3. History of previous statin intolerance or muscle disorders
      4. Unexplained ALT elevations >3 times ULN
      5. Client characteristics or concomitant use of drugs affecting statin metabolism
      6. History of hemorrhagic stroke

D. Have co-morbidities that complicate management including, but not limited to
   1. Kidney disease
   2. Heart failure
   3. Alcohol abuse
   4. ASCVD
E. Do not achieve anticipated lipid-lowering with statin
F. Triglycerides >500mg/dL and/or non-fasting non-HDL-C >220mg/dL
G. Choose or require treatment with cholesterol-lowering medications other than statins
H. Are planning a pregnancy
I. Are pregnant and plan to continue the pregnancy, unless the affiliate will be providing prenatal care

II. At the time of referral to a specialist, affiliate may continue therapy ONLY after consultation with the program director. Only program director may authorize additional medication refills.

16.8 SMOKING CESSATION

16.8.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

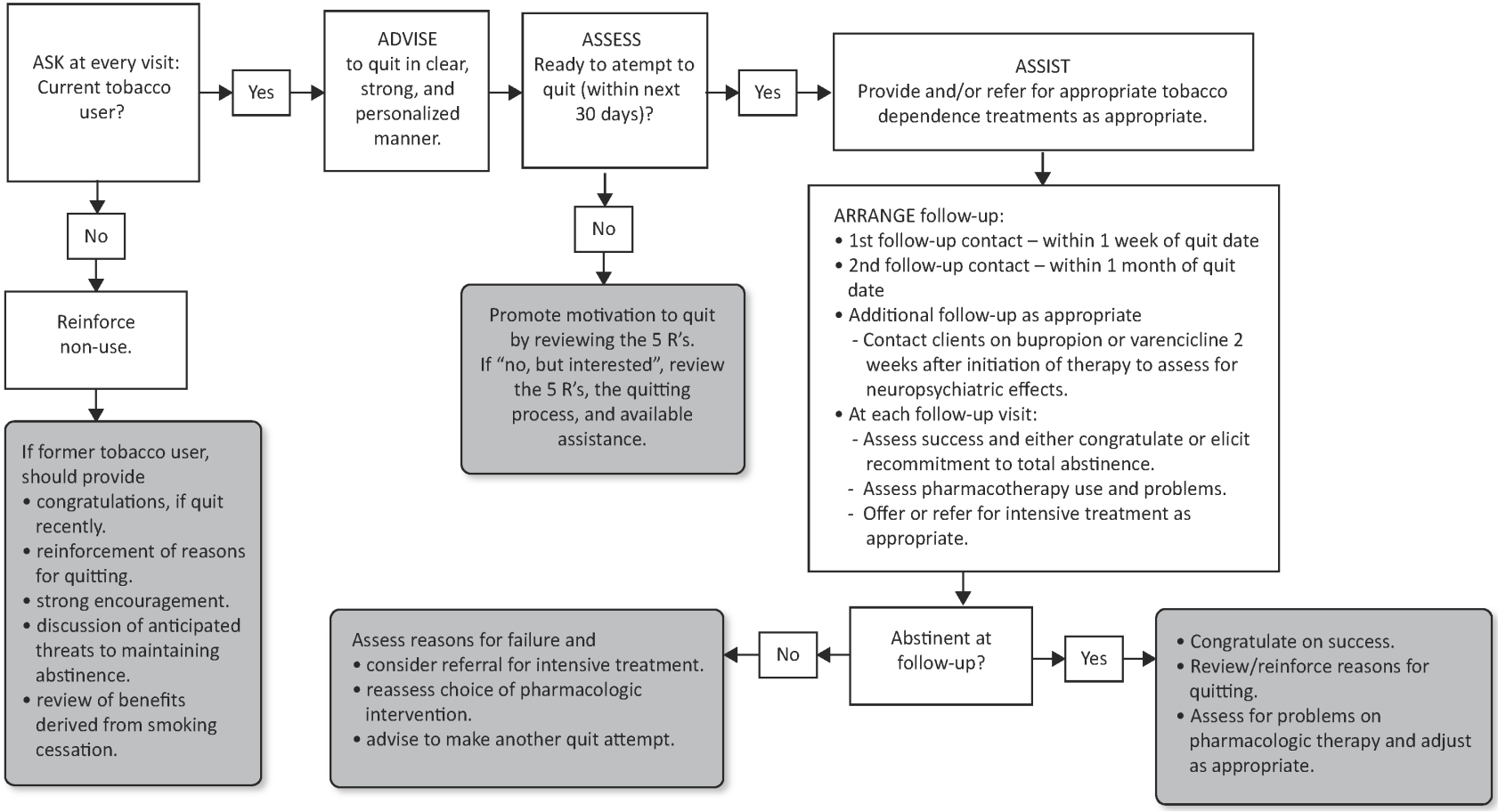
16.8.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	Should give
Information on appropriate interventions			●
List of local intensive programs			●

16.8.2 Interventions – the "5 A's" of Smoking Cessation

- ✓ FYI – Strategies for Implementing Advice to Quit
- ✓ FYI – The 5 R's of Motivational Intervention
- ✓ FYI – Assisting Client in Smoking Cessation

16.8.b. Algorithm: The "5 A's" of Smoking Cessation



16.8.c. Table: Special Considerations in Pharmacotherapy for Smoking Cessation

Type of Smoker	Special Consideration
Light smokers (< 10 to 15 cigarettes/day)	▪ If pharmacotherapy is used, consider reducing the dose of first-line nicotine replacement therapy (NRT) pharmacotherapies. ▪ No adjustment necessary when using bupropion SR.
Pregnant or breastfeeding smokers	▪ Encourage client to quit without pharmacologic treatment by o Providing or referring for intensive clinical intervention. ✓ FYI — Intensive Clinical Intervention for Smoking Cessation o Offering brief in-office counseling when intensive intervention is not possible. ▪ Consider pharmacotherapy only when a pregnant or breastfeeding woman is otherwise unable to quit, and when the likelihood of quitting, with its potential benefits, outweighs the risks of the pharmacotherapy and potential continued smoking. ✓ FYI — Pregnancy, Lactation and Pharmacologic Therapy for Smoking Cessation
Adolescent smokers	▪ No evidence that first-line pharmacotherapies are harmful to teens. ▪ Clinicians should be confident of the client's tobacco dependence and intention to quit before instituting pharmacotherapy. ▪ Consider degree of dependence, number of cigarettes per day and body weight when determining whether to start pharmacotherapy.

✓ FYI – Electronic Cigarettes

16.8.d. Table: Pharmacotherapies — First-Line Pharmacotherapies for Smoking Cessation

I. General Principles
   A. Pharmacotherapy should be offered to all smokers trying to quit except in the presence of medical contraindications.
   B. **Must** be prescribed according to the package labeling.
   C. Use clinical judgment, knowledge of client and familiarity with medications when choosing a first-line medication.

Pharmacotherapy	Dosage	Duration	Considerations	Precautions/CI	Side-effects
Bupropion SR (Zyban) RX	150 mg every AM for 3 days, then may increase to 150 mg bid.	7 to 12 weeks	Start 1 to 2 weeks *before* client's quit date.	**Precautions** ▪ Pregnancy Category D ▪ Possibly unsafe in lactation ✓ FYI — Pregnancy, Lactation and Pharmacologic Therapy for Smoking Cessation **Contraindicated** ▪ Seizure disorder ▪ Major head trauma ▪ Eating disorder ▪ Use of another form of bupropion (Wellbutrin or Wellbutrin SR) ▪ MAO inhibitor use in the past 14 days	Insomnia, dry mouth, nausea, seizures (1/1000)
Nicotine gum (Nicorette, Nicorette Mint) OTC (NRT — nicotine replacement therapy)	For ≥20 cigarettes/day, use 4 mg stick every hour. For <20 cigarettes/day, use 2 mg stick every hour. Maximum of 24 sticks/day of 4 mg gum. Maximum of 30 sticks/day of 2 mg gum.	2 to 3 months, with maximum use 6 months.	Maximum levels achieved within 20 to 30 minutes of use. Advise client to chew until spicy flavor begins, then "park" between cheek and gum for absorption. Remove after 30 minutes. Acidic beverages decrease absorption. Avoid consumption 15 minutes	**Precautions** ▪ Pregnancy Category C ▪ Probably safe in lactation ▪ Cardiovascular* ✓ FYI — Pregnancy, Lactation and Pharmacologic Therapy for Smoking Cessation **Contraindication** ▪ Active tempromandibular joint disease (TMJ)	Jaw fatigue, hiccups, dyspepsia, nausea These effects are generally mild and transient, and often can be alleviated by correcting the client's chewing technique.

Pharmacotherapy	Dosage	Duration	Considerations	Precautions/CI	Side-effects
			before and after chewing gum.		
Nicotine inhaler (Nicotrol) RX	80 puffs = 1 mg 3 to 4 puffs/minute for 20 to 30 minutes prn or every hour.	2 to 3 months	Maximum levels achieved in 20 minutes. Each cartridge good for approx. 20 minutes of continuous puffing. **Must** puff more frequently than cigarettes. Air temperature **must** be >40°F.	**Precautions** ▪ Pregnancy Category D ▪ Generally considered unsafe in lactation ▪ Cardiovascular* ▪ Use with caution in those with reactive airway disease. Careful instruction on spray technique is essential to avoid inducing bronchospasm. ✓ FYI — Pregnancy, Lactation and Pharmacologic Therapy for Smoking Cessation	Cough, mouth and throat irritation.
Nicotine lozenge	9 lozenges daily during initial weeks of therapy. 4 mg if first cigarette is within 30 minutes of waking; 2 mg if >30 minutes of waking. Then 1 lozenge every 1 to 2 hours for 6 weeks, then every 4 to 8 hours for the last 3 weeks.	12 weeks	Maximum levels achieved within 20 to 30 minutes of use. Place lozenge in mouth between cheek and gum and allow to dissolve over 20 to 30 minutes. Do not chew, bite, or swallow lozenge. Avoid acidic beverages 15 minutes before, during, or		Headache, diarrhea, flatulence, heartburn, hiccups, nausea, coughing, sore throat, upper respiratory infection.

Pharmacotherapy	Dosage	Duration	Considerations	Precautions/CI	Side-effects
	Maximum dose 20 lozenges/day.		after using a lozenge.		
Nicotine nasal spray (Nicotrol NS) RX	Spray every 30 to 60 minutes prn craving. Maximum 40 doses/day	2 to 3 months	Maximum levels achieved in 5 to 10 minutes. Most closely mimics nicotine delivery pattern of cigarette.	**Precautions** ▪ Pregnancy Category D ▪ Generally considered unsafe in lactation ▪ Cardiovascular* ▪ Asthma ✓ FYI — Pregnancy, Lactation and Pharmacologic Therapy for Smoking Cessation	Nasal Irritation / rhinorrhea (98% of users), sneezing, cough. Decreased severity of effects after 1st week.
Nicotine patch OTC or RX	>10 cigarettes/day, start with highest dose of given brand. For 5 to 10 cigarettes/day, use mid-range dose of given brand. Suggest ▪ Weeks 1 to 4 at highest dose of brand. ▪ Weeks 4 to 6 at next lowest dose of brand. ▪ Weeks 6 to 8 at lowest dose.	8 weeks	Maximum serum levels achieved in 2 to 3 days. No increase in long-term (52 weeks) cessation with longer duration. Taper recommended for psychological reasons, but does not increase efficacy. Rotate to new hairless skin site daily. Remove before bed with insomnia. May supplement with 2mg	**Precautions** ▪ Pregnancy Category D ▪ Probably safe in lactation ▪ Cardiovascular* ✓ FYI — Pregnancy, Lactation and Pharmacologic Therapy for Smoking Cessation	local skin reactions including pruritis, edema, or rash, insomnia

Pharmacotherapy	Dosage	Duration	Considerations	Precautions/CI	Side-effects
			nicotine gum in 1st 48 hours. May continue supplementation for 8 weeks or longer if effective.		
Varenicline (Chantix) RX	Start with 0.5 mg/day for 3 days, then 0.5mg bid for 4 days, then 1 mg bid.	12 weeks, with option to continue for another 12 weeks	Start 1 week before quit date. Take after eating with a full glass of water.	Precautions ▪ Pregnancy Category C ▪ Safety unknown in lactation ▪ Renal Insufficiency — No dosage adjustment necessary for mild to moderate renal impairment. For severe renal impairment, start dose is 0.5mg once daily. May increase to a maximum dose of 0.5mg twice a day. For end-stage renal disease undergoing hemodialysis, maximum dose of 0.5mg once daily may be given if tolerated well. ✓ FYI — Pregnancy, Lactation and Pharmacologic Therapy for Smoking Cessation	Nausea, insomnia, unusual dreams. Neuropsychiatric symptoms: Behavior changes, agitation, depressed mood, suicidality.
Nortriptyline (Aventyl HCl, Pamelor) RX	Titrate from 25 mg qhs slowly to 75 to 100 mg daily.	12 weeks	Not FDA approved for this indication, appropriate as second-line agent. Not been shown to be	**Precautions** ▪ Pregnancy Category D ▪ Safe in lactation ▪ Use with caution in clients >65 years old.	Drowsiness, dry mouth, constipation, nausea, orthostatic hypotension, dizziness, confusion,

Pharmacotherapy	Dosage	Duration	Considerations	Precautions/CI	Side-effects
(second line therapy)			effective for tobacco cessation in pregnant smokers.	▪ May impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a car; warn client accordingly. ✓ FYI — Pregnancy, Lactation and Pharmacologic Therapy for Smoking Cessation **Contraindications** ▪ Use of MAO inhibitors ▪ Recover from acute MI	urinary retention, sexual dysfunction
Clonidine RX (second line therapy)	Initial 0.1 mg PO BID 0.1 mg transdermal May be titrated to 0.2 mg PO BID 0.2 mg transdermal	3 to 10 weeks	▪ Start on or up to 3 days before quit date ▪ Place transdermal patch on hairless location between neck and waist. Change weekly. ▪ Discontinue use gradually over 2 to 4 days ▪ Not FDA-approved for this use	**Precautions** ▪ Pregnancy Category C ▪ Safety in lactation unknown ✓ FYI — Pregnancy, Lactation and Pharmacologic Therapy for Smoking Cessation **Contraindications** ▪ Avoid transdermal if on anticoagulation therapy, severe cardiovascular disease, or hemodynamically unstable	dry mouth, sedation, dizziness, constipation
* Not an independent risk factor for acute myocardial events. Contraindicated among particular cardiovascular client groups: those in the immediate (within 2 weeks) post-myocardial infarction period, those with serious arrhythmias, and those with serious or worsening angina pectoris.					

16.9 WEIGHT MANAGEMENT — ANOREXIA NERVOSA, BULIMIA NERVOSA, OBESITY

- ✓ FYI – Eating Disorders/Weight Management
- ✓ FYI – Screening Tools for Eating Disorders

16.9.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

- ✓ See Administrative Chapter 4 Client Education and Informed Consent

16.9.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	Should give
CI Tips for Losing Weight			●
Release When Test/Service/Consultation Will Not Be Obtained		Once	
Written information as appropriate			●

16.9.2 Classification of Weight

16.9.b. Table: Classification of Weight

Classification	BMI	Disease Risk* Relative to Normal Weight and Waist Circumference (if performed)	
		Men ≤ 102 cm (≤40 in) Women ≤88 cm (≤35 in)	Men >102 cm (>40 in) Women >88 cm (>35 in)
Underweight	18.5	N/A	N/A
Normal	18.5 to 24.9	N/A**	N/A**
Overweight	25.0 to 29.9	Increased	High
Obesity	30.0	High	Very High
	35.0 to 39.9	Very High	Very High
Extreme Obesity	≤40	Extremely High	Extremely High

*Disease risk for type 2 diabetes, hypertension, and CVD.
**Increased waist circumference can also be a marker for increased risk even in persons of normal weight.

16.9.3 Anorexia Nervosa and Bulimia Nervosa

I. Screening for Eating Disorders is indicated in clients with
   A. Amenorrhea or oligomenorrhea – see Chapter 8 Gynecological Conditions
   B. Depression – see 16.2.2 Depression
   C. Infertility concerns
   D. Low BMI
   E. Preoccupation with dieting
   F. Weight loss
   G. PCOS or diabetes

II. Evaluation – per Table 16.9.c.

✓ FYI – Differential Diagnoses for Anorexia and Bulimia

16.9.c. Table: Evaluation

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Should include ▪ Client's goal weight ▪ Specific behaviors ○ Laxatives, diuretics, ipecac, diet pills, cutting, restricting, and binging and purging ▪ Amount and type of exercise ▪ Menstrual history, with special attention to ○ Amenorrhea and/or irregular menses, especially in a late adolescent or young woman ▪ Prior therapies ○ Psychological, nutritional, pharmacological ▪ Review of systems	Should include ▪ Vital signs, including orthostatics ▪ Height ▪ Weight — weighed without shoes, facing outwards so clients do not see their weight. ▪ Waist circumference – see Table 16.9.b. ▪ BMI - known or suspected anorexics and bulimics should not see their BMI. ▪ HEENT including thyroid/endocrine, with special attention to bone pain, cold intolerance, dental caries, enamel loss, erythematous pharynx, fatigue, mouth sores, parotid hypertrophy ▪ Heart/lungs, with special attention to bradycardia, chest pain, cool extremities, dizziness and/or syncope, palpitations	Should consider ▪ Bone mineral density — as a baseline test, depending on the ○ Length of symptoms ○ Presence of amenorrhea ✓ FYI – Osteoporosis in Women with Eating Disorders ✓ FYI — Laboratory Findings Abnormal findings could be used to motivate client to obtain treatment. For those who have a long term history of anorexia nervosa, but are stable and not amenorrheic, ongoing monitoring of BMD should be determined by additional risk

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
○ bloating and/or early satiety, constipation, delayed gastric emptying, diarrhea, heartburn ✓ FYI — DSM-5 Criteria for Anorexia Nervosa and Bulimia Nervosa	▪ Abdomen, with special attention to pain, distention ▪ Extremities, with special attention to kyphosis, pitting edema, scarring on dorsum of hand ▪ Skin, with special attention to dry skin, easy bruising, hair loss, lanugo, poor skin turgor ▪ Neurological, with special attention to depressed mood, neuropathy	factors.

✓ FYI – Contraception for Women with Anorexia Nervosa

✓ FYI – Treatment of Anorexia Nervosa and Bulimia Nervosa

III. Referral and Follow-up

A. **Must** refer clients at risk for eating disorders (i.e., orthostatic, body mass index below 17, and/or actively engaging in behaviors suggestive of an eating disorder) immediately to either a primary care clinician, therapist, or nutritionist who specializes in eating disorders or to a local program that specializes in eating disorders.

B. Clients with a history of eating disorder(s)

1. May continue health care services at the affiliate, as long as stable and not amenorrheic. Otherwise, **must** refer out.
2. Should be monitored for relapse and long-term sequelae.

16.9.4 Obesity

I. Evaluation – per Table 16.9.d.

16.9.d. Table: Evaluation

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Should include ▪ HPI ○ Weight history and prior attempts to lose weight ○ Dietary habits and eating patterns ○ Physical activity ○ Sleeping patterns ○ Menstrual and pregnancy history ▪ PMH ○ Endocrine abnormalities ○ Established risk factors for CVD, such as hypertension or diabetes ○ Conditions associated with obesity, such as PCOS, osteoarthritis, stress incontinence, and cholelithiasis ○ Medications that could contribute to weight gain ○ Past psychiatric history – depression, eating disorders, other mood disorders ▪ Family history of obesity, genetic or racial predispositions ▪ Social history – drug, alcohol, tobacco use, barriers to diet and exercise	Should include ▪ BP ▪ Height, weight, and BMI - see Table 16.9.b. ▪ Compare BMI to a growth chart in adolescent clients ✓ CDC Growth Charts Consider measurement of waist circumference Additional examination focused on obesity-related conditions as appropriate, such as intertrigo, hirsutism.	May include ▪ Fasting blood glucose or A1C test – see 16.3 Diabetes Mellitus ▪ Fasting lipids ▪ TSH if not previously done ▪ AST and ALT in clients with BMI ≥ 30

II. Management

A. Manage per Table 16.9.e.

16.9.e. Table: Management of Obesity

I. General principles
   A. Cornerstone of weight management is eating less and exercising more.
   B. Weight loss goals should be achievable and not overwhelming to the client. In adult clients
      1. Short-term goals should be 10% weight loss over 6 months, usually allowing for a ½ to 2-lb weight loss per week.
      2. Long-term goals include both weight maintenance and prevention of either further weight gain or regaining previously lost weight.
   C. Consider associated mortality risk that varies across age, gender and ethnic groups.
   D. Most successful treatment involves a multi-pronged approach, including lifestyle modification, medication (occasionally), and/or surgery.
      1. Clients should understand these changes should be life-long and will require their ongoing participation. Counseling can be incorporated into visits for any problem, or preventive care

1. ADVISE client to lose weight.	Make recommendation to lose weight in a direct but sensitive and compassionate manner.
2. ASSESS client readiness to lose weight.	Perform prior to initiating treatment. ▪ If client not interested in/motivated for weight loss, provide information about the health risks of obesity and potential health benefits of weight loss. ○ Consider discussion of barriers to change ○ Reassess readiness to lose weight at regular intervals ▪ If client is interested in/motivated for weight loss, proceed to ASSIST.
3. ASSIST in weight loss attempt.	▪ Negotiate weight loss goals and management strategy with client. ▪ Advise lifestyle modification to include ○ Dietary changes to promote weight loss and overall health ✓ FYI – Meal Consistency ○ Exercise to promote weight loss and overall health ○ Sleep hygiene ✓ FYI — Lifestyle Modification in Management of Obesity ▪ Initiate pharmacotherapy, as appropriate, with Orlistat (Xenical). ○ **Must** only be considered for those clients who have been unable to either attain and/or maintain clinically significant weight loss to address their obesity-related symptoms (e.g., diabetes, hypertension) ○ Candidates include clients with

	• BMI ≥ 27 and risk factors OR • BMI ≥ 30 ○ May consider discontinuing therapy after 2 years ○ May only be prescribed for clients who are also following a weight loss plan ○ Recommended dose is 120 mg 3X per day. In the U.S., a 60-mg dose (Alli) is available over-the-counter ○ Contraindicated in pregnancy, clients with malabsorption disorders, and reduced gallbladder function ○ May interfere with vitamin absorption. Consider prescribing a vitamin supplement. ○ **Must** refer for use of other prescription weight-loss medications ▪ Consider referral for bariatric surgery in motivated clients who ○ Do not meet initial weight loss goals within 6 months OR ○ BMI ≥ 35 and risk factors OR ○ BMI ≥ 40 ○ Clients desiring surgery should be referred to board-certified bariatric surgeons working with a multi-disciplinary team ▪ Refer as appropriate for ○ Management of co-morbidities that cannot be managed within the affiliate ○ Additional medical and nutrition therapy*
4. ARRANGE follow-up.	▪ Schedule follow-up contacts, either in person or via telephone, to assess progress at regular intervals. Consider monthly contact by designated member of care team. ▪ Individualize frequency of contacts according to risk factors and readiness of client to lose weight. ▪ Follow-up visits should address ○ BMI calculation and BP measurement annually ○ Review and reinforcement of lifestyle modification and weight loss goals ○ Updated risk assessment for co-morbidities ○ Modification of treatment strategy in clients not meeting goals ○ Self-management support
*In clients with BMI ≥ 30, may consider referral for intensive therapy.[R3]	

16.10 ADDITIONAL INFORMATION

16.10.a. Table: For Your Information

Section	Topic	Detail	
16.1	Use of Spirometry in Asthma Diagnosis	The gold standard for diagnosis of asthma is spirometry. An increase in FEV1 greater or equal to 12% and greater or equal to 200ml after administration of a bronchodilator indicates a limitation of reversible airflow consistent with asthma. However, while spirometry is recommended (Evidence B), especially in the diagnosis of more complicated cases, it can be expensive and impractical in many settings, delaying appropriate care. For more information on evidence rankings, go to Guidelines for Diagnosis and Management of Asthma.	
16.1	Differential Diagnoses of Asthma	▪ CHF ▪ Upper or lower airway obstruction ▪ COPD ▪ PE ▪ Allergic reaction	▪ Chemical inhalations ▪ Pneumonia ▪ Bronchopulmonary aspergillosis ▪ Vocal cord dysfunction ▪ Dough secondary to ACEIs
16.1	Signs and Symptoms of Severe Asthma/Impending Respiratory Failure	Signs and symptoms of a severe asthma exacerbation include ▪ Breathlessness at rest ▪ Speech limited to words ▪ Respirations >30/minute ▪ Inability to recline ▪ Use of accessory muscles ▪ Audible inspiratory and expiratory wheezes ▪ Heart rate >120/minute ▪ Pulse paradoxus >25 mm/Hg (an abnormally large decrease in systolic BP during inspiration) ▪ Agitation	Signs and symptoms of impending respiratory failure include ▪ Breathlessness at rest ▪ Inability to speak ▪ Inability to recline ▪ Respirations >30/minute ▪ Paradoxical thoraco-abdominal movement ▪ Little air movement without wheezes ▪ Relative bradycardia ▪ Pulse paradoxus often absent ▪ Confused or drowsy mental status

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>16.1</td><td>Asthma Action Plan</td><td>Asthma action plans categorize the degree of the problem into three zones and provide guidance for the client as follows:
<table>
<tr><th>Green zone</th><th>Yellow zone</th><th>Red zone</th></tr>
<tr><td>▪ 80 to 100% of peak flow and asymptomatic
▪ Client continues usual medications</td><td>▪ 50 to 80% of peak flow with possible cough, wheezing, and chest tightness
▪ Client takes additional puffs of quick-acting bronchodilator
▪ Client begins or increases ICS and/or adds an oral steroid
▪ Client instructed to call physician</td><td>▪ < 50% of peak flow with worsening symptoms
▪ Client considers calling 911
▪ Client instructed to call physician
▪ Client takes additional puffs of bronchodilator
▪ Client takes an inhaled corticosteroid or oral steroid</td></tr>
</table>
http://www.nhlbi.nih.gov/health/public/lung/asthma/asthma_actplan.pdf.</td></tr>
<tr><td>16.2</td><td>Routine Screening for Depression</td><td>Routine screening for depression in clients without symptoms or risk factors has not been shown to be effective in the absence of care management systems to support a client through care. Therefore, doing so should be limited to affiliates with staff-assisted depression care supports in place or by referral.

Staff-assisted depression care supports refers to clinical staff that assist the clinician by providing some direct depression care, such as care support or coordination, case management, or mental health treatment. The lowest level of such support documented in the reviewed literature was a screening nurse who advised the clinician about the positive screening results and facilitated referral to mental health specialists.</td></tr>
<tr><td>16.2</td><td>The Patient Health Questionnaire – 2 (PHQ-2)</td><td>The PHQ-2 inquires about the frequency of depressed mood and anhedonia over the past 2 weeks. Its purpose is to screen for depression as a first step, not to establish final diagnosis or monitor severity.

Questionnaire
<table>
<tr><th>Over the past 2 weeks, how often have you been bothered by any of the following problems?</th><th>Not at all</th><th>Several days</th><th>More than half the days</th><th>Nearly every day</th></tr>
<tr><td>1. Little interest or pleasure in doing things</td><td>0</td><td>1</td><td>2</td><td>3</td></tr>
<tr><td>2. Feeling down, depressed, or hopeless</td><td>0</td><td>1</td><td>2</td><td>3</td></tr>
</table></td></tr>
</table>

Section	Topic	Detail
		A score of ≥3 is considered a positive screen. Alternatively, each question may be assigned a "yes" or "no" response. If the client response to both questions is "no," the screen is negative. A "yes" response to either question is a positive screen.
16.2	Risk Factors for Major Depression	Risk factors for major depression include: ▪ Family or personal history of major depression and/or substance abuse ▪ Recent loss ▪ Chronic medical illness ▪ Traumatic event(s) ▪ Stressful life event(s) that include loss (i.e., death of loved one, divorce) ▪ Major life changes ▪ Domestic abuse or violence
16.2	Common Presenting Symptoms for Depression	Common presentations for clients not complaining of major depression or anhedonia include: ▪ Multiple (>5 per year) medical visits ▪ Multiple unexplained symptoms ▪ Work or relationship dysfunction ▪ Dampened affect ▪ Changes in interpersonal relationships ▪ Poor behavioral follow-through with activities of daily living or prior treatment recommendations ▪ Weight gain or loss ▪ Sleep disturbance ▪ Fatigue ▪ Memory/other cognitive complaints such as difficulty concentrating or making decisions ▪ Irritable bowel syndrome ▪ Volunteered complaints of stress or mood disturbance
16.2	DSM-5 Criteria for Major Depressive Episode	In order to qualify for a diagnosis of a major depressive episode, the client **must** meet criteria A through E: A. **Must** have ≥5 of the following symptoms for at least 2 weeks that represent a change from previous functioning. One of the symptoms **must** be depressed mood or loss of interest or pleasure. o Depressed mood o Markedly diminished interest or pleasure in all or almost all activities o Significant (> 5% body weight) weight loss or gain, or increase or decrease in appetite

Section	Topic	Detail	
		○ Insomnia or hypersomnia ○ Psychomotor agitation or retardation ○ Fatigue or loss of energy ○ Feeling of worthlessness or inappropriate guilt ○ Diminished concentration or indecisiveness ○ Recurrent thoughts of death or suicide B. The symptoms present do not meet criteria for a mixed episode. C. The episode is not attributable to the physiological effects of a substance or to another medical condition. D. The occurrence of the major depressive episode is not better explained by schizoaffective disorder, schizophrenia, schizophreniform disorder, delusional disorder, or other specified and unspecified schizophrenia spectrum and other psychotic disorders. E. There has never been a manic episode or a hypomanic episode.	
16.2	DSM-5 Criteria for Diagnosis of Other Depressive Disorders[R4]	**Persistent Depressive Disorder**	Client **must** meet criteria A through H A. Depressed mood for most of the day, for more days than not, as indicated by either subjective account of observation by others, for at least 2 yrs. B. Presence while depressed of ≥2 of the following: ○ Poor appetite or overeating ○ Insomnia or hypersomnia ○ Low energy or fatigue ○ Low self-esteem ○ Poor concentration or difficulty making decisions ○ Feelings of hopelessness C. During the 2 year period of the disturbance, the individual has never been without the symptom in criteria A and B for >2 months at a time. D. Criteria for major depressive disorder may be continuously present for 2 years. E. There has never been a manic episode or hypomanic episode, and

Section	Topic	Detail	
			criteria have never been met for cyclothymic disorder. F. The disturbance is not better explained by persistent schizoaffective disorder, schizophrenia, delusional disorder, or other specified or unspecified schizophrenia spectrum or other psychotic disorder. G. The symptoms are not attributable to the physiological effects of a substance or another medical condition. H. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
		Other Specified Depressive Disorder	▪ Applies to presentations in which symptoms characteristic of a depressive disorder that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for any of the disorders in the depressive disorders diagnostic class. ▪ Used in situations in which the clinician chooses to communicate the specific reason that the presentation does not meet the criteria for any specific depressive disorder. This is done by recording "other specified depressive disorder" followed by the specific reason (e.g., "short-duration depressive episode").
		Unspecified Depressive Disorder	▪ Applies to presentations in which symptoms characteristic of a depressive disorder that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for any of the disorders in the depressive disorders diagnostic class. ▪ Use in situations in which the clinician chooses not to specify the reason that the criteria are not met for a specific depressive disorder, and includes presentations for which there is insufficient information to make a more specific diagnosis (e.g. in emergency room settings). ▪ Should be noted that premenstrual dysphoric disorder is now a separate diagnosis.

Section	Topic	Detail
16.2	Risk Factors for Suicide	▪ History of self-harm attempts, in combination with a history of well-developed suicide plans ▪ Ability to carry a suicide plan out or behaviors that ensure a means and opportunity to carry a plan out ▪ Within 2 weeks of hospital discharge ▪ Chemical dependency ▪ Personality disorder and/or physical illness ▪ Family history suicide ▪ Single status ▪ Recent loss by death, divorce, or separation ▪ Insomnia ▪ Panic attacks and/or severe psychic anxiety ▪ Diminished concentration ▪ Anhedonia ▪ Hopelessness post-traumatic stress disorder (PTSD) ▪ Suicidal ideation ▪ Comorbid major depressive episode and PTSD
16.2.d 16.2.3	Collaborative Care Model	Use of a collaborative care approach to management of the depressed client has been shown to be effective in improving client outcomes such as reduced suicidality, better adherence to medications and thus lower relapse rates. In addition, shared decision-making among the affiliate clinician, a depression care manager and a mental health professional and the client should be used in creating a treatment plan, in order to improve adherence and reach the goal of therapy: remission. Design of a team-based collaborative care approach involves ▪ Providers using an evidence-based approach to depression management, along with a standardized tool for measuring severity of disease and response to treatment. ▪ Systems for tracking and reminding clients of upcoming visits and monitoring treatment adherence ▪ A care manager who uses the affiliate tracking system to make frequent contact with the client in order to o Monitor adherence o Provide further client education o Facilitate treatment changes when needed ▪ Availability of a psychiatrist and behavioral health counselor for consultation and referral, when

Section	Topic	Detail
		needed A depression care manager is varyingly defined in the literature. This person is responsible for making sure the patient follows up as planned, checks in about medication side effects, and facilitates referrals. The clinician or the mental health professional can perform this role as well, with non-clinical, trained support staff. A mental health professional does not need to be involved in every case. The important function of the mental health professional is that a relationship with the clinician exists for phone consultation and referral for complex cases.
16.2	Considerations in Pharmacotherapy for Depression	Key concepts surrounding use of antidepressants ▪ Side effects typically occur before improvement in symptoms, and they usually go away over time. ▪ Typical time to full remission and prevention of recurrence is 6 to 12 months. ▪ Improvement in symptoms may occur as early as 2 weeks, but typically, full benefit is not seen for some weeks later. ▪ Factors such as severity of symptoms, suicidality, comorbid conditions and individual response to therapy impact the timeline for therapy. ▪ Clients should expect medication adjustment to maximize response. ▪ Clients should not stop their medication without talking with a clinician, because of withdrawal effects. Side effects can often be managed with medication adjustment. ▪ Clients should continue to take the medication, even once feeling better, because premature discontinuation is associated with an increased risk of recurrence.
16.2	Continuing Pharmacotherapy in Recurrent MDE	Analysis suggests that recurrence rates are reduced by 70% when clients are maintained on antidepressants for 3 years following their previous episode (average recurrence on placebo is 41% versus 18% on active treatment), although evidence is limited and of lower quality.
16.2	Relapse Prevention	Major depressive disorder is a disease naturally characterized by relapses and recurrences. Of those who recover fully after a first episode, 50% relapse, and recurrence is even higher after multiple episodes. Risk of relapse may be decreased with the following strategies:

Section	Topic	Detail
		▪ Focused psychotherapy through CBT ▪ Improving attitudes toward antidepressant medications and client ability to manage medication side effects
16.2	Postpartum Depression	Routine screening for depression in the postpartum period is recommended. Diagnostic criteria are similar to that of a MDE according to the DSM-V, only with a postpartum onset. Onset may occur between 2 weeks to 1 year postpartum and may last up to 20 months. Risk factors for postpartum depression include those for MDE as well as unintended pregnancy, low level of partner support, history of depression, postpartum depression, or "baby blues" (a mild and transient mood disturbance 3 to 5 days post-childbirth). Treatment of postpartum depression is also generally the same as treatment of MDE, with ▪ Psychotherapy as first-line treatment. ▪ Use of SSRIs as first-line pharmacotherapy, when indicated.
16.2	Risk Factors for Anxiety	Risk factors for anxiety disorder include ▪ Family history of anxiety (or other mental disorder) ▪ Personal history of anxiety in childhood or adolescence, including marked shyness ▪ Stressful life event and/or traumatic event ▪ Being female ▪ Comorbid psychiatric disorder (particularly depression)
16.2	Identifying Anxiety Disorders	Anxiety expressed as physical, emotional, and behavioral responses to perceived threats is a normal part of everyday life. It becomes a problem, and a disorder should be considered when ▪ It is of greater intensity and/or duration than usually expected, given circumstances of its onset, **OR** ▪ It leads to impairment or disability in occupational, social, or interpersonal functioning, **OR** ▪ Daily activities are disrupted by the avoidance of certain situations or objects in an attempt to diminish the anxiety, **OR** ▪ It includes clinically significant, unexplained physical symptoms and/or obsessions, compulsions, and intrusive recollections or memories of trauma. (Unexplained physical symptoms, intrusive thoughts, and compulsion-like behaviors are common in people who do not have an anxiety disorder.)

Section	Topic	Detail
16.2	DSM-V Diagnostic Criteria for Anxiety Disorders	▪ GAD ○ Excessive anxiety and worry (apprehensive expectation), occurring more days than not for at least 6 months, about a number of events or activities. ○ The individual finds it difficult to control the worry. ○ The anxiety and worry are associated with 3 or more of the following 6 symptoms (with at least some symptoms having been present more days than not for the past 6 months): • Restlessness or feeling keyed up or on edge • Being easily fatigued • Difficulty concentrating or mind going blank • Irritability • Muscle tension • Sleep disturbance ○ The anxiety, worry, or physical symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning. ○ The disturbance is not attributable to the physiological effects of a substance or another medical condition. ○ The disturbance is not better explained by another mental disorder. ▪ SAD ○ Marked fear or anxiety about one or more social situations in which the individual is exposed to possible scrutiny by others. ○ The individual fears that he or she will act in a way or show anxiety symptoms that will be negatively evaluated. ○ The social situations almost always provoke fear or anxiety. ○ The social situations are avoided or endured with intense fear or anxiety. ○ The fear or anxiety is out of proportion to the actual threat posed by the social situation or the sociocultural context. ○ The fear, anxiety, or avoidance is persistent, typically lasting 6 months or more. ○ The fear, anxiety or avoidance causes clinically significant distress or impairment in social,

Section	Topic	Detail
		occupational, or other important areas of functioning. ○ The fear, anxiety, or avoidance is not attributable to the physiological effects of a substance or another medical condition. ○ The fear, anxiety, or avoidance is not better explained by the symptoms of another mental disorder, such as panic disorder, body dysmorphic disorder, or autism spectrum disorder. ○ If another medical condition is present, the fear, anxiety, or avoidance is clearly unrelated or is excessive. ▪ Specific Phobia ○ Marked fear or anxiety about a specific object or situation ○ The phobic object or situation almost always provokes immediate fear or anxiety. ○ The phobic object or situation is actively avoided or endured with intense fear or anxiety. ○ The fear or anxiety is out of proportion to the actual danger posed by the specific object or situation and to the sociocultural context. ○ The fear, anxiety, or avoidance is persistent, typically lasting for 6 months or more. ○ The fear, anxiety, or avoidance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning. ○ The disturbance is not better explained by the symptoms of another mental disorder, including fear, anxiety, and avoidance of situations associated with panic-like symptoms or other incapacitating symptoms; objects or situations related to obsessions; reminders of traumatic events; separation from home or attachment figures; or social situations. ▪ OCD ○ Presence of obsessions, compulsions, or both ○ Obsessions or compulsions are time-consuming or cause clinically significant distress or impairment in social, occupational, or other important areas of functioning ○ The obsessive-compulsive symptoms are not attributable to the physiological effects of a substance or another medical condition ○ The disturbance is not better explained by the symptoms of another mental disorder ▪ PTSD ○ The person was exposed to: death, threatened death, actual or threatened serious injury, or actual

Section	Topic	Detail
		or threatened sexual violence as follows (1 required): • Direct exposure • Witnessing, in person • Indirectly, by learning that a close relative or close friend was exposed to trauma. If the event involved actual or threatened death, it must have been violent or accidental. • Repeated or extreme indirect exposure to aversive details of the event(s), usually in the course of professional duties. o The traumatic event is persistently re-experienced in the following way(s) (1 required): • Recurrent, involuntary, and intrusive memories • Traumatic nightmares • Dissociative reactions which may occur on a continuum from brief episodes to complete loss of consciousness • Intense or prolonged distress after exposure to traumatic reminders • Marked physiologic reactivity after exposure to trauma-related stimuli o Persistent effortful avoidance of distressing trauma-related stimuli after the event (1 required): • Trauma-related thoughts or feelings • Trauma-related external reminders o Negative alterations in cognitions and mood that began or worsened after the traumatic event (2 required): • Inability to recall key features of the traumatic event • Persistent negative beliefs and expectations about oneself or the world • Persistent distorted blame of self or others for causing the traumatic event or for resulting consequences • Persistent negative trauma-related emotions • Markedly diminished interest in (pre-traumatic) significant activities • Feeling alienated from others • Constricted affect: persistent inability to experience positive emotions o Trauma-related alterations in arousal and reactivity that began or worsened after the traumatic

Section	Topic	Detail
		event (2 required): • Irritable or aggressive behavior • Self-destructive or reckless behavior • Hypervigilance • Exaggerated startle response • Problems in concentration • Sleep disturbance o Persistence of symptoms for more than 1 month o Significant symptom-related distress or functional impairment o Disturbance is not due to medication, substance use, or other illness ▪ Agoraphobia o Marked fear or anxiety about 2 or more of the following 5 situations: • Using public transportation • Being in open spaces • Being in enclosed spaces • Standing in line or being in a crowd • Being outside of the home alone o The individual fears or avoids these situations because of thoughts that escape might be difficult or help might not be available in the event of developing panic-like symptoms or other incapacitating or embarrassing symptoms o The agoraphobic situations almost always provoke fear or anxiety o The agoraphobic situations are actively avoided , require the presence of a companion, or are endured with intense fear or anxiety o The fear or anxiety is out of proportion to the actual danger posed by the agoraphobic situations and the sociocultural context o The fear, anxiety, or avoidance is persistent, typically lasting for 6 months or more. o The fear, anxiety, or avoidance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Section	Topic	Detail
		○ If another medical condition is present, the fear, anxiety, or avoidance is clearly excessive. ○ The fear, anxiety, or avoidance is not better explained by the symptoms of another mental disorder. ▪ Panic Disorder ○ Recurrent unexpected panic attacks ○ At least 1 of the attacks has been followed by 1 month or more of one or both of the following: • Persistent worry or concern about additional panic attacks or their consequences • A significant maladaptive change in behavior related to the attacks ○ The disturbance is not attributable to the physiological effects of a substance or another medical condition ○ The disturbance is not better explained by another mental disorder
16.2	Conditions that may mimic or aggravate anxiety symptoms	▪ Endocrine – hyperthyroidism, hypothyroidism, hypoglycemia, adrenal insufficiency, hyperadrenocorticism, pheochromocytoma, menopause ▪ Cardiovascular – congestive heart failure, pulmonary embolism, arrhythmia, angina ▪ Respiratory – asthma, COPD, pneumonia ▪ Metabolic – diabetes, poryphoria ▪ Neurological – vestibular dysfunction, migraines, encephalitis ▪ Occupational exposures – lead poisoning ▪ GI – peptic ulcers, IBS ▪ Hematological – vitamin B_{12} deficiency, anemia ▪ GU – UTI (in elderly) ▪ Other – chronic fatigue, cancer
16.3	Nutritional Recommendations for Prevention of Type 2 Diabetes	▪ Individuals at high risk for type 2 diabetes should be encouraged to achieve the USDA recommendation for dietary fiber (14 g fiber/1,000 kcal) and foods containing whole grains (one-half of grain intake). (B) ▪ There is not sufficient, consistent information to conclude that low–glycemic load diets reduce the risk for diabetes. Nevertheless, low–glycemic index foods that are rich in fiber and other important nutrients are to be encouraged. (E) ▪ Observational studies report that moderate alcohol intake may reduce the risk for diabetes, but the data do not support recommending alcohol consumption to individuals at risk of diabetes. (B) ▪ No nutrition recommendation can be made for preventing type 1 diabetes. (E)

Section	Topic	Detail
		▪ Although there are insufficient data at present to warrant any specific recommendations for prevention of type 2 diabetes in youth, it is reasonable to apply approaches demonstrated to be effective in adults, as long as nutritional needs for normal growth and development are maintained. (E) ✓ Definitions of levels of evidence used by ADA
16.3	Goals* of Type 2 Diabetes Management	▪ Glycemic measurements — More- or less-stringent glycemic goals* may be appropriate for individuals. o A1C < 7% o Fasting/preprandial plasma glucose 70-130 mg/dL o Peak postprandial (one to two hours after beginning of meal) plasma glucose < 180 mg/dL o Postprandial glucose may be targeted if A1C goals are not met despite reaching preprandial glucose goals ▪ BP < 130/80 ▪ Lipids o LDL < 100 mg/dL (< 70 mg/dL if very high risk of CVD) o Triglyceride < 150 mg/dL o HDL > 50 mg/dL (women), > 40 mg/dL (men) *Goals should be individualized based on ▪ Duration of diabetes ▪ Age/life expectancy ▪ Comorbid conditions ▪ Known CVD or advanced microvascular complications (clients **must** be referred) ▪ Hypoglycemia unawareness ▪ Considerations of the client (for example, client's living situation makes control difficult)
16.3	Nutritional Recommendations for Management of Type 2 Diabetes	▪ **Carbohydrates** o A dietary pattern that includes carbohydrate from fruits, vegetables, whole grains, legumes, and low-fat milk is encouraged for good health. (B) o Monitoring carbohydrates, whether by carbohydrate counting, exchanges, or experience-based estimation, remains a key strategy in achieving glycemic control. (A) o The use of glycemic index and load may provide a modest additional benefit over that observed when total carbohydrate is considered alone. (B) o Sucrose-containing foods can be substituted for other carbohydrates in the meal plan. (A)

Section	Topic	Detail
		○ Relative to the general population, people with diabetes are encouraged to consume a variety of fiber-containing foods. However, evidence is lacking to recommend a higher fiber intake for people with diabetes than for the general population. (B) ○ Sugar alcohols and nonnutritive sweeteners are safe when consumed within the daily intake levels established by the FDA. (A) ▪ **Fat and Cholesterol** ○ Limit saturated fat to <7% of total calories. (A) ○ Two or more servings of fish per week (with the exception of commercially fried fish fillets) provide n-3 polyunsaturated fatty acids and are recommended. (B) ▪ **Protein** ○ High-protein diets are not recommended as a method of weight loss at this time. The long-term effects of protein intake >20% of calories on diabetes management and its complications are unknown. Although such diets may produce short-term weight loss and improved glycemia, it has not been established that these benefits are maintained long term, and long-term effects on kidney function for persons with diabetes are unknown. (E) ▪ **Alcohol** ○ If adults with diabetes choose to use alcohol, daily intake should be limited to a moderate amount (one drink per day or less for women and two drinks per day or less for men). (E) ○ In individuals with diabetes, moderate alcohol consumption (when ingested alone) has no acute effect on glucose and insulin concentrations. (B) ▪ **Micronutrients** ○ There is no clear evidence of benefit from vitamin or mineral supplementation in people with diabetes (compared with the general population) who do not have underlying deficiencies. (A) ○ Routine supplementation with antioxidants, such as vitamins E and C and beta-carotene, is not advised because of lack of evidence of efficacy and concern related to long-term safety. (A) ✓ Definitions of levels of evidence used by ADA
16.3	Aspirin Therapy	Consider aspirin therapy (75 to 162 mg/day) as a primary prevention strategy in those with type 1 or type 2 diabetes at increased cardiovascular risk. This includes most men >50 years of age or women >60 years of age who have at least one additional major risk factor (family history of CVD, HTN, smoking,

Section	Topic	Detail
		dyslipidemia, or albuminuria). (C) Aspirin should not be recommended for CVD prevention for adults with diabetes at low CVD risk (10-year CVD risk <5%, such as in men <50 years and women <60 years of age with no major additional CVD risk factors), since the potential adverse effects from bleeding likely offset the potential benefits. (C) In patients in these age groups with multiple other risk factors (e.g., 10-year risk 5–10%), clinical judgment is required. (E) ✓ Definitions of levels of evidence used by ADA
16.3	Hypoglycemia	▪ Causes - not enough food (skipping meals or delaying meals), high dose/mistimed dose of sulfonylurea, or too much exercise without enough food. ▪ Signs/symptoms - hunger, palpitations, sweatiness, confusion, dizziness, headache, nausea ▪ Treatment requires immediate attention to the symptoms and includes Ingestion of anything that contains glucose such as ½ cup orange juice, 3 tsp sugar, 2 tsp honey, 2 TBS raisins, 6 hard candies.
16.4	Definition and Classifications for GERD	A diagnosis of GERD may be applied when reflux into the esophagus, oral cavity, and/or the lung causes bothersome symptoms, esophageal injury, and/or other complications. ▪ Classification: NERD ○ Characteristic, troublesome symptoms (e.g. heartburn and/or acid regurgitation) with normal appearing esophageal mucosa on endoscopy ▪ Classification: Erosive esophagitis ○ Damaged esophageal mucosa on endoscopy without characteristic troublesome symptoms
16.4	*Helicobacter pylori* and GERD	The relationship between *H.pylori* infection and GERD remains controversial for the following reasons: ▪ Epidemiological data do not support a role for *H. pylori* in the pathogenesis of GERD. ▪ *H. pylori* infection almost certainly does not cause GERD (and, in fact, *may* protect against GERD and its complications). ▪ Data about the effects of *H. pylori* eradication in clients with GERD are limited. Therefore, routine screening for *H.pylori* and eradication of a known infection is not routinely recommended as part of anti-reflux therapy.

Section	Topic	Detail
16.4	Use of Tests and Imaging for the Diagnosis of GERD	Barium radiographs, upper endoscopy, routine biopsies, ambulatory esophageal reflux monitoring and/or esophageal manometry are not routinely recommended in the presence of typical GERD symptoms. Upper endoscopy is not required in the presence of typical GERD symptoms because it generates unnecessary costs and exposes clients to harms without improving outcomes. It should only be recommended in the presence of alarm symptoms and for screening of clients at high risk for complications, according to the following: ▪ Diagnosis of GERD is unclear ▪ Non-cardiac chest pain suspected due to GERD ▪ Heartburn and red flags for complications of GERD (e.g., cancer, stricture, or ulceration) or other diagnoses ▪ Refractory GERD (persistent GERD symptoms despite adequate therapy) ▪ GERD-like symptoms for at least 5 years AND additional risk factors for Barrett's esophagus and esophageal adenocarcinoma (e.g., white race, nocturnal reflux symptoms, hiatal hernia, elevated BMI, tobacco use, and intra-abdominal distribution of fat) in men > 50 years old Screening upper endoscopy should not be routinely done in women of any age or in men <50 years regardless of GERD symptoms because the incidence of cancer is very low in these populations.
16.4	Differential Diagnoses for GERD	▪ Pill esophagitis ▪ Infectious esophagitis ▪ Esophageal motor disorders: achalasia, diffuse esophageal spasm, hypertensive or spastic motility disorders ▪ Nonulcer dyspepsia ▪ Eosinophilic esophagitis ▪ Esophageal cancer ▪ Coronary artery disease ▪ Pregnancy ▪ Hypersecretory states (e.g. Zollinger-Ellison syndrome) ▪ Connective tissue disorders
16.4	Intermittent (on-demand) versus Continuous Therapy	▪ Intermittent therapy is associated with higher client satisfaction. ▪ Continuous therapy is associated with better symptom control, quality of life and higher endoscopic remission rates.
16.4	GERD in Pregnancy	GERD is frequent during pregnancy. It manifests as heartburn, may begin in any trimester, and usually resolves after delivery. Significant predictors of heartburn are increasing gestational age, heartburn before pregnancy, and parity.

Section	Topic	Detail
		Maternal age is inversely correlated. Race, pre-pregnancy BMI, and weight gain in pregnancy do not correlate. Diagnostic testing is generally not required. Management differs from the non-pregnant person.
16.5	Blood Pressure (BP) Measurement Techniques	▪ Client should avoid caffeine, exercise or smoking for at least 30 minutes prior to measurement. ▪ Take BP after client has been sitting in a chair for five minutes and with arm supported at heart level. ▪ Use appropriately sized cuff. ▪ Confirm an elevated reading with a repeat reading in contralateral arm 5 minutes later. ▪ Record the average of two measurements taken five minutes apart.
16.5	Risk Factors and Causes of Hypertension	**Risk Factors** ▪ Obesity (BMI ≥ 30) ▪ Hyperlipidemia ▪ Family history of early CVD: men < 55, women < 65 ▪ Physical inactivity ▪ Proteinuria ▪ Diabetes mellitus ▪ Tobacco ▪ Dyslipidemia ▪ Age: >55 in males, >65 in females **Identifiable Secondary Causes** ▪ Sleep apnea ▪ Drug-induced ▪ Chronic kidney disease ▪ Primary aldosteronism ▪ Renovascular disease ▪ Chronic steroid therapy and Cushing's syndrome ▪ Pheochromocytoma ▪ Coarctation of the aorta ▪ Thyroid or parathyroid disease
16.6	Screening and Diagnostic Testing for Hypothyroidism	The USPSTF states that there is insufficient evidence to recommend for or against routine screening with TSH testing in the general population. Screening should be considered in clients over the age of 60. According to the ACP (2009), clients with risk factors for hypothyroidism should be tested. Risk factors include symptoms of thyroid hormone deficiency, goiter; history of previous thyroid disease or treatment for a thyroid disorder; personal history of other autoimmune diseases especially Type 1 diabetes mellitus, adrenal insufficiency or vitiligo; or family history of thyroid disease.

Section	Topic	Detail
16.6	Common Causes of Hypothyroidism	**Primary Hypothyroidism** ▪ Hashimoto's thyroiditis ▪ Iatrogenic — radioactive iodine treatment of the thyroid, antithyroid drugs, surgical removal of the thyroid, and medications, including lithium ▪ Infiltrative disease (sarcoid, lymphoma) **Secondary and Tertiary Hypothyroidism** ▪ Processes affecting the pituitary or hypothalamic axis such as ▪ Neoplasm ▪ Congenital hypopituitarism ▪ Pituitary necrosis (Sheehan's syndrome)
16.6	Common Symptoms of Hypothyroidism	Common symptoms of hypothyroidism may include ▪ Apathy ▪ Lethargy ▪ Depressed mood ▪ Cold intolerance ▪ Dry skin ▪ Constipation ▪ Weight gain ▪ Hair loss ▪ Muscle cramps and weakness ▪ Menstrual irregularities ▪ Edema ▪ Dyspnea ▪ Hoarseness
16.6	Medications that Can Cause Thyroid Disease	▪ Lithium ▪ Sulfonamides ▪ Amiodarone ▪ Phenylbutazone ▪ Iodine ▪ Ethionamide ▪ Propylthiouracil ▪ Para-aminosalicylate (used to treat TB) Note: Usually associated with chronic use; TSH monitoring recommended every 6 to 12 months.
16.6	Understanding Lab Testing and the Diagnosis of Hypothyroidism	Primary hypothyroidism is the most common type of thyroid disease. It is due to the failure of the thyroid to release adequate hormone (measured as a serum free thyroxine or T4), despite the presence of adequate or elevated TSH. It is diagnosed by a high TSH and low free T4. In subclinical hypothyroidism, thyroid stimulating hormone (TSH) levels are slightly elevated (5-10 mU/L) with normal T4 and T3 levels. In secondary and tertiary hypothyroidism, there are insufficient levels of TSH to stimulate the thyroid. This is caused either by pituitary disease (secondary hypothyroidism) or hypothalamic disease (tertiary hypothyroidism). These are characterized by a low serum free T4, and a serum TSH that is not appropriately elevated. The T3 is not used as an initial screening test because even in cases of severe hypothyroidism, T3 levels are often normal.

Section	Topic	Detail
16.6	Hypothyroidism and Estrogen Therapy	Estrogen affects the clearance of thyroxine and changes thyroid binding globulin levels. Clients with hypothyroidism initiating estrogen therapy for treatment of menopause may need an increased dose of levothyroxine.
16.6	Treatment of Subclinical Hypothyroidism	Systematic review by Cochrane demonstrated that levothyroxine replacement does not appear to improve survival or decrease cardiovascular morbidity, nor does it significantly improve symptoms, mood, or quality of life indicators. Yet, some guidelines recommend treating subclinical hypothyroidism in clients whose TSH exceeds 10 mU/L and who are thus at increased risk for heart failure and cardiovascular mortality.
16.6	Hypothyroidism and Pregnancy	Based on current literature, thyroid testing in pregnancy should be performed on symptomatic women and those with a personal history of thyroid disease or other medical conditions associated with thyroid disease (e.g., diabetes mellitus). Without evidence that identification and treatment of pregnant women with subclinical hypothyroidism improves maternal or infant outcomes, routine screening for subclinical hypothyroidism currently is not recommended. Treatment of hypothyroidism in pregnant women is the same as for non-pregnant women and involves administering levothyroxine at sufficient dosages to normalize TSH levels.
16.7	Screening for Lipid Disorders	Various authorities have differing recommendations on when to screen for lipid disorders: ▪ USPSTF ○ Recommends screening for • All men ≥ 35 years old (Grade A) • Men 20 to 35 years old if at increased risk for cardiovascular disease (CVD) (Grade B) • Women ≥ 45 years old, if at increased risk for CVD (Grade A) • Women 20 to 45 years old, if at increased risk for CVD (Grade B) ○ No recommendation for or against routine screening in men 20 to 35 years old, or in women ≥ 20 years old who are not at increased risk for CVD (Grade C) ▪ ACC/AHA 2013 Guidelines ○ Cardiovascular risk assessment every 4 to 6 years in individuals aged 40 to 75 years old without clinical ASCVD or diabetes and with LDL-C 70 to 189mg/dL

Section	Topic	Detail
		• Risk assessment tool may be accessed at: http://my.americanheart.org/professional/StatementsGuidelines/PreventionGuidelines/Prevention-Guidelines_UCM_457698_SubHomePage.jsp • Risk assessment requires a lipid panel: total cholesterol, LDL cholesterol, HDL cholesterol, and triglyceride. Fasting lipid panel is preferred. • If non-fasting triglycerides are >500 mg/dL then a fasting lipid panel is required. • If non-fasting a non-HDL-C >220mg/dL may indicate genetic hypercholesterolemia that requires further evaluation or a secondary etiology • Risk assessment also requires a systolic blood pressure ✓ FYI – The 2013 ACC-AHA Blood Cholesterol Guidelines ▪ ACOG: o Lipid panel every five years beginning at age 45 years o Earlier screening may be indicated in women with the following high risk factors • Family history suggestive of familial hyperlipidemia • Family history of premature CVD • Previous personal history CVD or noncoronary atherosclerosis • Obesity (BMI >30) • Personal and/or family history of peripheral vascular disease • DM • Multiple CVD risk factors
16.7	Should clients have to fast before obtaining a lipid panel?	According to a November 2012 study in the Archives of Internal Medicine, fasting is not necessary before lipid panels. Cholesterol levels, with the exception of triglycerides, are similar when drawn after fasting or soon after a meal. Even triglyceride levels will be elevated by less than 20% if the client has not fasted.
16.7	Risk Factors for ASCVD	▪ Cigarette smoking ▪ HTN – See 16.5 Hypertension ▪ HDL cholesterol ≤ 40 mg/dL ▪ Family history of premature ASCVD (men ≤45 years; women ≤ 55 years) ▪ Diabetes

Section	Topic	Detail
16.7	Predisposition to Adverse Effects with Statin Therapy	The following characteristics may predispose a client to adverse effects with use of statins: ▪ History of muscle pain or disease ▪ History of statin intolerance ▪ Use of concomitant drugs that affect statin metabolism such as cyclosporine, macrolide antibiotics, various anti-fungal agents, and cytochrome P-450 inhibitors ▪ History of hemorrhagic stroke ▪ Asian ancestry
16.7	Secondary Causes of Hyperlipidemia	The most commonly encountered secondary causes of an elevated LDL-C include ▪ Diet – saturated or trans fats, weight gain, anorexia ▪ Drugs – diuretics, cyclosporine, glucocorticoids, amiodarone ▪ Diseases – biliary obstruction, nephrotic syndrome ▪ Disorders and altered states of metabolism – hypothyroidism, obesity, pregnancy
16.7.d 16.7.e 16.7.g	Statin Drug Choices	**High-Intensity Statin Therapy** - Daily dose lowers LDL-C on average, by approximately ≥50% ▪ Atorvastatin* 40-80 mg ▪ Rosuvastatin 20-40 mg **Moderate-Intensity Statin Therapy** - Daily dose lowers LDL-C on average, by approximately 30%-50% ▪ Atorvastatin* 10-20 mg ▪ Rosuvastatin 5-10 mg ▪ Simvastatin* 20-40 mg ▪ Pravastatin*† 40-80 mg ▪ Lovastatin*† 40 mg ▪ Fluvastatin XL 80 mg ▪ Fluvastatin* 40 mg bid Contraindications to statin drugs: active or chronic liver disease, pregnancy (category X), lactation (possibly unsafe) *Available as a generic †Available Target generic program (Pravastatin 10/20/40mg, Lovastatin 10/20mg)
16.7	Weighing Benefits and Risks of Statin Therapy	For primary prevention of ASCVD events, statin benefits far outweigh potential harms. The NNT to prevent 1 ASCVD event in the next 10 years is 15 to 82. In other words, for every 15 to 82

Section	Topic	Detail
		clients treated with statins for 10 years, 1 ASCVD event will be prevented. In clients with LDL ≥ 190 mg/dL, extensive evidence indicates that every 39 mg/dL reduction in LDL reduces ASCVD risk by about 20%. The higher the dose of statin, the greater the reduction in risk. The excess risk of diabetes is the main adverse effect to be considered. The risk of this is estimated to be 1/1000 clients treated with moderate- intensity statins for 1 year. This risk is estimated at approximately 3/1000 clients treated with high-intensity statins for 1 year. When treated for 1 year with statins, 155 to 185 clients need to be treated to prevent one ASCVD event. By contrast 333 to 1000 need to be treated to cause one additional case of diabetes. It is important to remember that a diagnosis of diabetes is NOT as devastating to health and quality of life as an ASCVD event. Muscle pain, in studies, has been the same in groups treated with statins as in groups treated with placebo.
16.7	Dyslipidemia in Women of Reproductive Age	The ATP-III recommended screening for dyslipidemia in women of reproductive age, while recommending prudence in the initiation of lipid-lowering drugs. Special attention should be given to use of an effective contraceptive method in women not seeking pregnancy, since statins are Class X during pregnancy. Furthermore, statins should not be used during breastfeeding. Additionally, the effect of a client's contraceptive method on her lipid metabolism should be considered: ▪ CHCs are a special condition in clients with a dyslipidemia (total cholesterol ≥240 mg/dL or LDL cholesterol ≥160 mg/dL or HDL cholesterol <40 mg/dL or triglycerides in the range of 200-499 mg/dL) because of adverse effect of CHCs on her lipid profile.
16.7	The 2013 ACC-AHA Blood Cholesterol Guideline	The 2013 ACC/AHA Blood Cholesterol Guideline uses Pooled Cohort Equations to estimate risk for a first myocardial infarction, coronary heart disease death, or fatal or nonfatal stroke on the basis of age, sex, race, smoking status, total cholesterol level, HDL-C level, systolic blood pressure, antihypertensive therapy, and diabetes. These equations use data from 5 NHLBI-sponsored longitudinal, population-based

Section	Topic	Detail
		cohorts of African American and non-Hispanic white men and women. In contrast to the earlier Framingham equations that calculated only coronary heart disease risk for non-Hispanic whites, the new equations provide sex- and race-specific estimates and include stroke as an outcome. Limitations of the 2013 ACC/AHA Guideline: ▪ The risk calculator has not been prospectively tested for its accuracy in predicting cardiovascular risk and appears to overestimate observed risks. ▪ The number of people who will have to start or stop statin therapy under the new guidelines is uncertain. ▪ More than half the panelists working on the guidelines had substantial ties with industry.
16.7	Lifestyle Modification Recommendations for Dyslipidemia[R7]	▪ Diet recommendations o Consume a dietary pattern that emphasizes intake of vegetables, fruits, and whole grains; includes low-fat dairy products, poultry, fish, legumes, non-tropical vegetable oils and nuts; and limits intake of sweets, sugar-sweetened beverages, and red meats. • Adapt this dietary pattern to appropriate calorie requirements, personal and cultural food preferences, and nutrition therapy for other medical conditions. • Achieve this pattern by following plans such as the DASH dietary pattern, the USDA Food Pattern, or the AHA Diet. o Aim for a dietary pattern that achieves 5 to 6% of calories from saturated fat. o Reduce percent of calories from saturated fat. o Reduce percent of calories from transfat ▪ Physical activity recommendations o Advise adults to engage in aerobic physical activity to reduce LDL-cholesterol, non-HDL-cholesterol, and blood pressure. • Frequency: 3 to 4 sessions a week • Intensity: Moderate to vigorous • Duration: 40 minutes on average ▪ Tobacco cessation – see 16.8 Smoking Cessation

Section	Topic	Detail
16.8	Strategies for Implementing Advice to Quit	▪ Advise to quit in a clear, strong, and personalized manner. o Be clear: "I think it is important for you to quit smoking now, and I can help you." o Be strong: "As your clinician, I need you to know that quitting smoking is the most important thing you can do to protect your health now and in the future." o Be personal: Tie tobacco use to current health/illness and/or its social and economic costs, motivation level/readiness to quit, and/or the impact of tobacco use on children and others in the household. ▪ Acknowledge the difficulty in quitting. ▪ Positively reinforce recent attempts at quitting.
16.8	The 5 R's of Motivational Intervention	**Relevance** ▪ Tie tobacco use to any or all of the following: o Current health/illness o Motivation level/readiness to quit o Social and economic costs o Impact of tobacco use on children and others in the household. For example, "Smoking is making your upper respiratory infections worse. It would be in your child's best interest for you to set a quit date in the near future." **Risks** ▪ Ask client to identify potential negative consequences of tobacco use: ▪ Acute risks - shortness of breath, exacerbation of asthma, impotence, infertility ▪ Long term risks - heart attacks, strokes, lung and other cancers, COPD ▪ Environmental risks - increased risk of lung cancer in spouse and children; higher rates of tobacco use by children; increased risk for SIDS, asthma, middle ear disease and respiratory infection in children **Rewards** ▪ Ask client to identify ▪ Any positive benefits they currently derive from tobacco use. Discuss alternative methods for filling the ▪ Potential void after cessation.

Section	Topic	Detail
		▪ Potential rewards of quitting tobacco use including improved health, improved taste, money saved, healthier children, freedom from addiction, and satisfaction with accomplishing a difficult personal goal. **Roadblocks** ▪ Ask client to identify barriers to quitting tobacco use (e.g., partner or co-worker who uses tobacco, fears about quitting tobacco use, weight gain, etc.). **Repetition** ▪ Repeat above strategies every time an unmotivated client has a visit.
16.8	Electronic Cigarettes	Little research exists on the safety and effectiveness of the electronic cigarette (e-cig). The e-cig is considered a tobacco product under the FD&C Act and is not advised for nicotine replacement therapy in smoking cessation. For tobacco cessation, recommend the nicotine inhaler or other nicotine substitutes.
16.8	Assisting Client in Smoking Cessation	Aid the client in quitting using the following strategies: ▪ Together with the client, devise a quit plan. Include the following: o Set a quit date — ideally within 2 weeks. o Tell family, friends, coworkers and request support. o Anticipate challenges like nicotine withdrawal symptoms. o Remove tobacco products from the client's environment. ▪ Provide practical counseling/problem-solving/training. o Help the client to recognize danger situations — events, internal states or activities that increase the risk of smoking or relapse. o Encourage the client to develop coping skills — typically intended to cope with danger situations. o Provide basic information about smoking and successful quitting: • Any smoking increases the likelihood of full relapse. • Withdrawal typically peaks within 1 to 3 weeks after quitting. • Withdrawal symptoms include negative mood, urges to smoke, and difficulty concentrating. ▪ Provide written take-home materials that support and reinforce quit plan. ▪ Provide a supportive clinical environment while encouraging the client in her attempt to quit.

Section	Topic	Detail
		▪ Encourage client to obtain social support for quit attempt. ○ Assist client in developing support solicitation skills (i.e., practice requesting social support from family, friends, and coworkers). ○ Inform client about available intensive interventions which may be affiliate based or available in the community. ▪ Provide pharmacotherapy – see Table 16.8.d. ▪ Provide or recommend Intensive Clinical Intervention as appropriate. ✓ FYI — Intensive Clinical Intervention for Smoking Cessation
16.8.c. 16.8.d.	Pregnancy, Lactation and Pharmacologic Therapy for Smoking Cessation	**Pregnancy** Intensive counseling interventions increase quit rates in pregnancy, although brief in-office counseling still has a beneficial effect. Studies show that less nicotine and fewer metabolites cross the placenta with NRT than with smoking itself, but have not demonstrated safety or efficacy of pharmacotherapy in pregnancy. Cautious use of NRT in addition to counseling may be considered for refractory cases after reviewing risks and benefits with the client. **Lactation** Smoking leads to a significant reduction in breast milk volume and increases the likelihood of early discontinuation. Data support the use of bupropion plus NRT in nursing mothers, with increased cessation rates. The safety profile is favorable, as less nicotine and fewer metabolites are found in breast milk with NRT, compared to smoking more than ½ pack per day. Additionally, eliminating environmental exposure to the infant is a favorable outcome. It is not known whether varencicline is excreted in human milk.
16.8.c. FYI	Intensive Clinical Intervention for Smoking Cessation	An intensive clinical intervention program format may be offered by the affiliate or by referral and may include ▪ Individual or group counseling ▪ Proactive telephone counseling ▪ Adjuvant self-help material ▪ Pharmacotherapy Suggested program intensity

Section	Topic	Detail
		▪ Session length — longer than 10 minutes; preferably 20 to 30 minutes ▪ Number of sessions — at least 4 to 7 ▪ Length in weeks — at least 2, but preferably up to 8
16.9	Eating Disorders / Weight Management	**Anorexia Nervosa and Bulimia Nervosa** The onset of anorexia nervosa and bulimia nervosa usually occurs in late adolescence. Most women with these disorders do not present with complaints of having an eating disorder. Rather, they often present with other unrelated physical or psychological complaints. For example, they may present with amenorrhea, depression, infertility concerns, or oligomenorrhea. Therefore, it is very important for health care providers to have a high index of suspicion and ask questions accordingly. **Obesity** Obesity is a chronic condition that affects more than one third of adults, and it is now the most common medical condition to affect U.S. children. It affects women more than men, and African Americans and Hispanics more than Caucasians. It is defined as an excess of body fat. Overweight adults have a body mass index (BMI) between 25 to 30, and obese adults have BMIs > 30. Morbid obesity occurs with BMI > 40. People with a BMI of ≥40 and people with a BMI of ≥35 and chronic diseases are candidates for bariatric surgery. Obesity is a risk factor for many other chronic diseases, including arthritis, diabetes, dyslipidemias, hypertension, obstructive sleep apnea, and some cancers. In addition, obesity is also a risk factor for menorrhagia, oligomenorrhea, and polycystic ovary syndrome. Early intervention is crucial to preventing both these short-term and long-term complications.
16.9	Screening Tools for Eating Disorders	**SCOFF Questionnaire (78 to 100% sensitivity; 87% specificity with 2 positive answers)** Screening tool — SCOFF questionnaire (developed in Great Britain) ▪ Do you ever make yourself **S**ick because you feel uncomfortably full? ▪ Do you worry that you have lost **C**ontrol over how much you eat? ▪ Have you recently lost more than **O**ne stone in a 3-month period? (one stone=14 pounds) ▪ Do you believe yourself to be **F**at when others say you are too thin? ▪ Would you say that **F**ood dominates your life?

Section	Topic	Detail
		Eating Disorder Screen for Primary Care (ESP) (100% sensitivity; 71% specificity with 2 positive answers) ▪ Are you satisfied with your eating patterns? (A "no" to this question is classified as an abnormal response). ▪ Do you ever eat in secret? (A "yes" to this and all other questions is classified as an abnormal response). ▪ Does your weight affect the way you feel about yourself? ▪ Have any members of your family suffered with an eating disorder? ▪ Do you currently suffer with or have you ever suffered in the past with an eating disorder? A two-question screen that has been shown to be sensitive, but less specific: ▪ Does your weight affect the way you feel about yourself? ▪ Are you satisfied with your eating patterns?
16.9	DSM-5 Criteria for Anorexia Nervosa and Bulimia Nervosa[R3]	**Anorexia Nervosa** ▪ Restriction of energy intake relative to requirements, leading to a significantly low body weight in the context of age, sex, developmental trajectory, and physical health. *Significantly low weight* is defined as a weight that is less than minimally normal or, for children and adolescents, less than minimally expected. ▪ Intense fear of gaining weight or becoming fat, or persistent behavior that interferes with weight gain, even though at a significantly low weight. ▪ Disturbance in the way in which one's body weight or shape is experienced, undue influence of body weight or shape on self-evaluation, or persistent lack of recognition of the seriousness of the current low body weight. **Bulimia Nervosa** ▪ Recurrent episodes of binge eating. An episode of binge eating is characterized by both of the following: o Eating, in a discrete period of time, an amount of food that is definitely larger than most people would eat during a similar period of time and under similar circumstances

Section	Topic	Detail
		○ A lack of control over eating during the episode ▪ Recurrent inappropriate compensatory behaviors in order to prevent weight gain, such as excessive exercise, fasting, misuse of laxatives, diuretics, enemas or other medications, or self-induced vomiting ▪ The binge eating and inappropriate compensatory behaviors both occur, on average, at least once a week for 3 months. ▪ Self-evaluation is unduly influenced by body shape and weight. ▪ The disturbance does not occur exclusively during episodes of anorexia nervosa. **Binge-Eating Disorder** ▪ Recurrent episodes of binge eating. An episode of binge eating is characterized by both of the following: ○ Eating, in a discrete period of time, and amount of food that is definitely larger than what most people would eat in a similar period of time under similar circumstances ○ A sense of lack of control over eating during the episode ▪ The binge-eating episodes are associated with 3 or more of the following ○ Eating much more rapidly than normal ○ Eating until feeling uncomfortably full ○ Eating large amounts of food when not feeling physically hungry ○ Eating alone because of feeling embarrassed by how much one is eating ○ Feeling disgusted with oneself, depressed, or very guilty afterward ▪ Marked distress regarding binge eating is present. ▪ The binge eating occurs, on average, at least once a week for 3 months. ▪ The binge eating is not associated with the recurrent use of inappropriate compensatory behavior as in bulimia nervosa and does not occur exclusively during the course of bulimia nervosa or anorexia nervosa.
16.9	Osteoporosis in Women with Eating Disorders	Women with disordered eating are especially at risk for low bone mass / osteoporosis. The causes of low bone mass in this population are multifactorial and different from post-menopausal osteoporosis. Forty to 60 percent of bone mass is accrued during late adolescence, which unfortunately coincides with the peak onset of eating disorders. Low bone mass is also related to lean body mass; hypercortisolemia, IGF-1 levels, and excessive exercise may also contribute.

Section	Topic	Detail
		Studies are conflicting on the use of estrogen replacement to prevent or treat bone density loss. However, some studies support a small, incrementally increasing amount of replacement estrogen orally, or transdermally. The cornerstone of treatment is weight gain as well as adequate calcium and vitamin D. Use of hormones either for contraceptive purposes or for bone health should be done in consultation with a primary care provider or specialist in osteoporosis or AN.
16.9	Differential Diagnoses for Anorexia and Bulimia	Most often, clients who present with signs and symptoms of an eating disorder have one. Rarely, other conditions cause symptoms similar to an eating disorder such as the following: ▪ Cancers ▪ Celiac disease ▪ GI tuberculosis ▪ Hypothalamic disorders ▪ Inflammatory bowel disorders, especially Crohn's ▪ Pituitary disorders, e.g., tumors
16.9	Laboratory Findings	Laboratory findings in patients with anorexia and/or bulimia are often normal. A workup typically includes the following: ▪ Basic chemistries o Clectrolyte abnormalities — Serum bicarbonate may be elevated and clients may have a metabolic alkalosis. In addition, hypokalemia is very common, especially in women who purge. These women are then at risk for cardiac arrhthymias. • Hypokalemic hypochloremic alkalosis (purge) • Hypomagnesemia and hypophosphatemia (laxative abusers) • Hypophosphatemia (refeeding syndrome) • Elevated BUN o Estrogen levels — hypoestrogenic (amenorrhea) ▪ Thyroid function ▪ Complete Blood Count — anemia

Section	Topic	Detail
		▪ Urinalysis — urine specific gravity; osmolality ▪ Sedimentation rate ▪ Electrocardiogram — bradycardia, other arrhythmias, prolonged Q-Tc o Sinus bradycardia is very common in women with eating disorders. It often reflects their low body weight and is not merely due to exercise
16.9	Contraception for Women with Anorexia Nervosa	Routine use of combined hormonal contraceptives may be detrimental to bone density in women with AN. Provision of hormonal contraception in these clients should be done in consultation with a primary care provider or specialist in osteoporosis or AN. History of AN is a special condition for use of DMPA. Other methods should be considered when evaluating the risks and benefits.
16.9	Treatment of Anorexia Nervosa and Bulimia Nervosa	A multidisciplinary, or triad, approach has been found to be most successful — psychiatric treatment (psychology, psychiatry, pharmacology), nutritional evaluation and follow-up, and a medical evaluation and treatment of complications: ▪ Psychiatric o Therapy: Depending on the severity of the illness, a patient may benefit from either outpatient therapy (for the most stable patients) to inpatient and/or residential therapy (for the sickest patients). In between are two more options, including intensive outpatient (iop) and partial hospitalization (php). To be successful, these four alternatives for therapy should all incorporate the three components of the triad approach. Various types of therapy have been studied, and cognitive behavioral therapy has been found to be one of the more successful approaches. o As with other psychiatric conditions, eating disorders often respond best to a combination of both therapy and pharmacology. o Psychiatric pharmacology: SSRIs are considered first-line therapy for bulimia, but are often used in other eating disorders, depending on concurrent signs and symptoms. High-dose SSRIs are useful for patients with obsessive-compulsive disorders, which are often coexistent with disordered eating. ▪ Nutritional/weight restoration —This requires the assistance of a nutritionist to work with the patient to develop a meal plan that will supply the necessary nutrients required for the patient to gain weight. In order to regain their lost weight, anorexic patients require more calories than other women. For

Section	Topic	Detail
		patients with bulimia, it is important to establish a meal plan to help curtail their binging and purging cycles. ▪ Medical— Medical therapy seeks to correct dehydration and electrolyte imbalances, as well as the longer term medical sequelae, such as bone loss.
16.9	Meal Consistency	Many people skip breakfast, a critical time to eat, because a person's metabolism will slow down without food. In addition, many patients will overeat at the following mealtime in order to compensate for the skipped meal. It is important to encourage regular meal and snack times with smaller meals and healthy, low-calorie snacks.
16.9	Lifestyle Modification in Management of Obesity	**Dietary considerations** ▪ To lose weight, clients must expend more energy than they consume in calories. ▪ Many different diet plans exist, and all that have lower caloric intake have been shown to be successful in acute weight reduction, but the client must understand the importance of maintenance and should choose her dietary changes accordingly: o Conventional diets include low carbohydrate, low fat, so-called fad diets (e.g., Atkins, South Beach), and balanced low-calorie / portion-control diets. The balanced low-calorie / portion-control diet has the longest staying power generally. o Avoidance of high-calorie, low-nutrient foods is a central and achievable goal. **Exercise recommendations** ▪ Advise regular exercise, with a goal of at least 150 minutes of moderate or 75 minutes of vigorous activity per week. ▪ Encourage clients to start slowly and build up to the recommended amount. Any amount of exercise is healthier than none. Optimally, clients will increase both the frequency and intensity of their workouts. ▪ Give concrete suggestions. ▪ Help clients find the exercise regimen that works best for them. **Sleep hygiene recommendations** ▪ Advise goal of 7 to 8 hours of sleep each night. ▪ Avoid caffeinated beverages after lunchtime.

Section	Topic	Detail
		▪ Plan to be in bed with lights off at least 7 hours before time to get up. ▪ Avoid activities that may be arousing around bedtime (e.g. texting, using computer). ▪ Establish relaxing activities such as writing in a journal, listening to relaxing music, stretching. ▪ Create a quiet, dark, and relaxing bedroom environment.
16.9	Bariatric Surgery	Multiple types of bariatric surgery exist, but the most common are the Roux-en-Y bypass, laparoscopic adjustable gastric banding, sleeve gastrectomy and duodenal switch. The band and sleeve procedures are functionally restrictive, while the switch and bypass are primarily malabsorptive in their function. Multiple studies have shown improvement in longer term mortality following these procedures as well as morbidity from chronic disease. They are best performed in a team setting with a multi-disciplinary approach, addressing, preoperative preparation, diet, exercise, psychological barriers to success and post-operative management and follow-up.

16.10.b. Table: References

Section	R#	Reference
16.1		NHLBI. Guidelines for the Diagnosis and Management of Asthma. Expert Panel Report 3, U.S. Department of Health and Human Services, 2007.
16.2		AHRQ. Screening for Depression in Adults and Older Adults in Primary care: An Updated Systematic Review. Evidence Report, AHRQ, AHRQ, 2009.
16.2		Bandelow, Borwin, et al. "Guidelines for the pharmacological treatment of anxiety disorders, obsessive-compulsive disorder, and posttraumatic stress disorder in primary care." International Journal of Pyschiatry in Clinical Practice 16 (2012): 77-84.
16.2	R2	Canadian Journal of Psychiatry. Clinical Practice Guidelines: MAnagement of Anxiety Disorders. Vol. 51. 8 vols. Ottawa: Canadian Journal of Psychiatry, 2006.
16.2		Canadian task Force on Preventive Health Care. "Screening for Depression in Primary Care." document, University of Alberta, 2013.
16.2	R4	DSM-V Manual 2013: American Psychiatric Association. (2013) Diagnostic and statistical manual of mental disorders, (5th ed.). Washington, DC

Section	R#	Reference
16.2	R1	ICSI. "Institute for Clinical Systems Improvement." Health Care Guideline: Adult Depression in Primary Care Guideline. September 01, 2013. https://www.icsi.org/_asset/fnhdm3/Depr.pdf#page17 (accessed May 21, 2014).
16.2		National Institute for Health and Clinical Excellence. Depression in Adults. clinical guidelines, NICE, National Health Service, 2009.
16.2	R3	USPSTF. Screening for Depression in Adults. Dec 2009. http://www.uspreventiveservicestaskforce.org/uspstf09/adultdepression/addeprrs.htm (accessed June 1, 2014).
16.3		American Diabetes Association. "Nutrition recommendations and interventions for diabetes: a position statement of the American Diabetes Association." Diabetes Care 31, no. Supplement 1 (January 2008): S61-S78.
16.3		American Diabetes Association. "Standards of Medical Care in Diabetes - 2014." Diabetes Care 37, no. S1 (Jan 2014): S14-S80.
16.4		ACP, "Clinical Guideline: Upper Endoscopy for Gastroesophageal Reflux Disease: Best Practice Advice from the Clinical Guidelines Committee of the American College of Physicians." Shaheen et al 2012
16.4		American College of Physicians (ACP), "In the Clinic: Gastroesphageal Reflux Disease." Jennifer F Wilson 2008: Ann Intern Med. 2008;149(3):ITC2-1. doi:10.7326/0003-4819-149-3-200808050-01002
16.4		The American Journal of Gastroenterology. "Guidelines for the Diagnosis and Management of GERD." 2013: Am J Gastroenterol 2013; 108:308–328; doi: 10.1038/ajg.2012.444
16.5		JNC 8. "2014 Evidence-based Guideline for the Management of High Blood Pressure in Adults." Journal of the American Medical Association 311, no. 5 (Feb 2014): 507-520.
16.5		NIH National Heart, Lung, and Blood Institute. Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. U.S. Department of Health and Human Services, National Institutes of Health, 2004.
16.6		ACOG practice bulletin No 37: Thyroid Disease in Pregnancy. Aug 2002 100(2) 387-96. Reaffirmed 2010.
16.6		Cochrane Summaries. Published online Jan 21 2009. Thyroid hormone replacement for subclinical hypothyroidism. Accessed June 2014.
16.6		Garber JR, Cobin RH, Gharib H, Hennessey JV, Klein I, Mechanick JI, Pessah-Pollack R, Singer PA, Woeber KA, American Association of Clinical Endocrinologists and American Thyroid Association. Clinical practice guidelines for hypothyroidism in adults: cosponsored by the American Association of Clinical Endocrinologists and the American Thyroid Association. Endocr Pract. 2012 Nov-Dec;18(6):988-1028. http://www.guideline.gov/content.aspx?f=rss&id=46419&osrc=12 . Accessed June 4, 2014
16.6		Gharib, Hossein, R. Michael Tuttle, H. Jack Baskin, Lisa H. Fish, Peter A. Singer, and Michael T. McDermott. "Subclinical thyroid dysfunction: a joint statement on management from the American Association of Clinical Endocrinologists, the American Thyroid Association, and the Endocrine Society." *The Journal of Clinical Endocrinology & Metabolism* 90, no. 1 (2005): 581-585.

Section	R#	Reference
16.7		American College of Cardiology/American Heart Association. "2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults." Circulation. Nov 12, 2013. http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a.full.pdf+html (accessed May 30, 2014).
16.7		American College of Cardiology/American Heart Association. "Guideline for Treating Blood Cholesterol to Reduce Cardiovascular Risk." July 2014. https://www.cardiosmart.org/Heart-Conditions/Guidelines/Cholesterol (accessed May 30, 2014).
16.7		American College of Cardiology/American Heart Association. "2013 CV Risk Calculator" 2013. http://my.americanheart.org/professional/StatementsGuidelines/PreventionGuidelines/Prevention-Guidelines_UCM_457698_SubHomePage.jsp (accessed May 2014)
16.7		Davies, Edward. "Cardiovascular risk guidelines and transparency." BMJ 347 (November 2013): f7022.
16.7		Kearney JF, Curfman GD, Jarcho JA, A Pragmatic View of the New Cholesterol Treatment Guidelines, New England Journal of Medicine (2014) 370;3, 275-276.
16.7		Lenzer, Jeanne. "Majority of panelists on controversial new cholesterol guideline have current or recent ties to drug manufacturers." BMJ 347 (Nov 2013): f6989.
16.7		Sidhu, Davinder, and Christopher Naugler. "Fasting Time and Lipid Levels in a Community-Based Population." Arch Intern med 172, no. 22 (Dec 2012): 1707-1710.
16.7		Stone, Neil. "Treatment of BLood Cholesterol to Reduce Atherosclerotic Cardiovascular Disease Risk in Adults: Synopsis of the 2013 ACC/AHA Cholesterol Guideline." Annals of Internal Medicine 160, no. 5 (March 2014): 339-343.
16.7		The NNT. "Statin Drugs Given for 5 Years for Heart Disease Prevention (Without Known Heart Disease)." http://www.thennt.com/statins-for-heart-disease-prevention-without-prior-heart-disease/. Accessed May 2014.
16.7		Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III Final Report). https://www.nhlbi.nih.gov/guidelines/cholesterol/atp3_rpt.htm. Accessed June 2014.
16.8		Agency for Healthcare Research and Quality (AHRQ) 2008 – same reference as old protocols: Agency for Healthcare Research and Quality (ARHQ). Systems Change: Treating Tobacco Use and Dependence. Based on the Public Health Service (PHS) Clinical Practice Guideline—2008 Update.
16.8		University of Michigan Health Systems. "Tobacco Treatment Guideline." UMHS. March 2012. http://www.med.umich.edu/1info/fhp/practiceguides/smoking/smoking.pdf (accessed May 22, 2014).
16.9		American Psychiatric Association. DSM-5, Feeding and Eating Disorders. 2013.
16.9		Australian Government Department of Health and Aging. Identifying people at risk of eating disorders. July 17, 2012.

Section	R#	Reference
		http://www.nedc.com.au/identifying-people-at-risk (accessed May 23, 2014).
16.9		Bulk, Cynthia, and Nancy Berkman. Eating Disorders: NEwer Practice Guidelines Reinforce Severity of Conditions But Still Reflects Deficits in Knowledge Base. Feb 25, 2008. http://www.guideline.gov/expert/expert-commentary.aspx?id=16450&search=anorexia (accessed May 23, 2014).
16.9		Cotton, Mary-Anne, Christopher Ball, and Paul Robinson. "Four Simple Questions can Help Screen for Eating Disorders." J gen Intern Med 18, no. 1 (Jan 2003): 53-56.
16.9		Institute for Clinical Systems Improvement. "Health Care Guideline: Prevention and Management of Obesity for Adults." ICSI. May 00, 2013. https://www.icsi.org/_asset/s935hy/Obesity-Interactive0411.pdf (accessed May 23, 2014).
16.9		National Institute for Clinical Excellence. Eating disorders: Core interventions in the treatment and management of anorexia nervosa, bulimia nervosa, and related eating disorders. Jan 00, 2004. http://www.nice.org.uk/nicemedia/live/10932/29218/29218.pdf (accessed May 23, 2014).
16.9		U.S. Preventive Services Task Force. Screening for and Management of Obesity in Adults. June 00, 2012. http://www.uspreventiveservicestaskforce.org/uspstf/uspsobes.htm (accessed May 23, 2014).
16.9		University of Michigan Health Systems. "UMHS Obesity Prevention and Management Guideline." UMHS Quality Management Program. July 00, 2013. http://www.med.umich.edu/1info/fhp/practiceguides/obesity/obesity.pdf (accessed May 23, 2014).
16.9		Yager, J. "Practice Guideline for the treatment of patients with eating disorders." American Psychiatric Association. Mar 18, 2012. http://psychiatryonline.org/content.aspx?bookid=28&sectionid=39113853 (accessed May 23, 2014).

16.10.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
General		
CI/CIIC	CI Preconception	Part 3, Chapter 02_21
Asthma		
Client Education	✓ NHLBI: So You Have Asthma ✓ NHLBI: My Asthma Wallet Card ✓ MedlinePlus: Asthma	

Type	Resource	Location
	✓ NHLBI: At-A-Glance: Asthma	
Depression and Anxiety		
Client Education	✓ University of Michigan Depression Toolkit ✓ CDC Patient Resources for Depression ✓ American Psychiatric Association: Mental Health ✓ M3 Screen for Evaluation of Bipolar Disorder, Anxiety, and PTSD *Mastering Your Fears and Phobias: Workbook* (Martin M. Anthony) – Self-help book for phobias	
Diabetes Mellitus (DM), Type 2		
Client Education	✓ ADA: Checking Your Blood Glucose ✓ ADA: Online Diabetes Management Program ✓ ADA: What Can I Eat ✓ FamilyDoctor.org: Diabetes and Nutrition ✓ National Diabetes Education Program (NDEP): 4 Steps to Control Your Diabetes For Life ✓ NDEP: Know Your Blood Sugar Numbers ✓ NDEP: Tips to Help You Stay Healthy	
Gastroesophageal Reflux Disease (GERD)		
Client Education	✓ National Digestive Diseases Information Clearinghouse Patient Resources: GERD ✓ ACP: Understanding and Treating Heartburn	
Hypertension		
CI/CIIC	CI Lower Your BP	Part 3, Chapter 02_16
Client Education	✓ American Heart Association: Diet and Lifestyle Recommendations ✓ American Heart Association: Healthy Diet Guidelines ✓ American Society of Hypertension: BP & Your Health Booklet ✓ Family Doctor.org: Hypertension ✓ Hypertension Foundation: Client Booklets ✓ MedlinePlus: High Blood Pressure and Diet	

Type	Resource	Location
	✓ MedlinePlus: Hypertension Client Education ✓ NHLBI: Delicious Heart Healthy Latino Recipes ✓ NHLBI: Your Guide to Lowering Your Blood Pressure with DASH ✓ U.S. Department of Agriculture and U.S. Department of Health and Human Services: Dietary Guidelines for Americans, 2010	
Hypothyroidism		
Client Education	✓ American Thyroid Association: Hipotiroidismo (Spanish) ✓ American Thyroid Association: Hypothyroidism ✓ FamilyDoctor.org: Hypothyroidism ✓ MedlinePlus: Hypothyroidism	
Lipid Disorders		
Client Education	✓ American Heart Association: Diet and Lifestyle Recommendations ✓ NHLBI: Your Guide to Lowering Blood Pressure with DASH ✓ USDA Choose My Plate	
Smoking Cessation		
Client Education	✓ Smokefree Women Client Resources ✓ U.S. Department of Health and Human Services Smoking Cessation Healthfinder Resource ✓ University of Michigan Clinical Care Guidelines for Smoking Cessation Patient Education Materials ✓ Women's Heart Foundation Smoking Cessation Planner	
Weight Management		
CI/CIIC	CI Tips for Losing Weight	Part 3, Chapter 02_16
Client Education	✓ CDC Healthy Weight Guide	

16.10.d. Table: Associated Resources for Staff

Type	Resource	Location
General		
Training	**CAL Courses** How to Administer Intramuscular Injections How to Measure Blood Pressure, Pulse, and Respiration	
	PPFA 2013 NMC session Common Primary Care Diagnoses in PP Setting	To be posted on the Extranet
Asthma		
Job Tools	✓ Global Initiative for Asthma: An Asthma Pocket Guide	
Sample Forms	✓ NHLBI: Asthma Action Plan	
Depression and Anxiety		
Job Tools	✓ University of Michigan Depression Guidelines, 2011 ✓ AFP Depression and Bipolar Disorder	
Diabetes Mellitus (DM), Type 2		
Job Tools	✓ NDEP: Small Steps. Big Rewards.	
Gastroesophageal Reflux Disease (GERD)		
Job Tools	✓ American College of Physicians GERD Decision Support Tool	
Lipid Disorders		
Job Tools	✓ American Heart Association: 2013 Prevention Guidelines Tools: CV Risk Calculator	
Smoking Cessation		
Job Tools	✓ University of Michigan Clinical Care Guidelines for Smoking Cessation	
Weight Management		
Job Tools	BMI Table	Part 3, Chapter 02_21
	✓ Clinician Tool for Screening for Eating Disorders	

CHAPTER 17: RECOVERY AREA CARE

June 2014

Chapter 17 Table of Contents

CHAPTER 17: RECOVERY AREA CARE

June 2014

17.1 RECOVERY AREA ASSESSMENT CRITERIA

17.1.1 Sedated Clients

I. **Must** assess the following at initiation of recovery and then every 15 minutes during the recovery process until discharge
   A. BP, respiratory rate, pulse, oxygen saturation
   B. Pain level
   C. Level of consciousness using Aldrete Scoring System - see Table 17.2.a.
   D. Amount of bleeding, when applicable

✓ FYI - Prevention and Management of Hypoxemia During Moderate Sedation

17.1.2 Non-sedated clients

I. **Must** assess the following at initiation of recovery and then every 15 minutes during the recovery process until discharge
   A. BP, respiratory rate, pulse (a minimum of 2 sets)
   B. Pain level
   C. Amount of bleeding, when applicable

17.1.3 All clients

I. If any complication or condition occurs or is suspected that is beyond the management capability of affiliate staff, **must** arrange for immediate hospitalization

17.2 DISCHARGE CRITERIA

17.2.1 Sedated clients

I. To qualify for medical discharge client **must** have
   A. A minimum of 9 out of 10 on Aldrete Scoring System - see Table 17.2.a.
   B. Pain level that is less than when admitted to recovery area or back to baseline from before the procedure
   C. Received last dose of sedation medication
      1. At least 15 minutes prior to discharge if IM
      2. At least 30 minutes prior to discharge if IV

D. Stable bleeding, when applicable

II. Client **must** be discharged to the care of a responsible person who will accompany them home.

17.2.2 Non-sedated clients

I. To qualify for medical discharge client **must** have
   A. Stable vital signs
   B. Pain level that is less than when admitted to recovery area or back to baseline from before the procedure
   C. Stable bleeding, when applicable

17.2.a. Table: Aldrete Scoring System

Parameter	Description of Client	Score
Activity Level	▪ Moves all extremities voluntarily/on command ▪ Moves 2 extremities ▪ Cannot move extremities	▪ 2 ▪ 1 ▪ 0
Respirations	▪ Breathes deeply and coughs freely ▪ Is dyspneic, with shallow, limited breathing ▪ Is apneic	▪ 2 ▪ 1 ▪ 0
Circulation (BP)	▪ ~~Is 20 mm Hg > preanesthetic level~~ ▪ ~~Is 20 to 50 mm Hg > preanesthetic level~~ ▪ ~~Is 50 mm Hg > preanesthetic level~~	▪ 2 ▪ 1 ▪ 0
Consciousness	▪ Is fully awake ▪ Is arousable on calling ▪ Is not responding	▪ 2 ▪ 1 ▪ 0
Oxygen saturation as determined by pulse oximetry	▪ Has level >90% when breathing room air ▪ Requires supplemental oxygen to maintain level >90% ▪ Has level <90% with oxygen supplementation	▪ 2 ▪ 1 ▪ 0

17.3 ADDITIONAL INFORMATION

17.3.a. Table: For Your Information

Section	Topic	Detail
17.1.1	Prevention and Management of Hypoxemia During Moderate Sedation	Supplemental oxygen should be considered for moderate sedation to reduce the frequency of hypoxemia and should be used if hypoxemia develops. If oxygen saturation drops below 93% a clinician **must** be informed. If oxygen saturation drops below 90% **must** initiate affiliate protocol for management of respiratory depression. (Refer to the ARMS Emergency Care Manual for sample protocol.)

17.3.b. Table: References

Section	Reference
Throughout	American Society of Anesthesiologists. "Postanesthesia Care, Standards for." American Society of Anesthesiologists. 2010. https://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx (accessed June 5, 2014).
Throughout	American Society of PeriAnesthesia Nurses. "2012-2014 Perianesthesia Nursing Standards, Practice Recommendations and Interpretive Statements." 2014.

17.3.c. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ American Society of Anesthesiologists: Standards for Postanesthesia Care	

CHAPTER 18: HEALTHCARE FOR TRANSGENDER PERSONS

Revised June 2014

Chapter 18 Table of Contents

CHAPTER 18: HEALTHCARE FOR TRANSGENDER PERSONS

Revised June 2014

18.1 CLIENT EDUCATION AND INFORMED CONSENT

18.1.1 Requirements

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

18.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	Should give
CIIC Feminizing (Male to Female) Therapy			●	
CIIC Masculinizing (Female to Male) Therapy			●	
Release When Test/Service/Consultation Will Not Be Obtained As Recommended		once		
Written information about any medication dispensed (package insert may be used)			●	
Written information, as appropriate				●

18.2 WELL-PERSON CARE FOR TRANSGENDER CLIENTS

✓ FYI – Terminology

18.2.1 Components of Well-Person Care

I. When providing well-person care for transgender clients, the particular screening services required are based on a combination of factors including the client's age, biological sex, surgical status (i.e. organs present), declared gender, past or current use of hormonal therapies and family history.

18.2.a. Table: History and Physical Exam Components of Well-Person Care

History	Physical Examination
Obtain comprehensive age-appropriate medical history, with particular attention to the following: ▪ Past or present hormone use ▪ Use of needles to inject hormones or silicone	Should be based on organs present rather than perceived gender of the client. It **must** include ▪ Transfemales (MTFs) ○ Prostate evaluation: digital rectal exam as for natal males in all clients regardless of hormones or surgery

History	Physical Examination
✓ FYI – The Significance of Silicone Obtain at the first visit and update annually.	○ BP in clients currently using hormones (as outlined in 18.3 Cross-Sex Hormone Therapy) ▪ Transmales (FTMs) — CBE and pelvic exam as appropriate by age - see Chapter 21 Well-Woman Care ✓ FYI – Physical Exam Considerations Unique to Transgender Clients

18.2.2 Laboratory and other Screening Components of Well-Person Care[R1, R2]

18.2.b. Table: Recommended Screening for Transgender Clients

Screening	Transfemales (MTFs)	Transmales (FTMs)
Cancer		
Breast	No past or current hormone use ▪ No screening needed Past or current hormone use ▪ Screening mammography in clients over age 50 with additional risk factors (e.g., estrogen and progestin use > 5 years, positive family history, BMI > 35) ▪ Annual clinical breast exam and periodic self-breast exam not recommended	All FTMs, regardless of hormone use/surgery ▪ Annual chest wall/axillary exam ▪ Screening mammography as for natal females (not necessary following chest reconstruction, but should be considered if only a reduction performed) - see Chapter 3 Breast Services
Cervical	Following vaginoplasty, regardless of hormone use ▪ Cervical cancer screening in neovaginas are not indicated	All ▪ Cervical cancer screening as for natal females (See Chapter 4 Cervical Cancer Screening and Management of Cervical Abnormalities) ▪ Inform pathologist if client is taking testosterone, as testosterone can result in atrophic changes to the cervical epithelium mimicking dysplasia ✓ FYI - Cervical Cancer Screening and Pelvic Examination in FTM Clients

Screening	Transfemales (MTFs)	Transmales (FTMs)
Uterine	n/a	No hysterectomy ▪ After menstrual cessation (whether from menopause or induced by testosterone), fully evaluate unexplained abnormal uterine bleeding - See Chapter 8.1.2 Abnormal Uterine Bleeding
Prostate ✓ FYI – Prostate Cancer Risk in MTFs	No past or current hormone use ▪ The American Cancer Society (ACS) recommends beginning discussions ○ At age 50 if low risk ○ At age 45 if high risk (African-American men and men who have a close relative — father, brother, or son — who had prostate cancer before age 65) ○ By age 40-45, if very high risk (more than 2 first-degree relatives with a history of prostate cancer) digital rectal exam as for natal males (See Chapter 12 Men's Sexual and Reproductive Health) Past or current hormone use ▪ PSA is falsely low in androgen-deficient setting even in presence of cancer; only consider PSA screening in high risk clients ▪ Digital rectal exam as for natal males	
Other	All MTFs and FTMs, regardless of hormone use/surgery ▪ Follow standard screening recommendations for other cancers (e.g., colon cancer, lung cancer, anal cancer)	
Cardiovascular		
CAD/Cerebrovascular disease	All MTFs and FTMs, regardless of hormone use/surgery ▪ Screen for modifiable cardiovascular risk factors	

Screening	Transfemales (MTFs)	Transmales (FTMs)
Hypertension (See Chapter 16.5 Hypertension)	All MTFs and FTMs not currently taking hormone therapy ▪ Screen as with non-transgender clients All MTFs and FTMs currently taking hormone therapy ▪ Monitor BP every 1 to 3 months	
Lipids (See Chapter 16.7 Lipid Disorders)	All MTFs and FTMs not currently taking hormone therapy ▪ Screen as with non-transgender clients All MTFs and FTMs currently taking hormone therapy ▪ Annual fasting lipid profile	
Other		
Diabetes (See Chapter 16.3 Diabetes Mellitus)	Not currently taking estrogen ▪ Screen and treat as with non-transgender clients Currently taking estrogen ▪ Consider annual fasting glucose test, esp. if family history of diabetes and/or > 5 kg weight gain ▪ Consider glucose tolerance testing and/or A1C test if evidence of impaired glucose tolerance without diabetes	All FTMs, regardless of hormone use/surgery ▪ Screen and treat as with non-transgender clients ▪ Consider screening (by client history) for polycystic ovarian syndrome (PCOS); diabetes screening is indicated if PCOS is present
Family planning ✓ FYI – Sexual Function Considerations		All FTMS ▪ Provide Reproductive Life Planning, preconception care, and contraception as appropriate. (See Chapter 21.2 Preconception Care) Currently taking testosterone or planning to take testosterone in future ▪ Advise that testosterone is not a contraceptive and provide contraception as indicated.

Screening	Transfemales (MTFs)	Transmales (FTMs)
Mental health ✓ FYI - Referral Considerations	All MTFs and FTMs, regardless of hormone use/surgery ▪ Screen for depression and interpersonal/intimate partner violence - see Chapter 16.2 Depression and Anxiety ▪ Refer, if needed, to trans-competent mental health provider	
Musculoskeletal health	Currently taking feminizing hormones ▪ Advise regular exercise to maintain muscle tone.	Currently taking testosterone ▪ In FTMs who are involved in strength training, advise to increase weight load gradually, with an emphasis on repetitions rather than weight and emphasize stretching, to avoid tendon rupture.
Osteoporosis	Pre-orchiectomy (regardless of hormone use) ▪ No screening unless additional risk factors ▪ Recommend calcium and Vitamin D (See Chapter 21 Well-Woman Care) Post-orchiectomy ▪ Either maintain estrogen therapy or consider combination of calcium/Vitamin D supplementation and bisphosphonate ▪ Consider bone density screening for clients > age 60 who have been off estrogen for > 5 years	No hormone use, no oophorectomy ▪ Follow screening recommendations for natal females - See Chapter 8.5 Menopause Taking testosterone for > 5 to 10 years, no oophorectomy ▪ Consider bone density screening if over age 50, earlier if additional risk factors ▪ Recommend supplemental calcium (1200 mg daily) and Vitamin D (600 units daily) Past or present hormone use, post-oophorectomy (or total hysterectomy) ▪ Continue testosterone therapy to reduce risk of bone density loss; if contradictions to testosterone therapy, consider bisphosphonate ▪ Consider bone density screening if over age 60 if taking testosterone for < 5 to 10 years; if taking testosterone for > 5 to 10 years consider at age 50, earlier if additional risk factors ▪ Recommend supplemental calcium (1200 mg daily) and Vitamin D (600 units daily)

Screening	Transfemales (MTFs)	Transmales (FTMs)
STI ✓ FYI – STI Prevention for Transgender Clients	All MTFs and FTMs, regardless of hormone use/surgery ▪ Screen and treat all clients with STIs and their partners according to guidelines for non-transgender clients - see Chapter 9 Infections ○ In MTFs with a neovagina, perform STI cultures, not PCR ▪ If ongoing risk behaviors for sexual or blood-borne transmission, consider HIV and Hepatitis B/C screening every 6 to 12 months; otherwise consider HIV and Hepatitis B/C screening at least once during lifetime ○ Offer Hepatitis B vaccination if client not already immune	
Substance use	All MTFs and FTMs, regardless of hormone use/surgery ▪ Screen (by history) for past and present use of tobacco, alcohol, and other drugs ▪ Refer, if needed, to trans-competent chemical dependency program	

18.2.3 Return Visits

I. Determine schedule of return visits according to particular findings of the screening visit and refer as appropriate for community resources

18.3 CROSS-SEX HORMONE THERAPY

18.3.1 Medical Screening And Evaluation

I. Cross-Sex Hormone Therapy **must** be individualized based on a client's goals, the risk/benefit ratio of medications, the presence of other medical conditions, and consideration of social and economic issues.

✓ FYI - Considerations When Prescribing Hormonal Therapies

II. Care of Transgender Minors — Treatment of minors requires a waiver from PPFA.

III. Evaluate for cross-sex hormone therapy according to Table 18.3.a.

18.3.a. Table: Evaluation for Cross-Sex Hormone Therapy

History	Physical Examination	Laboratory Testing and Diagnostic Imaging	
Must obtain comprehensive medical, surgical and sexual history when care is initiated and update annually or more frequently if necessary.	**Must** include ▪ BP ▪ Targeted exam as indicated	For MTF **must** include ▪ Fasting lipid panel ▪ Potassium and creatinine (if plan includes spironolactone)	For FTM **must** include ▪ Fasting lipid panel ▪ Hgb or Hct ✓ FYI - Determination of Hormone Levels

18.3.2 Contraindications and Special Conditions

I. **Must** use Table 18.3.b. when choosing a cross-sex hormone therapy.

18.3.b. Table: Contraindications and Special Conditions for Cross-Sex Hormone Therapy

LEGEND	
A	**Musts** and Shoulds
B	Contraindications — **must** not use
C	Special Conditions Requiring Further Evaluation — Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral **must** be based on protocols approved by the program director or medical director or in consultation with affiliate physician.
D	Other considerations - condition should be considered in risk/benefit analysis when choosing the method

Condition	A	B	C	D
Breast cancer – strong family history	If MTF decides to take estrogen, should recommend lowest feminizing dose			Estrogen only
Cardiovascular disease				
▪ Family history			Testosterone only	
▪ Presence of multiple risk factors such as age >40, smoking, obesity, sedentary lifestyle			Estrogen only	

Condition	A	B	C	D
▪ Coronary artery disease, current and stable or past history			Testosterone only	
▪ Coronary artery disease, unstable		Testosterone only	Estrogen only	
Diabetes mellitus – Type 2	Should consider decreasing estrogen if glucose is difficult to control or client is unable to lose weight.		•	
Estrogen-sensitive neoplasm				
▪ Personal history		Estrogen only	Testosterone only	
▪ Strong family history	If MTF decides to take estrogen, should recommend lowest feminizing dose			Estrogen only
Hyperkalemia		Spironolactone only		
Hyperlipidemia (See Chapter 16.7 Lipid Disorders)	**Must** consult with program director prior to initiation of testosterone		•	
Hypertension	Should consider using spironolactone as part of antihypertensive regimen in MTF clients		•	
Liver				
▪ Chronic liver disease	If LFTs are <3 times ULN, may be appropriate to start estrogen or testosterone and closely monitor LFTs.		•	
▪ Gallbladder*			•	
▪ Hepatitis – acute, with LFTs greater than 2 to 3 times ULN		•		
▪ End-stage liver disease		•		

Condition	A	B	C	D
PCOS			Testosterone only	
Polycythemia				
▪ Untreated, with hemoglobin ≥55%		Testosterone only		
▪ Other			●	
Pregnancy		Testosterone only		
Prolactinoma**			●	
Psychiatric disorders[†]				Testosterone only
Renal insufficiency		Spironolactone only		
Seizure disorder[††]			Estrogen only	
Tobacco use			●	
Vascular disease				
▪ Peripheral vascular disease or cerebrovascular, current or past history			Testosterone only	
Venous thrombotic event				
▪ Previous - due to underlying hypercoagulable condition		Estrogen only		
▪ Previous thrombosis or thromboembolism			Testosterone only	
▪ Increased risk for, such as presence of conditions associated with hypercoagulability			Estrogen only	
Warfarin use				Testosterone only

Condition	A	B	C	D

*Estrogen use increases risk of cholelithiasis and subsequent cholecystectomy

** Estrogen use increases risk of hyperprolactinemia among MTF clients in the first year of treatment, but this risk unlikely thereafter.

†Masculinizing therapy may increase risk of hypomanic, manic, or psychotic symptoms in clients with underlying psychiatric disorders that include such symptoms.

††Potential for altered estrogen metabolism

18.3.3 Transfemale Cross-Sex Hormone Therapy

I. Estrogen therapy – initiate according to Table 18.3.c.
   A. General principles of therapy
      1. Use lowest effective dose possible.
      2. Forms of estrogen **must** be individualized, weighing cost, theoretical risks, and client preference.
      3. Non–oral forms are preferred.
      4. Doses may be lowered by 25% to 50% after feminization has been achieved and after orchiectomy where the testes are removed.
      5. In MTF clients at increased risk for CAD, use transdermal estrogen and lowest dose of estrogen, and omit progestin from regimen.

18.3.c. Table: Estrogen Formulations and Dosing

✓ FYI - Effects and Time Course of Feminizing Hormones

Medication	Dose		Comments: All non-oral forms are first choice for hormone therapy
Estradiol (estrace) **Sublingual (SL)** Oral formulation but **SL** (needs to be specified on the prescription)	Starting: Average: Maximum:	1 mg / day (0.5 bid) 2 to 4 mg /day (2mg bid) 6 mg/day (3mg bid)	Sublingual is recommended as the initial choice by many experienced providers of transgender care because it costs less and is the easiest to take. Sublingual dosing results in a relatively higher serum level than oral administration; bid dosing is recommended. **Must** not be used orally due to safety concerns.
Estradiol transdermal patch	Starting: Maximum:	200 mcg/d (apply #2 100 mcg patches, change twice weekly) 400 mcg/d (apply #4 100 mcg patches, change twice weekly)	Generic patch is available but some find its large size a problem and the adhesive not as long-lasting.

Medication	Dose	Comments: All non-oral forms are first choice for hormone therapy
Estradiol valerate injection	Starting: 20 to 40 mg IM every 2 weeks Average: 40 mg IM every 2 weeks Maximum: 40 to 60 mg IM every 2 weeks	Some clients prefer injectable estrogen as they feel there is more rapid development of feminization. Some clients prefer a half dose at weekly IM intervals for mood stabilization. Anecdotally, some clients report mood dysphoria with injectable forms. Some guidelines recommend injections continue for no more than 2 years and then transition to an alternate route of administration.

II. Anti-androgen therapy – may consider in combination with estrogen therapy. Initiate according to Table 18.3.d.

18.3.d. Table: Anti-androgen Medications and Dosing

Medication	Dose	Comments: All non-oral forms are first choice for hormone therapy
Spironolactone	Start: 50 to 100 mg/d in single or divided dose Increase by up to 50 mg/week Max: 200 mg total/d	Most commonly used anti-androgen in the US; requires monitoring of BP and electrolytes; discontinue if/when testes removed; consider single am dose to avoid diuretic effects interrupting sleep. Side effects increase after 200 mg/d.
GnRH agonists		Expensive, only available as injections or implants
5-alpha reductase inhibitors Finasteride Minoxidil 5%	 Finasteride: 1 mg PO qd Minoxidil 5%: apply to scalp qd	To decrease progression of male pattern baldness Either medication will need to be continued indefinitely to maintain hair growth. Generic finasteride is only available in 5mg tablets and may be cut into quarters for use.

III. Progestins - may be considered in cases when spironolactone is contraindicated. Initiate according to Table 18.3.e.

18.3.e. Table: Progestin Regimens for Feminization

Medication	Dose	Comments: All non-oral forms are first choice for hormone therapy
Micronized progesterone	Start: 100 mg po qd Max: 200 mg po qd	Preferred regimen for safety reasons
Medroxyprogesterone	Start: 5 mg po qd	Can halve (to 2.5 mg) or double (to 10 mg) prn
Depot Medroxyprogesterone Acetate	150 mg IM q 3 months for 2-3 years	

18.3.4 Follow-up MTF Therapy

I. Client **must** be advised to return for evaluation if a significant hormonal therapy problem is suspected, with follow-up and surveillance of special conditions as per protocol.
   A. Routine follow up visits are indicated at 4 weeks, 3 months, 6 months and every 6 to 12 months thereafter.
   B. At each hormonal therapy related visit the client should be queried about
      1. Changes in personal history
      2. Signs and symptoms of complications related to the specific medication(s) they are taking

18.3.f. Table: Suggested Components of the Follow-up Visit

History	Physical Examination	Laboratory Tests and Diagnostic Imaging
Should include ▪ Mood changes ▪ Libido changes ▪ Sexual changes ▪ Mechanical hair removal issues	**Must** include ▪ BP Should include ▪ Assessment of progression of changes in o Male pattern hair growth o Breast/nipple development o Testicular volume o Breast and hip measurements or contour changes ▪ Other exams as indicated	Should include ▪ If using spironolactone measure serum potassium o At 4 weeks o At 3 months o Following any change in dose o Every 6 to 12 months with stable dose ▪ Serum prolactin once at 1 to 2 years after beginning therapy ▪ If using oral estrogen, consider LFTs

18.3.5 Management of Problems Associated with Therapy for MTFs

✓ FYI - Managing Erectile Dysfunction in MTFs

18.3.g. Table: Conditions/Signs/Symptoms that Develop While on Hormone Therapy in MTFs

Legend	
A	Contraindications — **must** discontinue
B	Special Conditions Requiring Further Evaluation — Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral **must** be based on protocols approved by the program director or medical director or in consultation with affiliate physician.
C	Other considerations - condition should be considered in risk/benefit analysis for continuing hormone

Management of Conditions/Signs/Symptoms	A	B	C
WITH ESTROGEN USE			
Elevated LFTs (ALT and AST >3 times ULN) - discontinue hormones during workup ▪ Consider other causes such as ○ Drug or chemical use — High doses of acetaminophen, alcohol, other hormone use, herbal products, OTC meds or other prescription drugs (especially phenytoin, valproic acid, isoniazid, sulfonamides, nitrofurantoin, rifampin, niacin, statins and methyldopa). ○ Hepatitis — Consider testing for hepatitis A, B or C. • If positive for hepatitis, withhold hormones until liver enzymes are normal • Refer acute hepatitis C. • Consider referral to gastroenterologist if negative viral studies and persistent elevation. ▪ If workup is negative, withhold hormones for 2 months and retest. ○ If results are normal or at baseline, hormone therapy was the probable cause of the elevation. • If hormones are restarted, use a lower or less frequent dose and monitor LFTs closely. • Consider switching to a different formulation. ▪ Refer out for persistent LFT abnormalities.	●		
Immobilization, prolonged (may be due to planned surgery) - discontinue estrogen 1 to 2 weeks prior to surgery, resume when recovered	●		

Management of Conditions/Signs/Symptoms	A	B	C
Lipid abnormalities		●	
Prolactin elevation – if results are			
▪ < 25 — continue to monitor			●
▪ 25 to 40 — requires close follow-up with visual fields check, BP, fundoscopic exams, and evaluate for misuse of estrogen or other hormonal products. Continue to monitor prolactin routinely.			●
▪ > 40 — examinations as above, plus decrease hormones by half or discontinue treatment, and recheck prolactin in 6 to 8 weeks.		●	
▪ > 100 — examinations as above, discontinue treatment, and recheck in 6 to 8 weeks. ○ If persistent elevation, refer to endocrinologist. ○ If level is falling, restart at lower dose and recheck in 6 to 8 weeks.	●		
WITH SPIRONOLACTONE USE			
Hyperkalemia - repeat measurement and ▪ If repeat potassium > 6.0 ○ Immediately discontinue spironolactone ○ **Must** refer to emergency room	●		
▪ If repeat potassium mildly elevated, decrease dose or discontinue; check urine electrolytes		●	
Intolerance to spironolactone ▪ Consider finasteride			●

18.3.6 Transmale Cross-Sex Hormone Therapy

I. Initiate testosterone therapy according to Table 18.3.h.
   A. General Principles of Therapy
      1. Goal is to use the lowest dose needed to maintain the desired clinical result.
      2. Precautions should be taken to maintain bone density.
      3. Oral forms should not be prescribed due to harmful effect on liver.
      4. Allergy Alert
         a. When prescribing testosterone for IM use, be sure to assess for allergy to vehicle.
         b. Commercially available testosterone cypionate is suspended in cottonseed oil which is more allergenic.
         c. Commercially available testosterone enanthate is suspended in sesame oil which is less allergenic.

d. Compounding pharmacies may be able to provide testosterone cypionate in sesame oil.

5. Options for FDA approved injectable testosterone are currently limited so compounded testosterone in oil may be appropriate and may be prescribed by waiver only.

18.3.h. Table: Testosterone Formulations and Dosing

- ✓ FYI – Prescribing Injectable Testosterone
- ✓ FYI - Effects and Time Course for Masculinizing Therapy
- ✓ FYI - Common Side Effects of Masculinizing Therapy

Medication	Dose	Comments: All non-oral forms are first choice for hormone therapy
Testosterone cypionate Testosterone enanthate	Start: 50-200 mg IM q week Start: 50-200 mg IM q week Titrate to effect: Usual dose: 200 mg q 2 weeks, but dosage may be split, e.g., 100 mg q week. If clients have side effects attributable to peak or trough levels, doses are changed to q 7 to 10 days depending on client's preference.	Clients should be taught to self-inject. A family member or friend may be taught to perform the injection for the client. Decrease dosing if client experiences excessive libido or problems with acne; may dose every 1 to 2 weeks. After masculinization, clients may prefer gel, cream or patch so as to not have to use injections.
Testosterone topical 1% (AndroGel, Testim) Testosterone topical 1% (AndroGel, Testim) (continued)	2.5 to 10 g/d	Avoid skin to skin contact with others. This can be easily avoided by applying at a time of day when one will not be intimate, and by applying on areas where contact is unlikely, such as back of leg. May be recommended if slower progress is desired, or for ongoing maintenance after desired virilization has been accomplished with intramuscular injection.

Medication	Dose	Comments: All non-oral forms are first choice for hormone therapy
Testosterone patch (Androderm) Available in 2 mg/24 and 4 mg/24 h patches	2 to 8 mg/d	May be recommended if slower progress is desired, or for ongoing maintenance after desired virilization has been accomplished with intramuscular injection.

18.3.7 Follow-up FTM Therapy

I. Client **must** be advised to return for evaluation if a significant hormonal therapy problem is suspected, with follow-up and surveillance of special conditions as per protocol.
II. Routine follow up visits are indicated at 4 weeks, 3 months, 6 months and every 6 to 12 months thereafter.
III. Follow-up labs are done generally 3 months after increases in testosterone and every 6 to 12 months thereafter (6 months for older clients, clients with other serious illnesses, and 12 months for young healthy clients).

18.3.i. Table: Suggested Components of the FTM Follow-up Visit

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Should include ▪ Changes in personal history ▪ Mood changes ▪ Libido changes ▪ Sexual changes ▪ Status of menses o Cessation of menses does not indicate cessation of ovulation and, if indicated, contraception should be provided. o If menses persist, consider increased dosage or use of a progestin. • Medroxyprogesterone can be used	Should include ▪ Assessment of progression of changes in o Male pattern hair growth o Acne o Voice change o Body changes ▪ Other exams as indicated	Should include ▪ Testosterone (as indicated) o Check if after 6 months on stable regimen client is having a difficult time virilizing or stopping menses, or experiencing anxiety or other mood symptoms. o Measure mid-cycle between injections, at times in trough (especially if mood or energy symptoms). ▪ Hgb o Be sure to compare hgb levels to age-appropriate male levels. ▪ Lipid profile

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
for a short period of time. • GnRH agonists can be also be used. ▪ Signs and symptoms of complications related to specific medications taken		

IV. Management of problems associated with Therapy for FTM
  A. Lipid abnormality — Provide or refer for hyperlipidemia management
  B. Polycythemia
    1. If hemoglobin persistently elevated, lower testosterone and recheck hemoglobin in 2 to 3 months.
    2. Address tobacco use, as indicated.
    3. If persistent, consider shortening dose interval or change to transdermal preparation.
    4. If persistent polycythemia after these interventions, consult with Program Director and consider referral for further evaluation.

18.4 ADDITIONAL INFORMATION

18.4.a. Table: For Your Information

Section	Topic	Detail
18.2	Terminology	**Biological sex** – male/female classification based on chromosomes, endocrine system and external genitalia **Gender identity** – sense of one's self as male or female **Gender expression** – external characteristics and behaviors (dress, mannerisms, social interactions) **Transgender** – umbrella term for those who experience and/or express gender differently from the sex assigned at birth. Individuals may identify as any of the terms listed below. ▪ FTM – transgender man, female to male, transmale, transman ▪ MTF– transgender woman, male to female, transfemale, transwoman ▪ Gender queer – neither male nor female, gender neutral, "out of the gender binary" ▪ Bigender – manifesting behaviors of either females or males at various times

Section	Topic	Detail
		▪ Androgynous – neither distinguishably masculine nor feminine ▪ Gender variant – not conforming to dominant gender norms ▪ Trans-questioning or gender questioning - exploring gender issues
18.2.a.	Physical Exam Considerations Unique to Transgender Clients	In general, when performing a physical exam on a transgender client, the exam should be tailored to the organs present rather than the perceived gender of the client. In addition, there are some special circumstances to consider. Pay particular attention to the skin. In MTF clients the use of false eyelashes, fingernails, wigs, padded garments, tight packing and silicone injections may cause problems. In FTM clients skin changes and vulvar irritation may arise secondary to the use of silicone injections, breast binders, and packers (to simulate the appearance of male genitals).
18.2.a.	The Significance of Silicone	Transmale persons may use silicone in the pectoral, gluteal and calf areas to produce a more masculine appearance. Common sites of silicone injection in transfemale persons are the lips, cheekbones, thighs and hips. Injections may be performed by unscrupulous practitioners or using questionable product and technique. Risks include local and systemic infection, embolization, painful granuloma formation, and a systemic inflammatory syndrome that can be fatal. Clients should be screened regarding current or past use of liquid silicone. Physical examination for signs of use is also important. Users of liquid silicone should be counseled against the practice and actively supported in adopting alternatives including medically prescribed cross gender hormonal therapy.
18.2.b.	Cervical Cancer Screening and Pelvic Examination in FTM Clients	Pap test can be traumatic for the FTM client both because of atrophic vaginal tissue as well as gender identity. In addition to approaches used for others with atrophic changes or trauma (e.g. moving speculum slowly, visualization, deep breathing, pressure on the muscles of the introitus before insertion of speculum to assist in relaxation and prevent vaginismus), it may be helpful to consider a non-traditional approach such as not using stirrups. Testosterone therapy causes significant atrophy in the cervical epithelium, mimicking dysplasia on the Pap test. Indicate that the client is on testosterone on the Pap requisition so that the pathologist can interpret the findings. Follow current guidelines for screening.

Section	Topic	Detail
18.2.b.	Prostate Cancer Risk in MTF	The prostate is not removed in transfemale genital surgery. Of note, the prostate is located anterior to the neovagina and should be checked through the vagina rather than the rectum. Feminizing hormone therapy appears to decrease the risk of prostate cancer, but the degree of reduction is unknown. Cases of prostate cancer have been reported in transfemale clients on feminizing hormones, both before and after genital surgery. Androgen antagonists may decrease serum levels of PSA, further complicating interpretation of PSA results in the transfemale client who is taking feminizing hormones.
18.2.b.	STI Prevention for Transgender Clients	STI prevention should reflect the client's anatomical and psychosocial needs. For example, to prevent condom breakage, supplemental lubrication should be made available to transfemales who have had vaginoplasty as needed (neovagina is not self-lubricating, whether constructed with penile inversion or a sigmoid loop) and to transmales who take testosterone (as decreased estrogen can result in vaginal atrophy and dryness). The unique difficulties faced by transgender people in negotiating safe sex should be acknowledged and explored.
18.2.b.	Sexual Function Considerations	Transgender clients considering or currently taking hormones ▪ Testosterone therapy tends to increase libido among transmale clients. ▪ Genital tissue may atrophy in FTM clients causing recurrent vaginitis-like symptoms. This can be treated with low dose topical estrogens, similar to treatment of natal female menopausal vaginal atrophy. ▪ Feminizing hormone therapy tends to reduce libido, reduce erectile function, and decrease ejaculation among transfemale clients. Following genital surgery ▪ Sexual function (libido, arousal, pain with sex, and orgasm) after genital surgery is variable and depends on pre-operative sexual function, the type of surgery performed, and hormonal status.
18.2.b.	Referral Considerations for Transgender Clients	An affiliate referral list for transgender clients should include listings of ▪ Licensed and/or certified mental health professionals with experience in transgender care. ▪ Social support and other resources in the community specifically knowledgeable of or dedicated to the needs of transgender individuals.
18.3.1	Considerations When Prescribing Hormonal Therapies	There is no evidence that custom compounded bioidentical hormones are safer or more effective than FDA-approved products. Further, compounded hormone products are generally not considered standard of care by PPFA.

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>18.3.a.</td><td>Determination of Hormone Levels</td><td>There are few indications for the use of baseline or serial monitoring of plasma levels of estradiol or testosterone. The variability of levels is wide, levels do not expressly correlate with signs or symptoms, and clinical interpretation of effects is typically not improved.

However, baseline or serial hormone measurements may be medically useful at times, e.g. with moderate to severe hyperlipidemia or polycythemia. Additionally, levels may be desired by the client to help assist with hormone dosage, especially if the client feels that a standard dose is not adequate. Interpreting hormone levels may require consultation with an experienced provider.</td></tr>
<tr><td>18.3.c.</td><td>Effects and Time Course of Feminizing Hormones[R3]</td><td>
<table>
<tr><th>Effect</th><th>Expected Onset</th><th>Expected Time to Maximum Effect[1]</th></tr>
<tr><td>Body fat redistribution</td><td>3 to 6 months</td><td>2 to 5 years</td></tr>
<tr><td>Decreased muscle mass/ strength</td><td>3 to 6 months</td><td>1 to 2 years[2]</td></tr>
<tr><td>Softening of skin/decreased oiliness</td><td>3 to 6 months</td><td>unknown</td></tr>
<tr><td>Decreased libido</td><td>1 to 3 months</td><td>1 to 2 years</td></tr>
<tr><td>Decreased spontaneous erections</td><td>1 to 3 months</td><td>3 to 6 months</td></tr>
<tr><td>Male sexual dysfunction</td><td>variable</td><td>variable</td></tr>
<tr><td>Breast growth</td><td>3 to 6 months</td><td>2 to 3 years</td></tr>
<tr><td>Decreased testicular volume</td><td>3 to 6 months</td><td>2 to 3 years</td></tr>
<tr><td>Decreased sperm production</td><td>variable</td><td>variable</td></tr>
<tr><td>Thinning and slowed growth of body and facial hair</td><td>6 to 12 months</td><td>> 3 years[3]</td></tr>
<tr><td>Male pattern baldness</td><td>No regrowth, loss stops 1-3 months</td><td>1 to 2 years</td></tr>
<tr><td colspan="3">[1] Estimates represent published and unpublished clinical observations.
[2] Significantly dependent on amount of exercise.
[3] Complete removal of male facial and body hair requires electrolysis, laser treatment, or both.</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td>18.3.5</td><td>Managing Erectile Dysfunction Associated with Feminizing Therapy</td><td>Consider adjusting the dose of hormones, while addressing the client's desires regarding the degree of feminization and level of erectile function. If this is unsuccessful, pharmacologic treatment of erectile dysfunction may be considered.</td></tr>
<tr><td>18.3.h.</td><td>Common Side Effects of Masculinizing Therapy</td><td>Acne and varying degrees of male pattern hair loss (androgenic alopecia) are common side effects of masculinizing hormone therapy. Affiliates should develop local protocols to assist clients in minimizing/managing these effects.</td></tr>
<tr><td>18.3.h.</td><td>Effects and Time Course for Masculinizing Therapy[R3]</td><td>
<table>
<tr><th>Effect</th><th>Expected Onset</th><th>Expected Time to Maximum Effect[1]</th></tr>
<tr><td>Skin oiliness/acne</td><td>1 to 6 months</td><td>1 to 2 years</td></tr>
<tr><td>Facial/body hair growth</td><td>3 to 6 months</td><td>3 to 5 years</td></tr>
<tr><td>Scalp hair loss</td><td>>12 months[2]</td><td>variable</td></tr>
<tr><td>Increased muscle mass/strength</td><td>3 to 6 months</td><td>2 to 5 years[3]</td></tr>
<tr><td>Body fat redistribution</td><td>1 to 3 months</td><td>3 to 6 months</td></tr>
<tr><td>Cessation of menses</td><td>2 to 6 months</td><td>N/A</td></tr>
<tr><td>Clitoral enlargement</td><td>3 to 6 months</td><td>1 to 2 years</td></tr>
<tr><td>Vaginal atrophy</td><td>3 to 6 months</td><td>1 to 2 years</td></tr>
<tr><td>Decreased sperm production</td><td>variable</td><td>variable</td></tr>
<tr><td>Deepened voice</td><td>3 to 12 months</td><td>1 to 2 years</td></tr>
<tr><td colspan="3">[1] Estimates represent published and unpublished clinical observations.
[2] Highly dependent on age and inheritance; may be minimal.
[3] Significantly dependent on amount of exercise.</td></tr>
</table>
</td></tr>
<tr><td>18.3.h.</td><td>Prescribing Injectable Testosterone</td><td>Clients using testosterone IM will require injection supplies including
Syringes
18 g needles for drawing up the testosterone from the vial
23 g needles, 1 ½ " length for IM injection
25 gauge needle, and/or 1" length can be used if the client desires smaller gauge or shorter needles</td></tr>
</table>

Section	Topic	Detail
		▪ Some clients prefer a single needle for both drawing up medication and for injecting, and use a 22 gauge 1" or 1 ½" for both Sample starting prescription: *Testosterone 200 mg/mL in sesame oil (or cottonseed oil) 0.5 mL IM q week, #1 10 mL vial.* Supplies for a 10 mL vial with weekly dosing include 3 mL syringes (#20), 18 g needle for drawing up oil(# 20), 23 g 1 ½ " needles for administering IM (#20). Some clients prefer using a single 22 g 1" or 1 ½" needle for drawing up and injecting.

18.4.b. Table: References

Section	R#	Reference
18.2.2	R1	Center of Excellence for Transgender Health - UCSF. *General Prevention and Screening*. 2012. http://transhealth.ucsf.edu/trans?page=protocol-screening (accessed June 2012).
18.2.2	R2	Feldman, Jamie L. and Goldberg, Joshua. *Transgender Primary Medical Care: Suggested Guidelines for Clinicians in British Columbia*. Vancouver, BC: Vancouver Coastal Health, Transcend Transgender Support & Education Society, and the Canadian Rainbow Health Coalition, 2006.
FYI Feminizing FYI Masculinizing	R3	WPATH. *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*. The World Professional Association for Transgender Health, Inc., 2011.

18.4.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIIC	CIIC Feminizing (Male to Female) Therapy CIIC Masculinizing (Female to Male) Therapy	Part 3, Chapter 02_18

Type	Resource	Location
Client Education	✓ Resources for Name and Gender Change for Public Documents - Transequality ✓ Resources for Name and Gender Change for Public Documents – Transgender Law	

18.4.d. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ Callen-Lorde: Protocols for the Provision of Hormone Therapy ✓ Center of Excellence for Transgender Health: General Prevention and Screening ✓ Special Issues in Women's Health: Health Care for Transgendered Individuals ✓ TransCare Project (Vancouver) ✓ TransLine: Project HEALTH ✓ The World Professional Association for Transgender Health, Inc. (WPATH) ✓ Standards of Care for Gender Identity Disorders, 7th Edition	
	Making Your Health Center Transgender Friendly	Part 3, Chapter 02_18
	Provider's Handbook on Culturally Competent Care: Lesbian, Gay, Bisexual and Transgender Population	To obtain copies of the handbook, contact: Kaiser Permanente National Diversity Department One Kaiser Plaza, 22 Lakeside Oakland, CA 94612 510-271-6663
Training	**CAL Course** Expanding LGBTQ Cultural Competency Series	

CHAPTER 19: ULTRASOUND SERVICES

Revised June 2014

Chapter 19 Table of Contents

CHAPTER 19: ULTRASOUND SERVICES

Revised June 2014

19.1 CLIENT EDUCATION AND INFORMED CONSENT

19.1.1 Requirements

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in the record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

19.1.a. Table: Requirements for Written Materials as indicated

Document	Document #	**Must** sign	**Must** offer
Release When Test/Service/Consultation Will Not Be Obtained As Recommended		Once	
Request for Medical Services or Request for Surgery or Special Procedures		If not already in the medical record	Once

II. Additionally, the client **must** be

A. Given the option to view the ultrasound image. Clients who request a copy of the ultrasound image should be accommodated whenever possible.

B. Given the option of being informed of a multiple pregnancy upon diagnosis by ultrasound

1. If there is evidence of a multiple pregnancy and the client requests to be told, she **must** be informed before the abortion begins, i.e., before cervical preparation or the administration of pain medications.
2. Client **must** also be informed about the limitations of this diagnosis, including the potential of spontaneous abortion — vanishing twin syndrome.

C. Informed of ultrasound evidence of fetal demise or a failed pregnancy and provided with appropriate information

D. Informed of limitations of the ultrasound being performed. For example, an ultrasound for pregnancy dating only, would not be evaluating fetal anatomy. Information may be given verbally.

19.2 PELVIC ULTRASOUND

✓ FYI — Performance and Interpretation

✓ FYI — Interpreting Ultrasound Information

19.2.1 Indications – include but are not limited to

I. Evaluation and management of gynecological conditions
II. IUC localization
III. Provision of infertility services

19.2.2 Components – depending upon reason for ultrasound, the following structures should be evaluated as indicated

I. Uterus
   A. Size, shape and orientation
   B. Endometrium – thickness and presence of abnormalities
   C. Myometrium – contour changes, echogenicity and masses
   D. Cervix – contour changes, echogenicity and masses
II. Adnexa
   A. Size of ovaries (width, length, depth)
   B. Presence of masses (if present, document size, echogenicity and internal characteristics)
III. Evaluation of cul-de-sac — for presence of free fluid or masses

19.3 OBSTETRIC ULTRASOUND

Obstetric ultrasound can be divided into 3 subtypes outlined below.

19.3.1 First Trimester Ultrasound

I. Indications — include but are not limited to
   A. Estimation of gestational age in abortion care
   B. Evaluation of early pregnancy and management of complications
   C. As part of prenatal care
II. Required Components
   A. Evaluation of uterus, cervix and adnexa for presence of gestational sac (document location)
   B. Evaluation of gestational sac for presence of yolk sac or embryo
   C. Classification of pregnancy according to the following:
      1. Definite Ectopic Pregnancy (EP): Extrauterine gestational sac with yolk sac and/or embryo (with or without cardiac activity)

2. Probable EP: Inhomogeneous adnexal mass or extrauterine sac-like structure
3. Pregnancy of Unknown Location (PUL): No signs of either EP or intrauterine pregnancy (IUP)
4. Probable IUP: Intrauterine echogenic sac-like structure
5. Definite IUP: Intrauterine gestational sac with yolk sac and/or embryo (with or without cardiac activity)

✓ FYI – Pregnancy of Unknown Location

D. Crown-rump length of embryo
E. Presence or absence of cardiac activity
F. Fetal number

III. Gestational dating in the first trimester
A. When dating early pregnancy, images should be taken using a longitudinal view of the uterus for clear documentation.
1. If accurate measurements can be made in the longitudinal view, no additional views are required. However, additional views may be necessary to assess gestational age.
B. Crown-rump length is a more accurate indicator of gestational age than is mean gestational sac diameter. However, mean gestational sac diameter may be recorded when an embryo is not identified.
C. If mean gestational sac diameter is to be used, 3 dimensions **must** be measured in 2 planes and at least 2 images **must** be documented in the client's medical record.

IV. Calculation of gestational age via ultrasound may be performed by either of the following
A. Pre-programmed software in the ultrasound machine.
B. Standard formulae, using mean sac diameter or embryonic length:
1. (Length + Height + Depth) / 3 = mean sac diameter in mm + 30 = gestational age in days (± 3 days)
2. embryonic length in mm + 42 = gestational age in days

✓ FYI — Ultrasound Measurements for Gestational Dating

19.3.2 Standard Second- or Third-trimester Examination

I. Indications — include but are not limited to
A. Prenatal care

II. Required Components
A. Fetal cardiac activity, number and presentation
B. Estimate of amniotic fluid volume

C. Placental location, appearance, and relationship to the internal cervical os
D. Umbilical cord visualization and identification of the number of vessels in the cord
E. Gestational age assessment
F. Fetal anatomic survey (after 18 weeks gestation)

19.3.3 Limited Examination– performed when a specific question requires investigation

I. Indications — include but are not limited to
   A. Mid-trimester abortion care
   B. Prenatal care
II. Components — when performed for mid-trimester abortion care **must** include
   A. All components of first trimester examination, when applicable
   B. Placental localization in a scarred uterus
   C. At least 2 measurements — one of which should be a biparietal diameter (BPD) or head circumference (HC).

19.3.4 Specialized Examination

I. Indications — include but are not limited to
   A. Abortion care
   B. Prenatal care
II. Components — specialized examinations include situations such as
   A. Doppler ultrasound to rule out abnormal placentation
   B. Fetal biophysical profile (BPP) in prenatal care

Important Information: Use of Ultrasound vs. LMP for Gestational Dating

The American College of Obstetricians and Gynecologists (ACOG) recommends that when dating a pregnancy, ultrasound-established dates should take preference over menstrual dates only when the discrepancy is greater than 7 days in the first trimester and greater than 10 days in the second trimester.

Many affiliates rely primarily on ultrasound dating of pregnancy prior to induced abortion as LMP may be unreliable and difficult to obtain. The issue was addressed by the National Medical Committee (2011) who made the following recommendations:

- Affiliates may date pregnancies using ultrasound to confirm LMP (ACOG recommendation, above) or by ultrasound alone.
- There **must** be consistency within the affiliate (i.e. if the affiliate provides abortion care and prenatal care, they cannot use different methods to date pregnancy in different services).
- Affiliates **must** follow all state and local regulations pertaining to pregnancy dating where applicable
- Affiliates with health centers in multiple states **must** maintain consistency on a state by state level

19.4 REFERRAL

19.4.1 Requirements

I. Referral out of the affiliate for ultrasound evaluation or other evaluation and management is required for
   A. Poor visualization of anatomical structures with the affiliate ultrasound
   B. Suspected placenta accreta or percreta in second or third trimester
   C. A visualized or suspected complex adnexal mass
   D. Known malignancy
   E. Suspected malignancy based on affiliate sonogram
   F. When a more comprehensive ultrasound is indicated
   G. Breast evaluation by imaging – breast ultrasound **must not** be performed at affiliate
   H. Prenatal care
      1. First trimester prenatal ultrasound if nuchal translucency is part of affiliate's program for aneuploidy screening
         a. Ultrasound for nuchal translucency **must** only be performed by NTQR-specially-trained experts/centers (https://www.ntqr.org/SM/default.aspx) using appropriate equipment and specific guidelines for measuring.
      2. 18-20 week prenatal ultrasound to assess fetal anatomy

19.5 ADDITIONAL INFORMATION

19.5.a. Table: For Your Information

Section	Topic	Detail
19.2	Performance vs. Interpretation of Ultrasound	▪ Performance of the ultrasound is the act of doing the examination — taking the measurements, creating a printed image, and reporting the findings for interpretation. ▪ Interpretation of the ultrasound is reviewing the findings, providing an impression or conclusion, and approving and signing the final written report.
19.2	Interpreting Ultrasound Information	▪ **Discriminatory Zone** — An hCG level of 1500-2000 mIU/ml is called the discriminatory zone because at that level a gestational sac should be visible with transvaginal ultrasound. ▪ **Landmarks of an Intrauterine Pregnancy** — The gestational sac is visualized with transvaginal ultrasound approximately one week earlier than with abdominal ultrasound. ▪ **Characteristics of a True Gestational Sac** o round or elliptical shape in longitudinal and transverse views o surrounded by an echogenic rim (choriodecidual reaction) o located in uterine fundus o sac is not directly midline, but implanted eccentrically (to one side of the uterine cavity line, without displacing it). ▪ **Pseudogestational Sacs** - The pseudogestational sac or pseudosac is an intrauterine accumulation of blood and/or fluid that has sloughed from the decidua. They occur in 10-15 percent of ectopic pregnancies. Pseudosacs may have an irregular shape, lack a choriodecidual reaction, and are usually found midline in the uterine cavity. ▪ **Size of Gestational Sac** — The gestational sac is usually present on vaginal ultrasound at about 35 days after LMP, and it grows an average of one mm/day. Depending on the resolution of the ultrasound equipment and the skill of the operator, the sac should be visible on ultrasound between 30 and 35 days LMP. ▪ **Yolk Sac** — The yolk sac is derived from embryonic tissue. When a yolk sac is seen within a gestational sac located in the endometrial cavity, there is nearly 100 percent certainty that the pregnancy is intrauterine. ▪ **Embryonic Pole Length** — The embryonic pole length is usually visible at about 42-48 days. It grows about one mm/day.

Section	Topic	Detail
19.3.1.	Pregnancy of Unknown Location[R1]	Pregnancy of unknown location (PUL) is a descriptive term applied to clients with a positive pregnancy test who have no evidence of either an intrauterine pregnancy (IUP) or ectopic pregnancy (EP) on ultrasound. This term is a classification and not a final diagnosis. Women with a PUL **must** be followed until a final diagnosis can be made. A consensus statement published by the International Society of Ultrasound in Obstetrics and Gynecology suggests that the incidence of PUL as an ultrasound finding should not be more than 15%.
19.3.1	Ultrasound Measurements for Gestational Dating	▪ Gestational dating is most accurately determined in the first half of pregnancy. First-trimester crown-rump measurement is the most accurate means for ultrasound dating of pregnancy. ▪ Beyond the first trimester, a variety of measurements can be used to estimate gestational age. ▪ Pregnancies should not be redated after a date has been calculated from an accurate earlier scan that is available for comparison. ▪ Per National Medical Committee recommendations (2011), biparietal diameter (BPD) and/or head circumference (HC) are preferable when dating a pregnancy prior to abortion in the second trimester. o HC is the most predictive parameter between 14-22 weeks gestation o HC is more reliable than BPD if the calvarium is abnormally shaped. ▪ Combining several parameters (some combination of BPD, HC, abdominal circumference (AC) and femur length (FL) improves the prediction of gestational age slightly over head circumference alone. ▪ If BPD and HC cannot be obtained, femur length alone is reliable after 14 weeks gestation or it may be combined with AC.

19.5.b. Table: References

Section	R#	Reference
19.2 19.3		Association of Women's Health, Obstetric and Neonatal Nurses. Ultrasound Examinations Performed by Nurses in Obstetric, Gynecologic, and Reproductive Medicine Settings: Clinical Competencies and Education Guide, 3rd Edition, 2010
19.2 19.3		American Institute of Ultrasound in Medicine. AIUM PRACTICE GUIDELINES—Documentation of an Ultrasound Examination, 2008

Section	R#	Reference
19.2 19.3		American Institute of Ultrasound in Medicine. AIUM PRACTICE GUIDELINES— Obstetric Ultrasound, 2007
19.2 19.3		American Institute of Ultrasound in Medicine. AIUM PRACTICE GUIDELINES— Female Pelvis, 2006
19.2 19.3		American College of Obstetricians and Gynecologists. ACOG Practice Bulletin: Ultrasonography in Pregnancy, Number 101, 2009
19.3 FYI	R1	Barnhart K, et al. Pregnancy of unknown location: A consensus statement of nomenclature, definitions, and outcome. *Fertil Steril* 2011;95:857-866.

19.5.c. Table: Associated Resources for Staff

Type	Resource	Location
Training	**CAL Courses** Ultrasound in Abortion Care Staff Training Series Ultrasound Program Director Proficiency Exam (Part 1-3)	

CHAPTER 20: VACCINATION SERVICES

June 2014

Chapter 20 Table of Contents

20.1 VACCINATIONS

20.1.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

20.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give
Personal Immunization Record that includes date, vaccine(s) given, and health center name and address			Or update with administration of each vaccine
Release When Test/Service/Consultation Will Not Be Obtained		Once	
Vaccine Information Sheet (VIS) for each vaccine*,**			●
*In the case of minors, federal law requires the VIS be given to a parent or legal guardian. **If a single VIS is not available for a combination vaccine, use individual VISs for each component vaccine.			

20.1.2 Evaluation

I. **Must** be performed to determine client eligibility to receive vaccine(s). Determine eligibility based on the following
   A. Client history:
      1. Vaccination history
      2. Current or planning pregnancy
      3. Medications
      4. Current moderate to severe acute illness, with or without fever
      5. Allergies to food, latex, medications, or a vaccine component
      6. History of adverse reaction after receiving vaccine
      7. Immune compromise
      8. Chronic medical conditions, such as asthma, diabetes, heart or kidney disease, HIV
   B. Contraindication and precautions

✓ Contraindications and precautions as indicated by the CDC Contraindications and Precautions to Commonly used Vaccines in Adults

C. CDC recommended schedules

✓ CDC Recommended Immunization Schedules

20.1.3 Administration

I. Vaccination Schedule
   A. All vaccines **must** be administered according to the CDC Recommended Immunization Schedules and should be recommended for clients in the youngest age group at risk for experiencing the disease for which efficacy and safety have been demonstrated. Vaccines should be administered as closely as possible to recommended vaccination schedules.

II. Technique
   A. Oral and intranasal vaccines - administer according to ACIP Guidelines.
   B. Injectable vaccines – administer according to Table 20.1.b.
      1. General considerations
         a. Reconstitution
            i. Vaccines **must** be reconstituted according to manufacturer guidelines.
            ii. Use only the specific diluent supplied by manufacturer for that vaccine.
            iii. Reconstitute vaccine just before administering.
            iv. Use all diluent supplied.
         b. Preparing syringe
            i. Shake vial to mix thoroughly.
            ii. Draw vaccine dose into syringe when ready to administer.
         c. Syringe selection – a separate needle and syringe **must** be used for each injection.
         d. Needle selection – should be based on prescribed route, size of the client, volume and viscosity of the vaccine, and injection technique.
         e. Needle-free injections – **must** follow manufacturer guidelines for use.

20.1.b. Table: Injectable Vaccine Administration

Injection	Age	Needle Length	Injection Site
Subcutaneous (SC) injection ▪ Use a 23- to 25-gauge needle. ▪ Choose injection site that is appropriate to client's age and body mass. ▪ Administer at 45° angle.	Infants (1 to 12 months old)	5/8"	Fatty tissue over anterolateral thigh muscle
	Children 12 months or older, adolescents, and adults	5/8"	Fatty tissue over anterolateral thigh muscle or fatty tissue over triceps
Intramuscular (IM) injection ▪ Use a 22- to 25-gauge needle. ▪ Choose injection site that is appropriate to client's age and body mass. ▪ Administer at 90° angle.	Newborns (first 28 days)	5/8"*	Anterolateral thigh muscle
	Infants (1 to 12 months)	1"	Anterolateral thigh muscle
	Toddlers (1 to 2 years old)	1 to 1 1/4" 5/8 to 1"*	Anterolateral thigh muscle or deltoid muscle
	Children and teens (3 to 18 years old)	5/8 to 1"* 1 to 1 1/4"	Deltoid muscle or anterolateral thigh muscle
	Adults ≥19 years old:		
	○ < 130 lbs	5/8 to 1"	Deltoid muscle
	○ Female 130 to 200 lbs ○ Male 130 to 260 lbs	1 to 1 1/2"	Deltoid muscle
	○ Female > 200 lbs ○ Male > 260 lbs	1 1/2"	Deltoid muscle

*A 5/8" needle may be used for clients weighing less than 130 lbs for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not pinched, and the injection is made at a 90 degree angle.

20.1.c. Table: Special Considerations

Consideration	Guidance
Multiple Doses	**Spacing** May accelerate schedule when necessary, using intervals between doses that are shorter than recommended. ▪ Avoid administration of vaccines at intervals shorter than these minimum intervals or at an age that is younger than the minimum age.

Consideration	Guidance
	▪ Doses administered ≤4 days before the minimum interval or age are acceptable. ✓ CDC Catch-up Immunization Schedule Doses of any vaccine administered ≥5 days earlier than the minimum interval or age should not be counted as valid doses and should be repeated as age appropriate. ▪ Space repeat dose after the invalid dose according to the recommended minimum interval. ▪ Repeat dose should be considered as the valid second dose. ✓ CDC TABLE 1. Recommended and minimum ages and intervals between vaccine doses **Lapsed Schedule** When an interruption in the vaccination schedule occurs, the entire series of a vaccine or toxoid or addition of extra doses is not required. Administer next dose. The only exception is oral typhoid vaccine.
Simultaneous administration — refers to administering ≥1 vaccine on the same clinic day, at different anatomic sites, and not combined in the same syringe.	Administer all vaccines for which a client is eligible at the time of a visit simultaneously.
Combination vaccines — refers to product containing components that can be divided equally into independently available routine vaccines.	Use combination vaccines when possible instead of separate injections of the equivalent component vaccines. ▪ An exception is the first dose of MMRV. Unless a parent or caregiver expresses a preference for MMRV vaccine, MMR and varicella vaccine should be administered separately for the first dose for children aged 12 to 47 months. Separate vaccines **must not** be combined into the same syringe to administer together unless mixing is indicated for the client's age and is explicitly specified on the FDA-approved product label inserts.
Interchangeability of formulations	May use a combination vaccine interchangeably with monovalent formulations and other combination products with similar component antigens produced by the same manufacturer to continue the vaccination series. Doses of vaccine in a series should come from the same manufacturer. ▪ If this is not possible or if the manufacturer of doses given previously is unknown, providers should administer the vaccine that they have available.

Consideration	Guidance
Extra doses of vaccine	Avoid administration of a combination vaccine when only a single component is indicated. Using combination vaccines containing certain antigens not indicated at the time of administration to a client may be justified when ▪ The extra antigen is not contraindicated. ▪ Products that contain only the needed antigens are not readily available. ▪ Potential benefits to the client outweigh the potential risk for adverse events associated with the extra antigens. ○ Consider benefits and risks of administering the combination vaccine with an unneeded antigen and discuss with the client or parent. ○ When inactivated or subunit vaccines are administered, consider the reactogenicity of the vaccine in balancing the benefits and risks of extra doses.
Interchangeability of single-component vaccines from different manufacturers	Avoid deferring vaccine because the brand used for previous doses is not available or is unknown. Use the higher number of doses for series completion if different brands of a particular vaccine require a different number of doses for series completion and both are administered to a client.
Nonsimultaneous administration	When simultaneous administration is not possible, may administer any inactivated vaccine at any time before or after a different inactivated vaccine or live vaccine. Injectable or nasally administered live vaccines not administered on the same day should be administered ≥4 weeks apart.
Unknown vaccination status ✓ FYI - Serologic Testing for Immunity	Avoid postponement of vaccinations if documentation of vaccination history is not available. Start clients on age-appropriate vaccination schedule if vaccination history records cannot be located within a reasonable time.

20.1.4 Adverse Reactions

I. Report promptly, accurately and completely, any adverse events following an immunization, using VAERS as appropriate.

✓ See Administrative Chapter 5 Medical Records, Documentation, and Reporting Requirements

20.1.5 Follow-up

I. Clients should be advised to return according to recommended vaccine schedule as indicated.

20.2 ADDITIONAL INFORMATION

20.2.a. Table: For Your Information

Section	Topic	Detail
20.1.c.	Serologic Testing for Immunity	Serologic testing for immunity is an alternative to vaccination for individual components of a vaccine (e.g. measles, rubella, hepatitis A, and tetanus). However, commercial serologic testing might not always be sufficiently sensitive or standardized for detection of vaccine-induced immunity (with the exception of hepatitis B vaccination at 1 to 2 months after the final dose) and research laboratory testing might not be readily available.

20.2.b. Table: References

Section	Reference
Throughout	Advisory Committee on Immunization Practices (ACIP). General Recommendations on Immunization. Jan 28, 2011. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm (accessed May 23, 2014).
Throughout	Immunization Action Coalition. Clinic Resources. n.d. http://www.immunize.org/clinic/ (accessed May 23, 2014).

20.2.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
Client Education	✓ Immunization Action Coalition Patient Information	

Type	Resource	Location
Required Forms	✓ CDC VIS Statements	

20.2.d. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ CDC Adult Immunization Schedule ✓ PPFA Influenza Vaccination Toolkit ✓ Immunization Action Coalition	
	✓ HPV Vaccination Toolkit	
Training	**CAL Course** How to Administer Intramuscular Injections	

CHAPTER 21: WELL-WOMAN CARE

Revised June 2014

Chapter 21 Table of Contents

CHAPTER 21: WELL-WOMAN CARE

Revised June 2014

21.1 PERIODIC WELL-WOMAN VISIT

21.1.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

21.1.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	Should give	May give
CI Cleaning Products					●
CI Fish					●
CI Fruits and Vegetables					●
CI Getting Enough Calcium and Vitamin D				●	
CI Lead					●
CI Personal Care Products					●
CI Pesticides					●
CI Plastic					●
CI Preconception Care				●	
CI Preventing Cardiovascular Disease				●	
CI Tobacco Smoke					●
Release When Test/Service/Consultation Will Not Be Obtained		Once			
Written information about any medication dispensed (package insert may be used)			●		
Written information, as appropriate				●	

21.1.2 Periodic Well-Woman Screening

I. Comprehensive Age-Specific Screening
   A. Components of visits — See Tables 21.1.b to 21.1.e for age-specific components of the well-woman visit.
   B. Frequency of visits —individualize the frequency of comprehensive age-specific screening visit based on the client's age, history, and identified risk factors

✓ FYI – Frequency of Periodic Well-Woman Visits

C. Return visits – client should be advised to return for
   1. Periodic well-woman screening visits at indicated intervals.
   2. Management/intervention follow-up visits — schedule depends on the specific findings.

21.1.b. Table: Periodic Well-Woman Assessments Ages 13 to 20

Periodic Well-Woman Assessments Ages 13 to 20		
History	Should include ▪ Reason for visit ▪ Health status — medical, surgical, and family ▪ Dietary/nutrition assessment ▪ Environmental risk assessment (See Part 3: Required Documents and Other Resources) ▪ Physical activity ▪ Use of complementary and alternative medicine ▪ Tobacco, alcohol, other drug use	▪ Abuse/neglect ▪ Intimate partner violence/ reproductive coercion (See Chapter 11) ▪ Sexual practices ▪ Reproductive life plan ✓ FYI - Reproductive Life Planning ▪ Contraceptive needs/Satisfaction ▪ OB history
Physical Examination	▪ Height, weight, BMI ▪ BP – routine beginning at age 18 (See Chapter 16) ▪ Secondary sexual characteristics (Tanner staging)	▪ Abdomen ▪ May include - Oral cavity
Laboratory Tests and Diagnostic Imaging	▪ Annual Chlamydia screening* if sexually active ▪ Dyslipidemia – once in late adolescence ▪ Periodic HIV screening if sexually active ▪ TB skin testing	▪ Diabetes (See Table 21.1.f.) ▪ Dyslipidemia – if elevated BMI ▪ As indicated ○ STI testing (See Chapter 9)

Periodic Well-Woman Assessments Ages 13 to 20		
Evaluation and Client Education	Should include ▪ Sexuality ○ Development ○ High-risk behaviors ○ Preventing unwanted/ unintended pregnancy ○ Postponing sexual involvement ○ Contraceptive options including EC ○ Preconception Care (See 21.2) ○ STI prevention ▪ Fitness and Nutrition ○ Dietary/nutrition assessment (including eating disorders) ○ Exercise ○ Folic acid supplementation (0.4 mg/d [avg risk]) ○ Calcium intake (1300 mg/day) ○ Vitamin D (400 IU/day) ▪ Psychosocial Evaluation ○ Depression - annually ○ Interpersonal/family relationships ○ Sexual identity ○ Personal goal development ○ Behavioral/learning disorders ○ Abuse/neglect ○ Intimate partner violence/reproductive coercion ○ Satisfactory school experience ○ Peer relationships	▪ Cardiovascular Risk Factors ○ Family history ○ Diabetes mellitus ○ Dyslipidemia ○ Hypertension ○ Obesity ▪ Health/Risk Behaviors ○ Hygiene (including dental) ○ Injury prevention • Safety belts and helmets • Recreational hazards • Firearms • Hearing • Occupational hazards • School hazards • Exercise and sports involvement ○ Skin exposure to ultraviolet rays ○ Suicide: depressive symptoms ○ Tobacco, alcohol, other drug use ○ Piercing and tattooing ○ Visual acuity screen– once before age 15 and repeat before age 18 ▪ Environmental Exposures
Vaccines	See Chapter 20 Vaccination Services	
* NAAT obtained by self-swab preferred for CT screening.		

21.1.c. Table: Periodic Well-Woman Assessments Ages 21 to 39

Periodic Well-Woman Assessments Ages 21 to 39	
History	Should include ▪ Reason for visit ▪ Health status — medical, surgical, and family ▪ Dietary/nutrition assessment ▪ Environmental risk assessment (See Part 3: Required Documents and Other Resources) ▪ Physical activity ▪ Use of complementary and alternative medicine ▪ Tobacco, alcohol, other drug use ▪ Abuse/neglect ▪ Intimate partner violence/ reproductive coercion (See Chapter 11) ▪ Sexual practices ▪ Reproductive life plan ✓ FYI - Reproductive Life Planning ▪ Contraceptive needs/Satisfaction ▪ OB history ▪ Urinary and fecal incontinence
Physical Examination	Should include ▪ Height, weight, BMI ▪ BP (See Chapter 16) ▪ abdomen ▪ CBE – every 1 to 3 years ▪ Pelvic exam*, as indicated ▪ Bimanual exam, as indicated ▪ May include – oral cavity
Laboratory Testing and Diagnostic Imaging	Should include ▪ Paps every 3 years ages 21 to 29; Paps every 3 years or co-tests every 5 years age 30 to 64 if criteria met for routine screening (See Chapter 4) ▪ Chlamydia screening** if sexually active — annually through age 25 ▪ Periodic HIV screening if sexually active ▪ As Indicated ○ Breast imaging ○ STI screening (See Chapter 9) ○ Genetic testing/counseling ○ Rubella titer ○ TB skin testing ○ Lipid profile ✓ FYI – Screening for Lipid Disorders ○ Colorectal cancer screening (See Table 21.1.f.) ○ Diabetes, as indicated (See Table 21.1.f.)

Periodic Well-Woman Assessments Ages 21 to 39	
Evaluation and Client Education	Should include ▪ Sexuality ○ High-risk behaviors ○ Contraceptive options including EC ○ Preconception Care ○ STI prevention ○ Sexual function ▪ Fitness and Nutrition ○ Dietary/nutrition assessment ○ Exercise ○ Folic acid supplementation (0.4 mg/d [avg risk]) ○ Calcium intake (1000 mg/day) ○ Vitamin D 400-800 IU/d ▪ Psychosocial Evaluation ○ Depression - annually ○ Interpersonal/ family relationships ○ Intimate partner violence/reproductive coercion ○ Work satisfaction ○ Lifestyle/stress ○ Abuse/neglect ○ Sleep disorders ▪ Cardiovascular Risk Factors ○ Family history ○ Hypertension ○ Dyslipidemia ○ Obesity ○ Diabetes mellitus ○ Lifestyle ▪ Health/Risk Behaviors ○ Hygiene (including dental) ○ Injury prevention • Safety belts and helmets • Occupational hazards • Recreational hazards • Firearms • Hearing • Exercise and sports involvement ○ BSA (See Chapter 3) ○ Skin exposure to ultraviolet rays ○ Suicide: depressive symptoms ○ Tobacco, alcohol, other drug use (See Chapter 16) ▪ Environmental Exposures ▪ Advance Directives
Vaccines	See Chapter 20 Vaccination Services
* A pelvic exam includes inspection of external genitalia and speculum exam. For an asymptomatic woman of any age, a pelvic exam should be performed during a periodic well-woman visit only when cervical cancer screening and/or STI screening is indicated and cannot be obtained by other modalities. **NAAT obtained by self-swab preferred for CT screening.	

21.1.d. Table: Periodic Well-Woman Assessments Ages 40 to 64

Periodic Well-Woman Assessments Ages 40 to 64	
History	Should include ▪ Reason for visit ▪ Health status — medical, surgical, and family ▪ Dietary/nutrition assessment ▪ Environmental risk assessment (See Part 3: Required Documents and Other Resources) ▪ Physical activity ▪ Use of complementary and alternative medicine ▪ Tobacco, alcohol, other drug use ▪ Abuse/neglect ▪ Intimate partner violence/ reproductive coercion (See Chapter 11) ▪ Sexual practices ▪ Reproductive life plan ✓ FYI - Reproductive Life Planning Contraceptive Needs/Satisfaction ▪ OB history ▪ Urinary and fecal incontinence
Physical Examination	Should include ▪ Height, weight, BMI ▪ BP (See Chapter 16) ▪ Abdomen ▪ CBE – annually (See Chapter 3) ▪ Pelvic exam*, as indicated ▪ Bimanual exam, as indicated ▪ Rectal exam (≥50 yrs old) ▪ May include – oral cavity
Laboratory Testing and Diagnostic Imaging	Should include ▪ Paps every 3 years or co-tests every 5 years if criteria met for routine screening (See Chapter 4) ▪ Mammography – annually, beginning at age 40 ▪ Total cholesterol and HDL or lipid profile ✓ FYI – Screening for Lipid Disorders ▪ Colorectal cancer screening at age 50 or age 45 if African-American (See Table 21.1.f.) ▪ Diabetes screening - every 3 years beginning at age 45 (See Table 21.1.f.) ▪ Periodic HIV screening, if sexually active (See Chapter 9) ▪ As Indicated o STI testing (See Chapter 9) o Diabetes screening < age 45 if risk factors o Total cholesterol and HDL or lipid profile before age 45 o BMD screening baseline at age 60 if risk factors (See Chapter 8) o TB skin testing o Colorectal cancer screening before age 50 o HCV infection – if risk factors, or once, in those born between 1945 and 1965 o Lung cancer screening by CT**

Periodic Well-Woman Assessments Ages 40 to 64	
Evaluation and Client Education	Should include ▪ Sexuality ○ High-risk behaviors ○ Contraceptive options including EC ○ Preconception Care ○ STI prevention ○ Sexual function ▪ Fitness and Nutrition ○ Dietary/nutrition assessment ○ Exercise ○ Folic acid supplementation (0.4 mg/d until age 50 [avg risk]) ○ Calcium intake (< 50: 1000 mg/d; ≥ 50: 1200mg/d) ○ Vitamin D intake (< 50: 400-800 IU; ≥ 50: 800-1000 IU) ▪ Psychosocial Evaluation ○ Depression - annually ○ Interpersonal/ family relationships ○ Intimate partner violence/reproductive coercion ○ Work satisfaction ○ Lifestyle/stress ○ Retirement planning ○ Sleep disorders ▪ Cardiovascular Risk Factors ○ Family history ○ Hypertension ○ Dyslipidemia ○ Obesity ○ Diabetes mellitus ○ Lifestyle ○ Daily aspirin – ages 55 to 79 ▪ Health/Risk Behaviors ○ Hygiene (including dental) ○ Hormone therapy ○ Injury prevention • Safety belts and helmets • Occupational hazards • Recreational hazards • Firearms • Hearing • Exercise and sports involvement ○ BSA (See Chapter 3) ○ Skin exposure to ultraviolet rays ○ Suicide: depressive symptoms ○ Tobacco, alcohol, other drug use (See Chapter 16) ▪ Environmental Exposures ▪ Advance Directives
Vaccines	See Chapter 20 Vaccination Services

* A pelvic exam includes inspection of external genitalia and speculum exam. For an asymptomatic woman of any age, a pelvic exam should be performed during a periodic well-woman visit only when cervical cancer screening and/or STI screening is indicated and cannot be obtained by other modalities.

** Annual screening for lung cancer using CT scan is indicated in adults age 55 to 80 who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. Discontinue screening once client has not smoked for 15 years or otherwise not indicated[R1].

21.1.e. Table: Periodic Well-Woman Assessments Ages 65 and Older

Periodic Well-Woman Assessments Ages 65 and Older	
History	Should include ▪ Reason for visit ▪ Health status — medical, surgical, and family ▪ Dietary/nutrition assessment ▪ Environmental risk assessment (See Part 3: Required Documents and Other Resources) ▪ Use of complementary and alternative medicine ▪ Tobacco, alcohol, other drug use and concurrent medication use ▪ Abuse/neglect ▪ Intimate partner violence (See Chapter 11) ▪ Sexual practices ▪ Urinary and fecal incontinence
Physical Examination	Should include ▪ Height, weight, BMI ▪ BP (See Chapter 16) ▪ abdomen ▪ CBE – annually (See Chapter 3) ▪ Pelvic exam*, as indicated ▪ Bimanual exam, as indicated ▪ Rectal exam ▪ May include – oral cavity
Laboratory Testing and Diagnostic Imaging	Should include ▪ Mammography – annually until approximately age 75 (See Chapter 3) ▪ Total cholesterol and HDL or lipid profile ✓ FYI – Screening for Lipid Disorders ▪ Colorectal cancer screening until age 85 (See Table 21.1.f.) ▪ BMD test q2 years as needed (See Chapter 8) ▪ HCV infection – if risk factors, or once, in those born between 1945 and 1965 ▪ As indicated o Cervical cytology (See Chapter 4) o STI testing (See Chapter 9) o HIV testing o Fasting glucose o TB skin testing o Lung cancer screening by CT**

Periodic Well-Woman Assessments Ages 65 and Older	
Evaluation and Client Education	Should include ▪ Sexuality ○ Sexual functioning ○ Sexual behaviors ○ STI prevention ▪ Fitness and Nutrition ○ Dietary/nutrition assessment ○ Exercise ○ Calcium intake (1200mg/d post-menopausal) ○ Vitamin D intake (800-1000 IU/d) ▪ Psychosocial Evaluation ○ Depression – annually ○ Neglect/abuse ○ Intimate partner violence ○ Lifestyle/stress ○ Depression/sleep disorders ○ Family relationships ○ Work/retirement satisfaction ○ Mild cognitive impairment ▪ Environmental Exposures ▪ Advance Directives ▪ Cardiovascular Risk Factors ○ Hypertension ○ Dyslipidemia ○ Obesity ○ Diabetes mellitus ○ Sedentary lifestyle ○ Daily aspirin – ages 55 to 79 ▪ Health/Risk Behaviors ○ Hygiene (including dental) ○ Hormone therapy ○ Injury prevention • Safety belts and helmets • Prevention of falls • Occupational hazards • Recreational hazards • Firearms • Exercise and sports involvement ○ Visual acuity/glaucoma ○ Hearing ○ BSA (See Chapter 3) ○ Skin exposure to ultraviolet rays ○ Suicide: depressive symptoms ○ Tobacco, alcohol, other drug use (see Chapter 16)
Vaccines	See Chapter 20 Vaccination Services

* A pelvic exam includes inspection of external genitalia and speculum exam. For an asymptomatic woman of any age, a pelvic exam should be performed during a periodic well-woman visit only when cervical cancer screening and/or STI screening is indicated and cannot be obtained by other modalities.

** Annual screening for lung cancer using CT scan is indicated in adults age 55 to 80 who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. Discontinue screening once client has not smoked for 15 years or otherwise not indicated[R1].

21.1.f. Table: Screening Recommendations

Condition	Screening Recommendations	Frequency
Colorectal cancer	Screen using one of the following methods: ○ Colonoscopy ○ Fecal occult blood testing (FOBT) or fecal immunochemical testing (FIT) ○ Flexible sigmoidoscopy ○ Double contrast barium enema ○ Computed tomography colonography ○ Stool DNA ▪ Women ≥ age 50 or ≥ age 45 if African American – initiate routine screening. ▪ Women age 75 to 85, routine screening is not recommended, although individual considerations may support screening. ▪ Women > age 85 should not be screened. ▪ In women at increased risk, screening may begin at age 40 (or 10 years younger than the age at which the youngest affected relative was diagnosed). NOTE: Screening should not be performed using in-office FOBT or FIT with sample collected from digital rectal exam. If gFOBT is performed for screening, instruct client to test 2 or 3 samples (depending on the product) on 3 consecutive bowel movements at home. If any test is positive, colonoscopy must be done.	Determine according to method of screening used ▪ FOBT or FIT – every year ▪ Colonoscopy – every 10 years ▪ Flex sigmoidoscopy, double contrast barium enema, and CT colonography – every 5 years ▪ Stool DNA – no interval determined
Diabetes	▪ clients ≥ 45 years and older ▪ At any age in asymptomatic client with sustained BP (either treated or untreated) ≥135/80 mmHg ▪ At any age if client has BMI ≥ 25 AND any of the following additional risk factors: ○ Physically inactive ○ Diabetes in first degree relative (parent, sibling, or child) ○ Latina/o, African American, Native American, Asian, or Pacific Islander ○ Hypertension (HTN) — BP > 140/90 or on therapy for HTN	At least every 3 years. Consider more frequent testing depending on initial results and risk factors.

Condition	Screening Recommendations	Frequency
	○ HDL < 35 mg/dL and/or triglyceride > 250 mg/dL ○ History of gestational diabetes mellitus or newborn > 9 lbs ○ History of cardiovascular disease (CVD) ○ Condition associated with insulin resistance such as acanthosis nigricans ○ Polycystic ovarian syndrome (PCOS)	
	▪ All clients with prediabetes per previous testing (A1C 5.7-6.4 or FPG 100-125 or OGTT 140-199)	Annually
Hypertension	Routinely in clients ≥ 18 years old	Repeat every ▪ Two years when BP<120/80 ▪ Year when systolic BP (SBP) 129-139 mmHg or diastolic BP (DBP) 80-90 mmHg
Lipid Disorders	✓ See FYI – Screening for Lipid Disorders	

21.2 PRECONCEPTION CARE

21.2.1 Client Education and Informed Consent

I. Informed consent **must** be obtained. All written materials given to the client **must** be documented in record.

✓ See Administrative Chapter 4 Client Education and Informed Consent

21.2.a. Table: Requirements for Written Materials as Indicated

Document	Document #	**Must** sign	**Must** give	Should give
CI Preconception				●
Release When Test/Service/Consultation Will Not Be Obtained As Recommended		once		
Written information about any medication dispensed (package insert may be used)			●	

✓ FYI Preconception Care

21.2.2 History and Evaluation

21.2.b. Table: History and Evaluation for Preconception Care

Address the following, as indicated by the client's level of readiness, risk for adverse perinatal outcomes, and visit type.

Evaluation	
Reproductive Life Plan ✓ FYI Reproductive Life Plan	Should include ▪ Assessment of the client's pregnancy intention in the short or long term ▪ Risk of becoming pregnant, whether intended or not.
History ✓ FYI - Common Agents that Can Harm the Fetus ✓ FYI – Environmental Toxins ✓ FYI – Carrier Screening by Ethnicity	Should focus on modifiable and non-modifiable reproductive risks. Key points include, but are not limited to ▪ Time since client's last pregnancy ▪ Intimate partner violence/reproductive coercion ▪ Teratogenic exposures, including prescription and over-the-counter medications, and dietary supplements ▪ Ethnic background, and family history focused on ○ Congenital abnormalities, with attention to • Neural tube defects • Congenital heart disease • Mental retardation • Autism • Fragile X Syndrome ○ genetic, chromosomal, and/or familial disorders, including non-syndromic hearing loss ▪ Social history ▪ STI risk factors ▪ Immunization history ▪ Obstetric history, focused on any complications or adverse outcomes ▪ History of chronic illness(es) including ○ Hypertension ○ Asthma ○ HIV ○ Rheumatologic disease (i.e., systemic lupus erythematosus and rheumatoid arthritis) ○ Renal disease ○ Thyroid disease ○ Seizure disorder ○ Diabetes mellitus ○ Phenylketonuria (PKU) ○ Thrombophilias ○ Mental health problems

Evaluation	
Physical Examination	May include, as indicated ▪ Height ▪ BP ▪ Weight ▪ BMI
Laboratory Tests and Diagnostic Imaging ✓ FYI – Carrier Screening by Ethnicity	May include, as indicated based on client's history, risk for pregnancy, and level of readiness ▪ HIV (client and partner) ▪ Syphilis (client and partner) ▪ Hepatitis B and C (client and partner) ▪ Chlamydia and gonorrhea ▪ Tuberculosis ▪ Diabetes screening – see Table 21.1.f. ▪ Cystic fibrosis carrier screening – should be offered to all clients regardless of ethnicity. ▪ Rubella IgG antibody screen ▪ Other testing based on ethnicity, genetic screening, etc.

21.2.3 Management and Interventions

I. Lifestyle Modification – advise clients on strategies to promote overall health, which may include the following:
   A. Nutrition
   B. Exercise
   C. Avoidance of risks such as substance abuse, exposure to toxic substances

II. Vaccinations — Provide or refer for all recommended vaccinations, with annual review and update of immunization status of the following:
   A. Tetanus-diptheria toxoid or diphtheria-tetanus-pertussis
   B. Measles, mumps, and rubella
   C. Varicella

✓ See Chapter 20 Vaccination Services

✓ CDC immunization schedules

21.2.c. Table: Vaccines in Preconception Care

Vaccine	Information
Influenza	Inactivated virus vaccine recommended annually for women planning a pregnancy. Live attenuated virus not recommended.
Tetanus	Women of reproductive age should be up to date for tetanus toxoid.
Hepatitis B	High-risk women not previously vaccinated should receive Hepatitis B vaccine before pregnancy.
Pertussis	Clients having close contact with infant(s) (<12 mos) should have up-to-date pertussis vaccination: ▪ This can be given by substituting Tdap for a Td booster. ▪ While this can be done anytime, preconception or postpartum visits are recommended. ▪ This should be given at least 2 weeks before coming into close contact with an infant.
Rubella	Rubella-susceptible women should be vaccinated prior to pregnancy: ▪ Women vaccinated or referred for vaccination **must** be advised to avoid pregnancy for at least 1 month following vaccination. ▪ Rubella-susceptible women who refuse vaccination **must** be warned about the possibility of congenital rubella syndrome.
Varicella	Women who do not have evidence of varicella immunity (either by history of vaccination, history of previous infection, or laboratory evidence) should be vaccinated before pregnancy. Women vaccinated or referred for vaccination **must** be advised to avoid pregnancy for at least 1 month following vaccination.

III. Genetic screening
   A. When clients are determined to be at risk for genetic conditions, based on ethnicity or family history, they should be offered genetic counseling.

IV. Chronic Illnesses
   A. For women with high-risk medical conditions, advise care of a primary care provider or specialist prior to conception.

21.3 ADDITIONAL INFORMATION

21.3.a. Table: For Your Information

Section	Topic	Detail
21.1.2	Frequency of the Periodic Well Woman Visit	Available evidence supports periodic screening visits rather than a yearly comprehensive one. This gives the clinician an opportunity to use clinical judgment when deciding the frequency of screenings for healthy women.

Section	Topic	Detail
		Depending on a woman's health/risk behaviors, psychosocial evaluation, or nutrition assessment, for example, it may be appropriate to see her annually even when less frequent visits are recommended for other asymptomatic women her age. In fact, if a woman is particularly receptive to changing a behavior, you may want to see her for an interim visit related to that particular healthcare intervention. In addition, the timing of subsequent periodic well-woman visits may not necessarily coincide with a particular client's cervical cancer screening schedule, STI screening schedule, or any management intervention deemed necessary. For example, you may advise that she be seen every 3 years for a Pap, and more frequently for preventive assessments and targeted interventions such as weight loss counseling, immunizations, and smoking cessation. Moving to this model will be a culture change for clinicians, health center staff and clients. Gradual implementation and acceptance should be expected. Funding sources may limit the adoption of these changes.
21.1.b. 21.1.c. 21.1.d. 21.2.b.	Reproductive Life Planning	A reproductive life plan (RLP) is a set of personal goals about having or not having children that also states how to achieve those goals. A RLP should be based on an individual's values, goals, and resources. Important considerations are ▪ RLPs are never right or wrong. ▪ RLPs are fluid. They are not set in stone, because circumstances and people change. Reproductive life planning should be offered to all clients, irrespective of assumptions or biases about their circumstances.
21.1.c. 21.1.d. 21.1.e. 21.1.f.	Screening for Lipid Disorders	Various authorities have differing recommendations on when to screen for lipid disorders: ▪ U.S. Preventive Services Task Force (USPSTF)[R2, R3] o Recommends screening for • All men ≥ 35 years old (Grade A) • Men 20 to 35 years old if at increased risk for cardiovascular disease (CVD) (Grade B) • Women ≥ 45 years old, if at increased risk for CVD (Grade A) • Women 20 to 45 years old, if at increased risk for CVD (Grade B) o No recommendation for or against routine screening in men 20 to 35 years old, or in women ≥ 20 years old who

Section	Topic	Detail
		are not at increased risk for CVD (Grade C) ▪ ACC/AHA 2013 Guidelines[R4] ○ Cardiovascular risk assessment every 4 to 6 years in individuals aged 40 to 75 years without clinical ASCVD or diabetes and with LDL-C 70-189mg/dL • Risk assessment tool may be accessed at: http://my.americanheart.org/professional/StatementsGuidelines/PreventionGuidelines/Prevention-Guidelines_UCM_457698_SubHomePage.jsp • Risk assessment requires a lipid panel: total cholesterol, low density lipoprotein (LDL) cholesterol, high density lipoprotein (HDL) cholesterol, and triglyceride. Fasting lipid panel is preferred. • If non-fasting triglycerides are >500 mg/dL then a fasting lipid panel is required. • If non-fasting a non-HDL-C >220mg/dL may indicate genetic hypercholesterolemia that requires further evaluation or a secondary etiology • Risk assessment also requires a systolic blood pressure ▪ American College of Obstetricians and Gynecologists (ACOG)[R5]: ○ Lipid panel every 5 years beginning at age 45 years ○ Earlier screening may be indicated in women with the following high risk factors • Family history suggestive of familial hyperlipidemia • Family history of premature CVD • Previous personal history CVD or noncoronary atherosclerosis • Obesity (BMI >30) • Personal and/or family history of peripheral vascular disease • Diabetes mellitus (DM) • Multiple CVD risk factors
21.2.1	Preconception Care	Preconception care describes an intervention aimed at reproductive-aged women and men, with the specific aim of reducing reproductive risks: ▪ In general, not considered to be a special type of clinical visit, though some individuals may seek care specifically for this purpose. ▪ May be incorporated into any visit type.

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td></td><td></td><td>
▪ May be covered in more than one visit, as time and client need and interest dictate.

Clients who should receive preconception care include
▪ Women who are
  ○ Seeking pregnancy
  ○ Open to pregnancy
  ○ At risk for unintended pregnancy
▪ Any male client interested in preconception care may be offered the same information.

The extent of the preconception care intervention will depend on the
▪ Client's level of interest and readiness
▪ Client's risk for adverse perinatal outcomes
▪ Visit type
</td></tr>
<tr><td></td><td>Caffeine and Pregnancy</td><td>ACOG guidelines[R6] allow for moderate caffeine consumption during pregnancy. The relationship of caffeine consumption to intrauterine growth restriction remains undetermined. Moderate caffeine intake does not affect preterm birth. Studies have reached conflicting results with regard to caffeine consumption and early pregnancy loss.

"Moderate" caffeine consumption is defined as less than 200 mg per day. The U.S. Department of Agriculture's National Nutrient Database contains information on the caffeine content of many commercially available foods, supplements, and beverages.</td></tr>
<tr><td>21.2.b.</td><td>Carrier screening by ethnicity[R7, R8]</td><td>
<table>
<tr><th>Ethnic origin</th><th>Screening recommended</th><th>Test</th><th>Frequency</th></tr>
<tr><td>Black</td><td>▪ Sickle cell trait
▪ B-Thalassemia</td><td>▪ Hemoglobin electrophoresis
▪ CBC with MCV < 80 and normal iron status</td><td>▪ 10%
▪ 5%</td></tr>
<tr><td>Eastern European Jewish</td><td>▪ Tay-Sachs disease carrier; Canavan, cystic fibrosis, familial dysautonomia</td><td>▪ Hexosaminidase A</td><td>▪ 4%</td></tr>
<tr><td>French Canadian</td><td>▪ Tay-Sachs disease carrier</td><td>▪ Hexosaminidase A</td><td>▪ >5%</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Section</th><th>Topic</th><th>Detail</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>Mediterranean</td><td>▪ α, β-Thalassemia</td><td>▪ CBC with MCV < 80 and normal iron status</td><td>▪ 10-20%</td></tr>
<tr><td>Southeast Asian (Laotian, Thai, Cambodian, Hmong)</td><td>▪ α, β-Thalassemia</td><td>▪ CBC with MCV < 80 and normal iron status</td><td>▪ 20-40%</td></tr>
<tr><td>Indian, Middle Eastern</td><td>▪ Sickle cell trait
▪ α, β-Thalassemia</td><td>▪ Hemooglobin electrophoresis
▪ CBC with MCV < 80 and normal iron status</td><td>▪ Unknown
▪ Unknown</td></tr>
<tr><td colspan="4">MCV = mean corpuscular volume.</td></tr>
</table>
</td></tr>
<tr><td>21.2.b.</td><td>Common Agents That Can Harm the Fetus[R7]</td><td>
<table>
<tr><th>Agent</th><th>Reasons Used</th><th>Fetal Effects</th></tr>
<tr><td>Alcohol</td><td>Social reason, dependency</td><td>Growth restriction and mental retardation</td></tr>
<tr><td>Androgens and testosterone by-products (such as danazol)</td><td>To treat certain types of infertility, breast problems, and edema (swelling)</td><td>Genital abnormalities, male-like characteristics in female babies, and advanced sexual development in male babies</td></tr>
<tr><td>ACE inhibitors (such as enalapril or captopril)</td><td>To help treat high blood pressure and heart failure</td><td>Growth restriction, problems with brain and kidneys</td></tr>
<tr><td>Anticonvulsants</td><td>To treat seizure disorders and irregular heartbeat</td><td>Growth restriction and mental retardation, developmental problems, neural tube defects</td></tr>
<tr><td>Cancer drugs</td><td>To treat cancer and psoriasis (skin disease)</td><td>Increased risk of miscarriage, various defects</td></tr>
<tr><td>Coumadin by-products (such as warfarin)</td><td>To prevent blood clots</td><td>Problems with development of bones and eyes, growth restriction, nerve problems, developmental delays</td></tr>
<tr><td>Illegal drugs</td><td>Dependency</td><td>Problems with placenta, preterm birth, or fetal death or brain injury and developmental problems</td></tr>
</table>
</td></tr>
</table>

Section	Topic	Detail			
		Isotretinoin	Treatment for cystic acne	Increased risk of miscarriage, developmental problems	
		Lead	Industries involving smelting, paint manufacture and use, printing, ceramics, and pottery glazing	Problems in development of the central nervous system	
		Lithium	To treat the manic part of manic-depressive disorders	Congenital heart disease	
		Methylmercury	Pollutant found in certain types of fish, including tuna and particularly shark, swordfish, king mackerel, and tile fish	Problems with development of nerve system	
		Streptomycin and kanamycin	Antibiotics used to treat infection	Hearing loss	
		Tetracycline	An antibiotic used to treat infection	Underdevelopment of tooth enamel, incorporation of tetracycline into bone	
		Thalidomide	To treat or prevent certain skin diseases	Abnormal or missing limbs or ears and heart and gastrointestinal defects	
		Tobacco	Dependency, social reasons	Low birth weight baby, stillbirth, problems with the pregnancy	
21.2.b.	Environmental toxins[R9]	Hazard	Types	Associated Outcomes	Sources of exposure
		Metals	Lead	Abnormal sperm, menstrual disorders, miscarriages, stillbirths, mental retardation	Solder, lead pipes, batteries, paints, ceramics, smelter emissions.
			Mercury	Impaired fetal motor and mental development	Thermometers, mirror coating, dyes, inks, pesticides, dental fillings, fish from contaminated waters
		Solvents	Tricholorethylene, chloroform, benzene, toluene	Birth defects	Dry cleaning fluids, degreasers, paint strippers, drug and electronics industries

Section	Topic	Detail			
		Plastics	Vinyl chloride	Decreased fertility, chromosomal aberrations, miscarriages, stillbirths, birth defects	Plastic manufacturing
		Pollutants	Polycholorinated biphenyl, polybrominated biphenyl	Low birth weight, stillbirths	Pesticides, carbonless copy paper, rubber, chemicals, and electronics industries, fire retardants, food chain
		Pesticides	2,4,5-T and 2,4-D organophosphates	Birth defects, miscarriages, low birth weight	Farm, home, and garden insect sprays; wood treatment
		Gases	Carbon monoxide	Low birth weight, stillbirths	Auto exhaust, furnaces, kerosene heaters, cigarette smoke
			Anesthetic gases	Decreased fertility, miscarriages, birth defects	Dental offices, operating rooms, chemicals
		Radiation	Radiographs, radioactive materials	Sterility, birth defects	Medical and dental offices, electronics industries

21.3.b. Table: References

Section		Reference
21.1.d.	R1	*Screening for Lung Cancer*, Topic Page. U.S. Preventive Services Task Force (USPSTF). http://www.uspreventiveservicestaskforce.org/uspstf/uspslung.htm. (Accessed June 4, 2014)
21.3.a.	R2	USPSTF Screening for Lipid Disorders, 2008. http://www.uspreventiveservicestaskforce.org/uspstf/uspschol.htm (Accessed June 2014)
21.3.a.	R3	USPSTF Grading: http://www.uspreventiveservicestaskforce.org/uspstf/gradespre.htm#arec. (Accessed June 2014)
21.3.a.	R4	American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines: http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a. (Accessed June 2014).
21.3.a.	R5	ACOG. Well-Woman care: Assessments and Recommendations (2013): http://www.acog.org/~/media/Departments/Annual%20Womens%20Health%20Care/PrimaryAndPreventiveCare.pdf?dmc=1

Section		Reference
		&ts=20140604T1423402312. (Accessed June 2014)
21.3.a.	R6	Moderate caffeine consumption during pregnancy. Committee Opinion No. 462. American College of Obstetricians and Gynecologists. Obstet Gynecol 2010;116:467–8.
Throughout		ACOG Well-Woman Task Force Recommendations 2014. In press.
21.3.a. 21.3.a. (#2)	R7	ACOG Practice Bulletin No. 77: Screening for Fetal Chromosomal Abnormalities. Jan 2007. 109(1): 217-28.
21.3.a.	R8	Cowchock FS, Johnson A, Jackson LG. Screening for genetic abnormalities. Infertil Reprod Med Clin North Am. 1994;5:177–95.
21.3.a.	R9	Brent RL. How does a physician avoid prescribing drugs and medical procedures that have reproductive and developmental risks? Clin Perinatol 2007:34(2);233–262

21.3.c. Table: Associated Resources for Clients

Translated documents are located in Part 3 and are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese.

Type	Resource	Location
CI/CIIC	CI Cleaning Products CI Fish CI Fruits and Vegetables CI Getting Enough Calcium and Vitamin D CI Lead CI Personal Care Products CI Pesticides CI Plastic CI Preconception CI Preventing Cardiovascular Disease CI Tobacco Smoke	Part 3, Chapter 02_21
Client Education	Reproductive Life Planning Resources ✓ Reproductive Life Planning Client Tools – CDC ✓ Famplan.org Resources	

Type	Resource	Location
	✓ Utah Department of Health Reproductive Life Planning Tool - Adolescents	
	Preconception Resources ✓ The March of Dimes ✓ Preconception Health Panel of California	
	✓ Planned Parenthood Health: What is a Well Woman Visit Video	

21.3.d. Table: Associated Resources for Staff

Type	Resource	Location
Job Tools	✓ CDC Providing Quality Family Planning Services (QFP) ✓ NPWH Well Woman Visit App	
Training	**CAL courses** Green Choices Well Woman Visit	
	PPFA 2013 VOICE The Well Woman Visit	Accessed through the CAL
Sample Forms	Environmental Risk Assessment Form	Part 3, Chapter 02_21

PART 3: REQUIRED DOCUMENTS AND ADDITIONAL RESOURCES

June 2014

TABLE OF CONTENTS

Documents are listed according to associated chapter. Items that are marked with * are available in additional languages.

PART 3: REQUIRED DOCUMENTS AND ADDITIONAL RESOURCES

June 2014

TABLE OF CONTENTS

PART 3: REQUIRED DOCUMENTS AND ADDITIONAL RESOURCES

June 2014

TABLE OF CONTENTS

PART 3: REQUIRED DOCUMENTS AND ADDITIONAL RESOURCES

June 2014

TABLE OF CONTENTS

Laboratory Application Form

(affiliate name and telephone number)

IDENTIFYING INFORMATION

Name of Laboratory:

Address: _____ City: _____ State: _____ Zip: _____

Contact person: _____

Phone: _____ E-mail: _____ Fax: _____

Name of Laboratory Owner(s) _____

_____

Year laboratory began performing cytology services:

Please indicate any past/present Planned Parenthood contracted services (append list if necessary):

Name of Affiliate:	Years covered

SERVICES PERFORMED

Please indicate the numbers currently performed per year for the following services:

_____ Pap tests _____ Cervical Biopsies

Does your lab perform any of these other services?

Pathology: Biopsies Yes ☐ No ☐ POC Yes ☐ No ☐

Chlamydia testing: Yes ☐ No ☐

Herpes testing: Yes ☐ No ☐

Gonorrhea testing: Yes ☐ No ☐

HPV typing: Yes ☐ No ☐

Liquid Based Cytology: Yes ☐ No ☐

Other (specify):_____

Do you have a reporting system for Pap data that permits reporting of results by Bethesda Classification and age?

Yes ☐ No ☐

Can you report statistical data?

Monthly: Yes ☐ No ☐

Quarterly: Yes ☐ No ☐

Annually: Yes ☐ No ☐

Total affiliate and by center: Yes ☐ No ☐

Please submit a sample report for Pap smear data.

Do you contract out for cytology services when you have a backlog? Yes ☐ No ☐

If yes, to whom? _____

If yes, do they meet the same criteria as your lab personnel? Yes ☐ No ☐

Do you match biopsy specimens to Pap tests when both are submitted? Yes ☐ No ☐

CERTIFICATION/ACCREDITATION

Please indicate the date of most recent certification/accreditation approval for the following agencies:

State		HCFA		CAP		COLA	
JCAHO		ASC		Other			

Are you licensed in the state of New York for cytology screening? Yes ☐ No ☐

Are you licensed in the state of California for cytology screening? Yes ☐ No ☐

Can you provide copies of the following?

State license Yes ☐ No ☐ CLIA Accreditation Yes ☐ No ☐ CAP Accreditation Yes ☐ No ☐

Any other license, certification/accreditation your organization has achieved Yes ☐ No ☐

Describe: _____

Do you only employ cytotechnologists that are certified by ASCP or board eligible? Yes ☐ No ☐

QUALITY ASSURANCE

What is your average routine (QA) rescreening rate for QA? _____

What is your overall ASCUS rate? _____

What is your ASCUS/LSIL ratio? _____

What is your overall dysplasia rate (CIN I, CIN II, CIN III)? _____

What is your average turn-a-round-time for Pap Tests? _____

What is your maximum turn-around-time for Pap Tests? _____

What is your average rescreening rate for QA? _____

Who is available to consult with clinicians (names, position, phone number)?

Cytopathologist

Name	Position	Phone number

Supervising Cytotechnologist

Name	Position	Phone number

If PPFA requires an onsite inspection of your laboratory by a cytopathologist do you agree to let them conduct that inspection? Yes ☐ No ☐

Submit proof and amount (per claim and per year) of the lab's liability and malpractice insurance coverage.

_____ _____

Signature Date

_____ _____

Print Name Title

PPFA CIs AND CIICs

Master List, by Chapter

June 2014

All CI/CIICs are located in Part 3: Required Documents and Other Resources. They are available in the following languages: Arabic, Brazilian Portuguese, Chinese Simplified, Chinese Traditional, French, Spanish, and Vietnamese. Documents are organized alphabetically by Chapter and grouped by language. Each language is designated by a unique letter as indicated in the table below. The file naming convention includes Part3_ Language ID_ClinicalChapter_ Type_short name. Exception: note that English language files do not have the language ID in the file name so those files remain organized with non-translated documents.

1.1 Language Identification

Series Letter	Language	Sample File Name
a	English	03_ 02_01_ CI Abortion Options
b	Spanish	03_ b_02_01_ CI Abortion Options
c	Arabic	03_ c_02_01_ CI Abortion Options
d	Chinese (Simplified)	03_ d_02_01_ CI Abortion Options
e	Chinese (Traditional)	03_ e_02_01_ CI Abortion Options
f	French	03_ f_02_01_ CI Abortion Options
g	Brazilian Portuguese	03_ g_02_01_ CI Abortion Options
h	Vietnamese	03_ h_02_01_ CI Abortion Options

In the table below * designates CIICs/CIs that are relevant to more than one Chapter. The home location of the document is listed in parenthesis after the title.

1.2 Master List of CI/CIICs

Chapter	CI/CIIC Name	Status (As of June 2014)
02_01 Abortion	**CIs:**	
	Abortion Options	NEW
	Ectopic Pregnancy* (located in Part 3, Chapter 02_13)	Reformatted
	Rho(D) Immune Globulin*	Reformatted
	How To Take Your Pills – Buccal	Revised
	How To Take Your Pills – Oral	Revised
	Taking Care of Yourself After An In-Clinic Abortion	Revised

Chapter	CI/CIIC Name	Status (As of June 2014)
	When A Small Amount of Pregnancy Tissue Was Seen	Reformatted
	CIICs:	
	Cervical Prep with Dilators or Miso	Reformatted
	Digoxin	Reformatted
	In-Clinic Abortion	Revised
	Reaspiration after In-Clinic Abortion/Aspiration after Using the Abortion Pill	Reformatted
	Second Dose of Misoprostol	Reformatted
	Using the Abortion Pill	Revised
	When You Decide To Stop Your In-Clinic Abortion	Reformatted
02_02 Analgesia and Sedation	**CIs:**	
	Taking Care of Yourself After Sedation	NEW
	CIICs:	
	Sedation	NEW
02_03 Breast Services	**CIs:**	
	Breast Engorgement and Mastitis*	NEW
	Breast Health – What You Can Do	Revised
	CIICs:	
	Breast Cyst Aspiration	Reformatted
02_04 Cervical Cancer Screening and Management of Cervical Abnormalities	**CIs:**	
	Pap and HPV Test	Reformatted
	CIICs:	
	Cryotherapy	Reformatted
	Colposcopy and Biopsy	Reformatted
	Endometrial Biopsy* (located in Part 3, Chapter 02_08)	Reformatted
	LEEP	Reformatted
02_05 Contraception – Permanent	**CIs:**	
	Hysterosalpingogram (HSG)*	Revised

Chapter	CI/CIIC Name	Status (As of June 2014)
	Before and After Your Tubal	NEW
	Before and After Your HTS	NEW
	Before and After Your Vasectomy	NEW
	CIICs:	
	Hysteroscopic Tubal Sterilization	Revised
	Transabdominal Tubal Sterilization	Reformatted
	Vasectomy	Revised
02_06 Contraception – Reversible	**CIs:**	
	After Insertion of the Implant	Reformatted
	After Taking Out the Implant	Reformatted
	Condoms and Female Condoms*	NEW
	Fertility Awareness-Based Methods	Reformatted
	How To Use the Cervical Cap	NEW
	How To Use The Diaphragm	NEW
	How To Use The Patch	Revised
	How To Use The Pill	NEW
	How To Use The Ring	Revised
	IUC Pregnancy	Revised
	CIICs:	
	Diaphragm and Cervical Cap	Revised
	DMPA	Reformatted
	HC Special Conditions	Revised
	Implant	Reformatted
	IUC	Reformatted
	IUC Continued Use of IUC Beyond Recommended Removal Date	Reformatted
	IUC Removal – Missing String	Reformatted
	IUC Special Conditions	Revised
	Pill Patch and Ring	Revised

Chapter	CI/CIIC Name	Status (As of June 2014)
	Preparing Your Cervix with Misoprostol	Reformatted
	POPs	Reformatted
	Taking Out the Implant	Reformatted
02_07 Emergency Contraception	**CIICs:**	
	Emergency Contraception	Revised
02_08 Gynecological (Non-infectious)	**CIs:**	
	Getting Enough Calcium and Vitamin D* (located in Part 3, Chapter 02_21)	Revised
	Hot Flashes	Reformatted
	Menopause and Perimenopause	NEW
	Preventing CVD	Reformatted
	Problems Sleeping	Reformatted
	CIICs:	
	Endometrial Biopsy*	Reformatted
	Menopausal Hormone Therapy (MHT)	Reformatted
	Treatment of Bartholin's Duct Cyst or Abscess	Reformatted
	Vulvar Biopsy* (located in Part 3, Chapter 02_09)	Reformatted
02_09 Infections	**CIs:**	
	Acute PID	Reformatted
	Condoms and Female Condoms* (located in Part 3, Chapter 02_06)	NEW
	Directions for Sex Partners – Chlamydia	Reformatted
	Directions for Sex Partners – Gonorrhea	Revised
	Directions for Sex Partners – Trichomoniasis	Reformatted
	Genital Herpes	NEW
	HIV Test	Revised
	Reducing Your Risk for STIs	NEW
	STI Testing	NEW
	UTI	Reformatted

Chapter	CI/CIIC Name	Status (As of June 2014)
	CIICs:	
	PEP	NEW
	PrEP	NEW
	STI Treatment Without Testing	Reformatted
	Treatment of Genital Warts	Reformatted
	Treatment of Molluscum Contagiosum	Reformatted
	Vulvar Biopsy*	Reformatted
02_10 Infertility	**CIs:**	
	Hysterosalpingogram (HSG)* (located in Part 3, Chapter 02_05)	Revised
	Testing Your Semen	Reformatted
	CIICs:	
	Endometrial Biopsy* (located in Part 3, Chapter 02_08)	Reformatted
02_11 Intimate Partner Violence, Reproductive Coercion, and Abuse	**CIs:**	
	Healthy Relationships	NEW
02_12 Men's Sexual and Reproductive Health Services	**CIs:**	
	Benign Prostatic Hyperplasia (BPH)	Revised
	Erectile Dysfunction	Reformatted
	Premature Ejaculation	Revised
	CIICs:	
	Skin Biopsy	Reformatted
	Tests for Prostate Cancer	Reformatted
02_13 Pregnancy Evaluation and Management of Complications	**CIs:**	
	Ectopic Pregnancy*	Reformatted
	Miscarriage	Revised
	Molar Pregnancy	Reformatted
	Positive Pregnancy Test – No Pregnancy Seen on Ultrasound	Reformatted

Chapter	CI/CIIC Name	Status (As of June 2014)
	Rho(D) Immune Globulin* (located in Part 3, Chapter 02_01)	Reformatted
	Taking Care of Yourself – Miscarriage	NEW
	CIICs:	
	Treatment of Miscarriage: The Abortion Pill	Revised
	Treatment of Miscarriage: Misoprostol	Revised
	Treatment of Miscarriage: Suction Procedure	Revised
	Treatment of Miscarriage: Wait and See	Revised
02_14 Pregnancy Testing and Options Counseling	**CIs:**	
	Early Pregnancy Symptoms	Reformatted
	Preconception* (located in Part 3, Chapter 02_21)	NEW
02_15 Prenatal and Postpartum Care	**CIs:**	
	Breast Engorgement and Mastitis* (located in Part 3, Chapter 02_03)	NEW
	CIICs:	
	Genetic Counseling and Diagnostic Testing	Reformatted
	Prenatal Care	Reformatted
	Screening for Birth Defects	Reformatted
02_16 Primary Care	**CIs:**	
	Lower Your BP	NEW
	Preconception* (located in Part 3, Chapter 02_21)	NEW
	Tips for Losing Weight	Reformatted
02_17 Recovery Area Care	**None**	
02_18 Transgender Services	**CIICs:**	
	Feminizing (Male to Female) Therapy	Reformatted
	Masculinizing (Female to Male) Therapy	Reformatted
02_19 Ultrasound Services	None	
02_20 Vaccination Services	None	

Chapter	CI/CIIC Name	Status (As of June 2014)
02_21 Well-Woman Care	**CIs:**	
	Cleaning Products	Reformatted
	Fish	Reformatted
	Fruits and Vegetables	Reformatted
	Getting Enough Calcium and Vitamin D*	Revised
	Lead	Reformatted
	Personal Care Products	Reformatted
	Pesticides	Reformatted
	Plastic	Reformatted
	Preconception*	NEW
	Preventing Cardiovascular Disease	Reformatted
	Tobacco Smoke	Reformatted

1.3 List of Deleted PPFA CI/CIICs (June 2014)

Name of Deleted CI/CIIC	Rationale
CIIC Donation of Blood And/Or Aborted Pregnancy Tissue	Moved into Part 3 as a resource
CIIC FNA of Breast	No longer a service provided by Planned Parenthood
CI Instructions for After Your HTS	Replaced with new CI Before and After Your HTS
CI Instructions for After Your Vasectomy	Replaced with new CI Before and After Your Vasectomy
CIIC Minimal Sedation	Replaced with new CIIC Sedation
CIIC Moderate Sedation	Replaced with new CIIC Sedation

(affiliate name and telephone number)

DATE: _____ **CLIENT #:** _____

NAME OF CLIENT: _____

DATE OF BIRTH: _____ **TELEPHONE #:** _____

Reason for recommended test/service/consultation:

- □ Breast Condition: I understand I have a breast mass. I understand that it is very important that I go for the recommended testing to be sure the mass is not cancer.
- □ Breast Condition: I understand I have a breast mass. I understand that it is very important that I go for the recommended testing to be sure the mass is not cancer. If the mass is cancer, I understand that using hormones like those found in birth control or to treat menopause, *could cause the cancer to spread and/or make it more difficult to treat*.
- □ HPV or Pap Tests: I understand that if I do not have the HPV or Pap test that has been recommended, the possible cervical condition may progress to a more serious condition or even to cancer.
- □ Colposcopy: I understand that if I do not have a colposcopy (and possibly additional treatment), the abnormal cells on my cervix may progress to a more serious condition or even to cancer. The detection of this condition could be delayed, resulting in increased risk.
- □ Other (Specify condition, including risks of not seeking consult): _____

_____

I have been given information about the recommended test/service/consultation, including the benefits, risks, possible problems/complications and alternate choices. I understand that I should ask questions about anything I do not understand. I understand that a clinician is available to answer any questions I may have. **I understand that it is my responsibility to get follow-up care**.

Even though I have been advised to have the above test/service/consultation, I do not plan to do so now.

I hereby release Planned Parenthood and its medical staff and employees from any and all liability arising out of or connected with my decision not to follow the above medical recommendation.

_____ _____

Signature of Client Date

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

_____ _____

Witness signature Date

□ CHECK HERE IF CLIENT'S GUARDIAN OR RELATIVE IS LEGALLY REQUIRED TO SIGN BELOW.

_____ _____

Signature of any other person consenting Date Relationship to client

I witness the fact that the client's legal guardian (or person consenting in her/his behalf) received the above mentioned information and said she/he read and understood same.

_____ _____

Witness signature Date

Items to Add to Request for Medical Services for Affiliates Who Provide Training
Privacy Practices

All trainees **must** be given written consent by the client prior to the trainee's performance of any examination or procedure. This consent is in addition to all other informed consent requirements. To obtain written consent, affiliates who provide training **must** include the following language in form I-B-2a Request for Medical Services:

"Please note that [affiliate name here] is a teaching institution, and that persons in training, under strict supervision, may be involved in some aspects of your care."

(affiliate name and phone number)

REQUEST FOR MEDICAL SERVICES AND ACKNOWLEDGEMENT OF RECEIPT OF NOTICE OF HEALTH INFORMATION PRIVACY PRACTICES

PUT LABEL HERE

PATIENT # _____

NAME OF PATIENT _____

DATE OF BIRTH _____

Before you give your consent, be sure you understand the information given below. If you have any questions, we will be happy to talk about them with you. You may ask for a copy of this form.

I understand that I must tell the staff if language interpreter services are necessary to my understanding of the written or spoken information given during my health care visits. I understand that free interpretive services may not be immediately available and Planned Parenthood may need to refer me to another health care facility to provide the services necessary for my care.

I understand that the information I will provide is true, accurate, and complete and that my healthcare choices will depend on that information.

I will be given information about the test(s), treatment(s), procedure(s), and contraceptive method(s) to be provided, including the benefits, risks, possible problems/complications, and alternate choices. I understand that I should ask questions about anything I do not understand. I understand that a clinician is available to answer any questions I may have.

No guarantee has been given to me as to the results that may be obtained from any services I receive. I know that it is my choice whether or not to have services. I know that at any time, I can change my mind about receiving medical services at Planned Parenthood.

I understand that if tests for certain sexually transmitted infections are positive, reporting of positive results to public health agencies is required by law.

I will be given referrals for further diagnosis or treatment if necessary. I understand that if referral is needed, I will assume responsibility for obtaining and paying for this care. I will be told how to get care in case of an emergency.

I understand that confidentiality will be maintained as described in [NAME OF AFFILIATE's] *Notice of Health Information Privacy Practices*. I consent to the use and disclosure of my health information as described in *Notice of Health Information Privacy Practices*.

Request for Medical Services and Acknowledgement of Receipt of Notice of Health Information Privacy Practices

I hereby request that a person authorized by Planned Parenthood provide appropriate evaluation, testing, and treatment (including a birth control drug or device, if I request it).

I hereby acknowledge receipt of [NAME OF AFFILIATE's] notice of health information privacy practices.

Signature of patient _____

Date _____

I witness the fact that the patient received the above mentioned information and said she/he read and understood same and had the opportunity to ask questions.

Signature of witness _____

Date _____

	CHECK HERE IF PATIENT'S GUARDIAN OR RELATIVE IS LEGALLY REQUIRED TO SIGN BELOW

Signature of any other person consenting _____

Relationship to patient _____

Date _____

I witness the fact that the patient's legal guardian (or person consenting in her behalf) received the above mentioned information and said she read and understood same.

Signature of witness _____

Date _____

Items to Add to "Request for Surgery / Special Procedure for Comprehensive Prenatal Care Clients"

Clients receiving comprehensive prenatal care must sign the [PPFA] Request for Surgery and Other Special Services/ Procedures. The following two items must be added to that request form.

I give my permission for the transfer of my medical records to _____ Hospital and to other medical providers, if necessary. I also consent to the transfer of laboratory reports and delivery records from the hospital back to Planned Parenthood.

I understand that AFFILIATE NAME does not provide delivery services. I am being referred to _____ Hospital for delivery. I also understand that the health care providers at the hospital who will provide delivery services are not acting at the direction of or as agents of Planned Parenthood.

(affiliate name and phone number)

REQUEST FOR SURGERY OR SPECIAL PROCEDURE AND ACKNOWLEDGEMENT OF RECEIPT OF NOTICE OF HEALTH INFORMATION PRIVACY PRACTICES

PUT LABEL HERE

PATIENT # _____

NAME OF PATIENT _____

DATE OF BIRTH _____

Before you give your consent, be sure you understand the information given below. If you have any questions, we will be happy to talk about them with you. You may ask for a copy of this form.

I understand that I must tell the staff if language interpreter services are necessary to my understanding of the written or spoken information given during my health care visits. I understand that free interpretive services may not be immediately available and Planned Parenthood may need to refer me to another health care facility to provide the services necessary for my care.

I will be given information about the test(s), treatments, service(s)/procedure(s)/ surgery to be provided, including the benefits, risks, possible problems/complications and alternate choices. I was given *written patient information* and/or a copy of the Planned Parenthood Client Information for Informed Consent sheet. It was reviewed with me.

I understand that with any service/procedure/surgery, there is also the possibility of side effects. I understand that I should ask questions about anything I do not understand. I understand that a clinician is available to answer any questions I may have.

No guarantee about the results from this service/procedure/surgery has been given to me. I know that it is my choice whether or not to have this service/procedure/surgery. I know that I can change my mind about receiving this service at Planned Parenthood at any time.

I will be given referrals for further diagnosis or treatment if necessary. I understand that if referral is needed, I will assume responsibility for obtaining and paying for this care. I will be told how to get care in case of an emergency.

If there is an unexpected complication during the service/procedure/surgery, I request and authorize the clinician and authorized Planned Parenthood staff to do whatever is necessary to preserve my health and welfare.

In the event I need more pain medication to safely continue or complete the procedure, I request and authorize Planned Parenthood staff to give me medications they believe necessary. This may include medications to reduce pain and/or anxiety. I understand every medication carries a small risk. I understand the clinician will only use medications if s/he believes it is clinically indicated.

I request that a person authorized by Planned Parenthood provide appropriate evaluation, testing, and treatment (including a birth control drug or device, if I request it) and perform the following service(s)/ procedure(s)/surgery:

- □ In-Clinic Suction Abortion – Removal of uterine pregnancy less than 13 weeks gestational age by mechanical method.

- □ In-Clinic Dilation & Evacuation (D&E) Abortion – Removal of uterine pregnancy at 13 weeks or greater gestational age by mechanical method.
- □ Osmotic Dilator Insertion prior to Surgical Abortion – Short thin rods placed in the cervix (opening of uterus) to stretch the opening before the abortion procedure.
- □ The Abortion Pill – Prescription medicine taken to stop pregnancy development and cause passage of uterine pregnancy up to 9 weeks gestational age.
- □ Uterine Aspiration – Removal of blood or remaining pregnancy tissue from uterus following abortion.
- □ Treatment of Miscarriage with a Suction Procedure – Removal of remaining pregnancy tissue from uterus following an early pregnancy loss.
- □ Treatment of Miscarriage with Abortion Pill – Prescription medicine taken to cause passage of pregnancy tissue following an early pregnancy loss.
- □ Colposcopy – Use of microscope to look for abnormal cells on cervix (opening of uterus).
- □ Cervical Biopsy and Endocervical Sampling (ECS) – Removal of small piece(s) of tissue on cervix to check for abnormalities.
- □ Endometrial Biopsy – Removal of cells from lining of uterus to check for abnormalities.
- □ Vulvar Biopsy – Removal of small piece of tissue from the lips of vagina to check for abnormalities.
- □ Cryotherapy of Cervix – Freezing of top layer of cervix (opening of uterus) to treat abnormal cells.
- □ LEEP – A small electrical wire loop used to remove abnormal tissue from the cervix.
- □ IUC Insertion – Placement of □ Mirena □ Skyla □ ParaGard into the uterus to prevent pregnancy.
- □ Contraceptive Implant Insertion – After a shot of numbing medicine, birth control device (flexible 1 ½" rod) is placed under skin of upper arm to prevent pregnancy.
- □ Contraceptive Implant Removal – After a shot of numbing medicine, small cut is made in skin and the birth control device is removed through it.
- □ Prenatal Care – Healthcare provided during pregnancy.
- □ Hysteroscopic Tubal Sterilization (Essure®) – A method of permanent birth control. A tiny device, called a microinsert, is used to close the opening of each of the fallopian tubes (the tubes that carry the eggs from the ovaries to the uterus).
- □ Vasectomy – A method of permanent birth control. After a shot of numbing medicine, the vas deferens are cut or blocked.
- □ Cervical polyp removal – Removal of growth at opening of the uterus. The growth will be sent to the laboratory for testing.
- □ Fine Needle Aspiration of Breast (FNA) – Use of a thin needle to remove cells or fluid fluid from a lump in the breast. The cells or fluid will be sent to the laboratory for testing.
- □ Breast Cyst Aspiration – Use of a thin needle to remove the fluid from a fluid filled lump in the breast.
- □ Treatment of Bartholin's Duct Abscess (I & D) – Small cut made to infected area to drain fluid from it.
- □ Skin Biopsy – Removal of a very small piece of skin to check for disease or remove the problem.
- □ Sedation
- □ Other: _____

I understand that if tests for certain sexually transmitted infections are positive, reporting of positive results to public health agencies is required by law.

I understand that confidentiality will be maintained as described in [NAME OF AFFILIATE's] *Notice of Health Information Privacy Practices*. I consent to the use and disclosure of my health information as described in *Notice of Health Information Privacy Practices*.

I hereby acknowledge receipt of [NAME OF AFFILIATE's] notice of health information privacy practices

Client Signature	Date

I witness that the client received this information, said she/he read and understood it, and had an opportunity to ask questions.

Witness signature	Date

□ CHECK HERE IF CLIENT'S GUARDIAN OR RELATIVE IS LEGALLY REQUIRED TO SIGN BELOW.

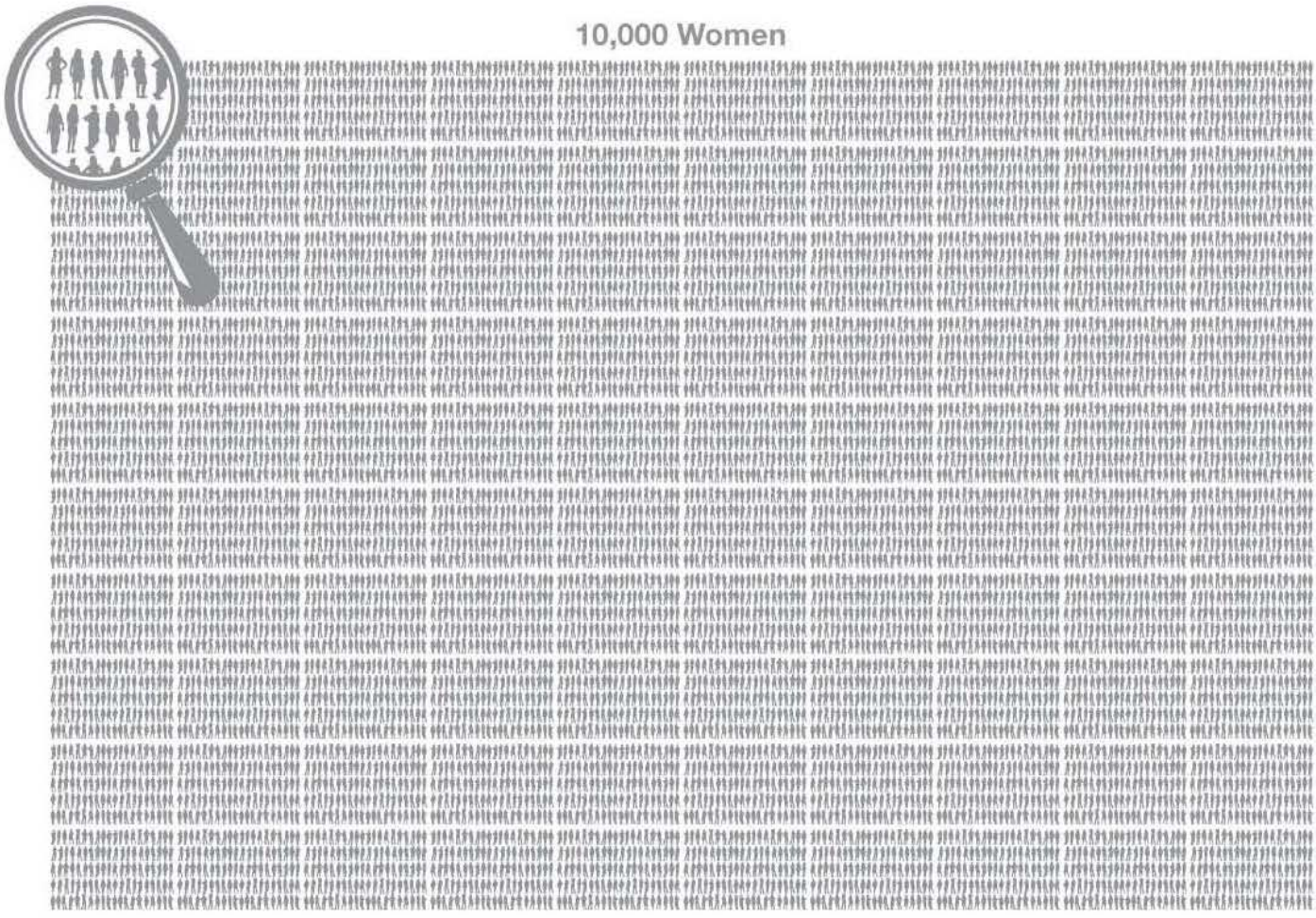
Signature of any other person consenting	Date	Relationship to client

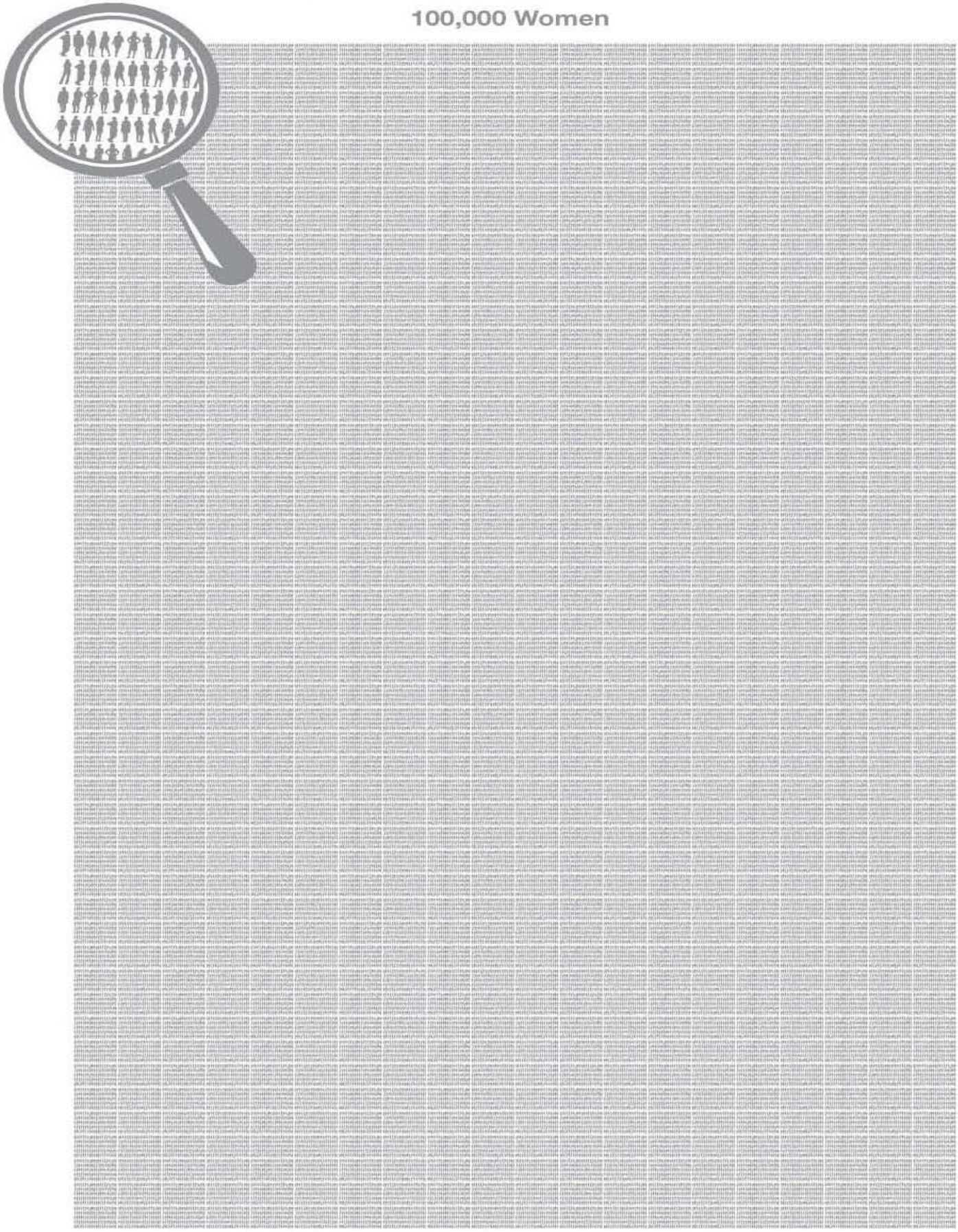
I witness the fact that the client's legal guardian (or person consenting in her/his behalf) received the above mentioned information and said she/he read and understood same.

Witness signature	Date

100 Women

10,000 Women





PPFA MS&GS ABBREVIATIONS LIST

June 2014

Numeric

The 5 A's	Ask, Advise, Assess, Assist, Arrange
The 5 R's	Relevant, Risk, Rewards, Roadblocks, Repeat

A

A1C	Glycosalyted Hemoglobin (A component of Hemoglobin that binds with glucose. A measurement of a person's average glucose level over the last 2-3 months.)
AACR	American Association for Cancer Research
AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
AC	Abdominal Circumference (ultrasound)
ACCME	Accreditation Council for Continuing Medical Education
ACEI	Angiotensin-Converting Enzyme Inhibitor
ACIP	Advisory Committee on Immunization Practices
ACOG*	American College of Obstetrics & Gynecology
ACP	American College of Physicians
ACQ	Asthma Control Questionnaire
ACR	American College of Radiology
ACS	American Cancer Society
ACT	Asthma Control Test
ADA	American Diabetes Association
AED	Accreditation & Evaluation Department
AED	Anti-Epilepsy Drugs
AFP	Alpha Fetoprotein
AGC	Atypical Glandular Cells
AGC-NOS	Atypical Glandular Cells – Not Otherwise Specified
AgNO3	Silver Nitrate
AGUS*	Atypical Glandular Cells – Undetermined Significance
AHA	American Heart Association
AHRQ	Agency for Healthcare Research & Quality (A U.S. government agency whose mission is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans.)
AIDS*	Acquired Immune Deficiency Syndrome
AIUM	American Institute of Ultrasound in Medicine
AIS	Adenocarcinoma In Situ
ALT	Alanine Aminotransferase
ALTS	ASCUS/LSIL Triage Study for Cervical Cancer
AMC	Affiliate Medical Committee
APA	American Psychological Association
APC	Advanced Practice Clinician
5-ARI	5-Alpha Reductase Inhibitor
ARB	Angiotensin II Receptor Blocker
ARMS*	Affiliate Risk Management Services
ART	Assisted Reproductive Technology
ASC	Atypical Squamous Cells
ASCCP	American Society for Colposcopy & Cervical Pathology (Founded in 1964, this society educates & trains clinicians in colposcopy, and strives to improve clinician competence, performance, & patient outcomes in the evaluation of lower genital tract disorders.)
ASC-H	Atypical Squamous Cells – cannot exclude High Grade Lesion
ASCP	American Society for Clinical Pathology
ASC-US*	Atypical Squamous Cells of Undetermined Significance
ASCVD	Atherosclerotic cardiovascular disease
AST	Aspartate Aminotransferase
ATAQ	Asthma Therapy Assessment Questionnaire
ATP III	3rd Report of the Expert Panel on Detection, Evaluation, & Treatment of High Blood Cholesterol in Adults

**cross-listed with ARMS abbreviation list*

PPFA MS&GS ABBREVIATIONS LIST

June 2014

B

β_2 Agonist	Beta-2 Adrenergic Agonist
BB	Beta Blocker
BBT*	Basal Body Temperature or Thermometer
BCA	Bichlorocetic Acid
BE	Bacterial Endocarditis
BID*	Twice a day (Latin: bis in die.)
BI-RADS	Breast Imaging-Radiology Data Systems
BLS	Basic Life Support
BMD	Bone Mineral Density
BMI*	Body Mass Index
BP*	Blood Pressure
BPD	Biparietal Diameter (ultrasound)
BPH	Benign Prostatic Hypertrophy
BPP	Biophysical Profile
BRCA	**Br**east **Ca**ncer
BRSQ	Breast Risk Screening Questionnaire
BSA	Breast Self-Awareness
BTL*	Bilateral Tubal Ligation
BUN	Blood Urea Nitrogen
BV*	Bacterial Vaginosis
BVM	Bag Valve Mask

C

C+S+4	Calvarium-spinal column + 4 extremities
C3T	Clomiphene Citrate Challenge Test
Ca*	Cancer
CAD	Coronary Artery Disease
CAL	Center for Affiliate Learning
CAPS	Consortium of Abortion Providers
CAPS	Center for AIDs Prevention Studies
CBC*	Complete Blood Count
CBE*	Clinical Breast Exam
CBT	Cognitive Behavioral Therapy
CCB	Calcium-Channel Blocker
CC	Clomiphene Citrate
CD	Cycle Day
CDC*	Center for Disease Control
CEE	Conjugated ethinyl estradiol
CEO	Chief Executive Officer
CEU	Continuing Education Unit(s)
CHC*	Combined Hormonal Contraception (tive)
CHD*	Coronary Heart Disease
CHF	Congestive Heart Failure
CI*	Client Information
CI	Confidence Interval
CIA	Chemiluminescense immunoassay (used for the detection of Hepatitis C virus)
CIIC*	Client Information for Informed Consent
CIN*	Cervical Intraepithelial Neoplasia
CIS*	Carcinoma In Situ
CK	Creatinine Kinase
CKD	Chronic Kidney Disease
CLAS	Culturally & Linguistically Appropriate Services
CLIA	Clinical Laboratory Improvement Amendments
CMA	Certified Medical Assistant
CME	Continuing Medical Education
CMS	Centers for Medicare & Medicaid Services
CMV*	Cytomegalovirus
CNM*	Certified Nurse Midwife

**cross-listed with ARMS abbreviation list*

CNS*	Central Nervous System
CO_2	Carbon Dioxide
COC*	Combined Oral Contraception (tive)
COHS	Controlled Ovarian Hyperstimulation
COPD	Chronic Obstructive Pulmonary Disease
CPP	Chronic Pelvic Pain
CPR	Cardio-Pulmonary Resusitation
CRNA	Certified Registered Nurse Anesthesist
CSF	Cerebrospinal Fluid
CSII	Continuous Subcutaneous Insulin Infusion
CT*	Chlamydia Trachomatis
CT	Computerized Tomography
Cu	Copper
CVA*	Cerebral Vascular Accident
CVD	Cardiovascular Disease
CVR*	Contraceptive Vaginal Ring
CVS*	Chorionic Villus Sampling
CXR	Chest X-Ray

D

D&C*	Dilatation & Curettage
D&E	Dilatation & Evacuation
DASH	Dietary Approaches to Stop Hypertension
DBP	Diastolic Blood Pressure
DES*	Diethylstilbesterol
DEXA	Dual Energy X-Ray Absorptiometry
DFA	Direct Fluorescent Antibody
DHEA	Dehydroepiandrosterone
DHEA-S	Dehydroepiandrosterone-Sulfate
DIC	Disseminated Intravascular Coagulation
DKA	Diabetic Ketoacidosis
DM*	Diabetes Mellitus
DMPA*	Depot Medroxyprogesterone acetate
DNA	Deoxyribonucleic Acid
DO*	Doctor of Osteopathy
DRE	Digital Rectal Exam
DS	Double Strength
DSM	Diagnostic & Statistical Manual of Mental Disorders
DSME	Diabetes Self-Management Education
	DSM-IV
DSM-5	Diagnostic & Statistical Manual of Mental Disorders, Fourth Edition or Fifth Edition
DTR	Deep Tendon Reflexes
DVT*	Deep Vein Thrombosis

E

E_2	Estradiol
EC*	Emergency Contraception
ECP*	Emergency Contraceptive Pill(s)
ECS*	Endocervical Sampling
ED	Erectile Dysfunction
EE*	Ethinyl Estradiol
EGA*	Estimated Gestational Age
EGW	External Genital Warts
EIA	Enzyme Immunoassay
EIB	Exercise-Induced Bronchoconstriction or Spasm
EKG	Electrocardiogram
EMR	Electronic medical record
EMS	Emergency Medical System
ENG	Etonogestrel

**cross-listed with ARMS abbreviation list*

EP	Ectopic Pregnancy
EPL	Early Pregnancy Loss
EPR3	Expert Panel Report 3
EPT	Estrogen-Progesterone Therapy
ER*	Emergency Room
ESR	Erythrocyte Sedimentation Rate
ET*	Estrogen Therapy
ETOH	Alcohol

F

FAM*	Fertility Awareness Method
FBS*	Fasting Blood Sugar
FDA*	Food & Drug Administration
Fe	Iron
FEV_1	Forced Expiratory Volume (maximum air forcefully exhaled in one second, then converted to a percentage)
FL	Femur Length (ultrasound)
FNA*	Fine needle aspiration
FNP	Family Nurse Practitioner
FOBT/gFOBT	Fecal Occult Blood Test (G=guaiac)
FPG	Fasting Plasma Glucose
FRAX	Fracture Risk Assessment Tool (Released in 2008, this is a fracture risk assessment tool developed by the WHO to determine the 10 year probability of developing a bone fracture.)
FSH*	Follicle Stimulating Hormone
FSP	Fibrinogen Split Products
FTA-ABS*	Fluorescent Treponemal Antibody – Absorbed (Syphilis Testing)
FTM	Female-to-Male
F/U*	Follow-Up
FVC	Forced Vital Capacity (amount of air which can be forcibly exhaled from the lungs after taking the deepest breath possible)

G

G*	Gram, Gravida
GAD	Generalized Anxiety Disorder
GBS	Group Beta Streptococcus
GC*	Neisseria Gonorrhoeae
GDM*	Gestational Diabetes Mellitus
GERD	Gastro-Esophageal Reflux Disease
GI*	Gastrointestinal
Gm	Gram
GNID	Gram-Negative Intracellular Diplococci
GnRH	Gonadotropin Releasing Hormone
GTT*	Glucose Tolerance Test
GU*	Genitourinary
GYN*	Gynecology

H

H_2	Histamine
H. pylori	Helicobacter pylori
HAARTs	Highly Active Antiretroviral Therapy
HA or HAV	Hepatitis A Virus
HB_cAB	Hepatitis B Core Antibody
HB or HBV*	Hepatitis B Virus
HB_sAG*	Hepatitis B Surface Antigen
HC	Head Circumference (ultrasound)
HC	Hormonal Contraception

**cross-listed with ARMS abbreviation list*

HC2	Hybrid Capture 2
HCA	Health Care Assistant
hCG*	Human Chorionic Gonadotropin
HCL	Hydrogen Chloride
HCV*	Hepatitis C Virus
Hct*	Hematocrit
HDL*	High Density Lipoprotein (cholesterol)
HEENT	Head-Ears-Eyes-Nose-Throat
Hep-Lock	Heparin-Lock (IV access)
Hg	Mercury
Hgb*	Hemoglobin
HIPAA*	Health Insurance Portability & Accountability Act (Enacted in 1996, this act allows workers to keep their health insurance if they change or lose their jobs. It set privacy standards for the release of health information, and it established national identifiers for providers.)
HIV*	Human Immunodeficiency Virus
HMGCoA	5-hydroxy-3-methylglutaryl-coenzyme A reductase (A statin drug lowers cholesterol by inhibiting this enzyme.)
hpf*	High Power Field
HPI	History of Present Illness
HPV*	Human Papilloma Virus
HR	Human Resources
HR	Heart Rate
HROB	High-Risk Obstetrician
HRT	Hormone Replacement Therapy
HS	At bedtime (hors somni – at the hour of sleep); Half-strength
HSG	Hysterosalpingogram
HSIL	High Grade Squamous Intraepithelial Lesion
HSPT	High-sensitive Pregnancy Test
HSV*	Herpes Simplex Virus
HSV-1(gG1)	Herpes Simplex Virus 1, glycoprotein G1
HSV-2 (gG2)	Herpes Simplex Virus 2, glycoprotein G2
HT*	Hormone Therapy
HTN*	Hypertension
HTS*	Hysteroscopic Tubal Sterilization

I

IBD	Irritable Bowel Disease
IBS	Irritable Bowel Syndrome
IC	Interstitial Cystitis
ICEC	International Consortium for Emergency Contraception
IC/PBS	Interstitial Cystitis/Painful Bladder Syndrome
ICS	Inhaled Corticosteroid
ICSI	Intracytoplasmic Sperm Injection
ICU	Intensive Care Unit
IDU	Intravenous/Injection Drug User
IE	Infective Endocarditis
IFA*	Immunofluorescent Assay
IFG	Impaired Fasting Glucose
igE	Immunoglobulin E (An antibody that is implicated in allergic reactions. It is usually found in lungs, skin, & mucous membranes.)
IGF-1	Insulin-like Growth Factor – 1 (A hormone similar to insulin and implicated in the growth of almost all cells found in the body.)
IgG	Immunoglobulin G (The most common & smallest antibody & found in all body fluids. It can be used to measure antibody response to certain infections and vaccines.)

**cross-listed with ARMS abbreviation list*

IgM	Immunoglobulin M (The largest antibody that is found in blood & lymph. It is the first antibody made to fight infection & can be measured to ascertain if infection is present.)
IGT	Impaired Glucose Tolerance
IHPS	Infantile Hypertrophic Pyloric Stenosis
IM*	Intramuscular
Intravag	Intravaginal
IOP	Intensive Outpatient Program (A treatment & support program used mainly with clients who have eating or drug dependency disorders. Most programs are 10-12 hours per week allowing clients to continue working.)
IPV	Intimate Partner Violence
IRB	Institutional Research Board
ISMP	Institute for Safe Medication Practices
ISSVD	International Society for the Study of Vulvo-Vaginal Disease
IU	International Units
IUC*	Intrauterine Contraceptive
IUGR	Intrauterine Growth Retardation
IUI	Intrauterine Insemination
IUP*	Intrauterine Pregnancy
IUS*	Intrauterine System
IV*	Intravenous
IVF*	In-vitro fertilization

J

K

Kcal	Kilocalorie (A large calorie worth 1000 small calories.)
KCL	Potassium Chloride
KOH*	Potassium hydroxide

L

LABA	Long-Acting Beta Agonist
LAM*	Lactation-Amenorrhea Method
LASA	Look-Alike Sound-Alike (drugs)
LCIS	Lobular Carcinoma In Situ
LDL*	Low-Density Lipoprotein
LE*	Leukocyte Esterase
LEEP*	Loop Electro-Excision Procedure (A fine wire loop is heated with an electric current and is used to remove abnormal cells from the cervix.)
LEP	Limited English Proficiency
LFTs*	Liver Function Tests
LGBT*	Lesbian-Gay-Bisexual-Transgender
LGV*	Lymphogranuloma Venereum
LH*	Leutinizing Hormone
LMP*	Last Menstrual Period
LNG	Levonorgestrel
LNMP*	Last Normal Menstrual Period
LOL	Limits of Lesion
LOOP	Loop Electrosurgical Excision Procedure (also known as LEEP, see above)
LPN*	Licensed Practical Nurse
LSIL	Low Grade Squamous Intraepithelial Lesion
LSPT	Low-Sensitive Pregnancy Test
LTRA	Leukotrene Receptor Antagonist
LVN	Licensed Vocational Nurse

**cross-listed with ARMS abbreviation list*

M

MAO	Monoamine Inhibitor
MCV	Mean Corpuscular Volume
MD*	Medical Doctor
MDE	Major Depressive Episode
MDI	Multi-dose Inhaler
MeDC	Medical Director Council
Mg/d	Milligrams/day
Mg/dL	Milligrams/deciliter
MHT	Menopause Hormone Therapy
MHz	Megahertz
MI	Myocardial Infarction
Miso	misoprostol
mIU	Milli-International Units
mL*	Milliliters
MLAP	MedicoLegal Advisory Panel
Mm/Hg	Millimeters of Mercury
MMR	Measles-Mumps-Rubella (vaccine)
MMWR	Morbidity & Mortality Weekly Report
MNT	Medical Nutrition Therapy
MPA	Medroxy Progesterone Acetate
MRI	Magnetic Resonance Imaging (A machine that uses a magnetic field and pulses of radio wave energy to make digital pictures of structures inside the body. It can usually see small problems not seen by x-ray, ultrasound, or CAT Scan.)
MRSA*	Methicillin-Resistant Staphylococcus Aureus
MS&G	Medical Standards & Guidelines
MSAFP	Maternal Serum Alpha Fetoprotein
MSM*	Males who have sex with Males
MTF	Male-to-Female

N

N9	Nonoxynol-9
NAAT	Nucleic Acid Amplification Test
NaCl	Sodium Chloride
NAMS	North American Menopause Society
NCCN	National Comprehensive Cancer Network
NDEP	National Diabetes Education Program
NERD	Nonerosive Reflux Disease
NFP*	Natural Family Planning
NHLBI	National Heart Lung Blood Institute
NIDDK	National Institute of Diabetes, Digestive, & Kidney Diseases
NIH*	National Institutes of Health
NIL	Negative for Intraepithelial Lesion
NILM	Negative for Intraepithelial Lesion or Malignancy
NLM	National Library of Medicine
NMC*	National Medical Committee
NNEDV	National Network to End Domestic Violence
NNT	Number needed to treat
NOF	National Osteoporosis Foundation
NOS	Not Otherwise Specified
NP*	Nurse Practitioner
NPH	Neutral Protamine Hagedorn insulin (Also known as Humulin N, it is an intermediate insulin used to control blood sugar in diabetes.)
NPO	Nothing Per Os
NPV	Negative Predictive Value (A statistic used to determine the proportion of negative tests that are true negatives.)
NRI	Norepinephrine Reuptake Inhibitor

**cross-listed with ARMS abbreviation list*

NRT	Nicotine Replacement Therapy
NSAID	NonSteroidal Anti-Inflammatory Drug
NSGC	National Society of Genetic Counselors
NSS	Normal Saline Solution
NT	Nuchal Translucency
NTQR	Nuchal Translucency Quality Review Program (A group established in 2005 to credential physicians & sonographers in this technique & to review their data for accurate measurements as part of prenatal risk assessment.)

O

O_2	Oxygen
OAB	Overactive Bladder
OB*	Obstetrics
OB/Gyn*	Obstetrics & Gynecology
OC*	Oral Contraceptive(s)
OCD	Obsessive-Compulsive Disorder
OGTT	Oral Glucose Tolerance Test
OHSS	Ovarian Hyperstimulation Syndrome
OPA	Office of Population Affairs (A Title X Family Planning research, education, & training organization.)
OR	Odds Ratio
Os	Opening
OSHA	Occupational Safety & Health Act/Administration
OTC*	Over-the-Counter
OTIS	Organization of Teratology Information Specialists (A group providing information to mothers & clinicians about medication & and other exposures during pregnancy & lactation.)

P

P	Progesterone
p53	A gene that contains a tumor suppressor protein. Mutations of this gene are involved in many cancers.
PA*	Physicians' Assistant
PAETC	Pacific AIDS Education & Training Center
Pap	Papanicolaou Test (A scraping of cells from the cervix to test for cervical cancer and pre-cancerous cervical cells.)
PAPP-A	Pregnancy-Associated Plasma Protein A (This is a blood test used in screening pregnancies for Down Syndrome. Low levels are associated with fetuses with an abnormal number of chromosomes.)
PCN	Penicillin
PCOS*	Polycystic Ovarian Syndrome
PCPT	Prostate Cancer Prevention Trial
PCR	Polymerase Chain Reaction (A technology developed in the 1980's to amplify segments of DNA by heating a small sample & separating the DNA into 2 strands. Thus a small sample can be analyzed for bacteria, viruses, or genetic disorders.)
PDD	Persistent Depressive Disorder
PDQ	Physician Data Query (The National Cancer Institutes' comprehensive cancer database.)
PE*	Physical Exam
PE	Pulmonary Emoblism
PEP	Positive Expiratory Pressure (Usually delivered with a special mask during exhalation, resistance is created that allows deep airways to be cleared of mucus and bring oxygen up to normal levels.)

**cross-listed with ARMS abbreviation list*

PEP	Post-Exposure Prophylaxis (Medication treatment started immediately after exposure to a pathogen to prevent infection or disease.)
PFT	Pulmonary Function Test
PFM	Pelvic Floor Muscle
PFME	Pelvic Floor Muscle Exercise
Pg/ml	Picograms per millileter
pH	"power of Hydrogen". (pH is the measure of hydrogen ions in a solution with the numerical value indicating whether the solution is an acid or base.)
PHQ-9	Patient Health Questionnaire (This is a self-administered tool of 9 questions that can be used by clinicians in diagnosing depression & to monitor treatment response.)
PID*	Pelvic Inflammatory Disease
PIN	Penile Intraepithelial Neoplasia
PKU	Phenylketonuria
PMDD*	Premenstrual Dysphoric Disorder
PMS*	Premenstrual Syndrome
PO*	Per Os (orally)
POC*	Products of Conception
POPs*	Progestin-Only Pills
PP*	Planned Parenthood
PPFA*	Planned Parenthood Federation of America
PPOB	Planned Parenthood Obstetrician
PPV	Pneumoccocal Vaccine
PPV	Positive Predictive Value or Precision Rate (the proportion of positive test results that are true positive tests)
PQRST	**P**recipitating factors or Previous treatments; **Q**uality (pain); **R**adiation (fixed or variable pain); **S**everity (use pain scale); **T**emporal factors (menses, intercourse, penetration)
Prl*	Prolactin
Prn*	Pro re nata (as needed)
PSA	Prostate Specific Antigen (This is a protein produced by the prostate. A blood test for this antigen is used to screen men for prostate cancer & to monitor their response to treatment.)
PT*	Prothrombin Time
PTEN	Phosphatase and Tensin Homolog (This is a tumor suppressor gene. A mutation of this gene is implicated in many cancers.)
PTSD	Post-traumatic Stress Disorder
PTT*	Partial Thromboplastin Time
PTU	Propylthiouracil (A medication used to treat hyperthyroidism.)
PUL	Pregnancy of Unknown Location
PV*	Per Vagina (prescriptions)
PVR	Post-Void Residual
PVSA	Post-Vasectomy Semen Analysis

Q

q*	Every (as in written prescriptions)
qd*	Every Day
QID*	Four times per day (Latin: quater in die)
Q-T Interval	Bradycardia

R

RCT	Randomized Controlled Trials
REDUCE	Reduction by Dutasteride of Prostate Cancer Events (A study that determined that dutasteride reduced the risk of prostate cancer in men who were at risk for the disease.)

**cross-listed with ARMS abbreviation list*

Repap	Repeat pap
Rh*	Rhesus Factor (This is an inherited specific protein found on red blood cells. If a client has the protein, he/she is Rh positive. If the client lacks the protein, he/she is Rh negative.)
RHEDI	**R**eproductive **H**ealth **ED**ucation **I**n Family Medicine (Established in 2004, the goal of this group is to integrate comprehensive abortion & family planning education into U.S. family medicine residency programs.)
RhIG	Rh Immune Globulin (An injection of Rh antibodies given to pregnant women who are Rh negative to prevent her from forming her own antibodies that would attack the Rh positive blood of her fetus.)
$Rh_o(D)$	Also known as Rh Immune Globulin.
RIBA	Recombinant immunoblot assay (A blood test to detect specific antibodies to the Hepatitis C virus.)
RLP	Reproductive Life Planning
RN*	Registered Nurse
RNA	Ribonucleic Acid (The single strand of nucleic acid in cells that along with DNA carry the genetic information that is inherited from one generation to the next.)
R/O*	Rule Out
RPL	Recurrent Pregnancy Loss
RPR*	Rapid Plasma Reagent
RT	Radiation Therapy
Rx*	Prescription

S

S1-S4	Sacral Vertebrae 1 – 4
SABA	Short-Acting Beta Agonist
SAD	Social Anxiety Disorder
SANE	Sexual Assault Nurse Examiner
SART	Society for Assisted Reproductive Technology
SBE*	Self-Breast Exam
SBP	Systolic Blood Pressure
SCJ	Squamous-Columnar Junction
S/Co	Signal to Cut-Off
SD	Standard Deviation
SERMs	Selective Estrogen Receptor Modulators
SL	Sublingual
SLE*	Systemic Lupus Erythematosis
SMBG	Self-Monitoring Blood Glucose
SNRI	Serotonin-norepinephrine reuptake inhibitor
SQ*	Subcutaneous
SR	Slow Release
SSRI	Selective Serotonin Reuptake Inhibitor
STARS	Web-based auditing tool used by affiliates to ensure compliance with PPFA MS&Gs.
STI*	Sexually Transmitted Infection
SUI	Stress Urinary Incontinence

T

T_3*	Triiodothyronine
T_4*	Serum Free Thyroxine
TB*	Tuberculosis
TCA*	Trichlorocetic Acid
TCA	Tricyclic Antipdepressant
TCP*	Transdermal Contraceptive Patch
Td	Tetanus – Diptheria (vaccine)
TDap	Tetanus-Diptheria-acellular Pertusis

**cross-listed with ARMS abbreviation list*

TG*	Triglycerides
TIA	Transient Ischemic Attack
TIBC	Total Iron Binding Capacity
TID*	Three times per day (Latin: ter in die.)
TIS	Teratogen Information Service (See also OTIS)
TLC	Therapeutic Lifestyle Changes
™	Trademark
TMP-SMX	Trimethoprim-sulfamethoxazole
TOC	Table of Contents
TOC	Test of Cure
TP53	Tumor Protein 53 (See also p53)
TP-PA	Treponema Pallidum Particle Agglutination assay (A blood test to detect antibodies from *Treponema Pallidum*, the cause of syphilis.)
T-Score	A measurement of bone density used to diagnose osteoporosis. The score is given in standard deviations from what would be expected in a healthy adult of the same sex.
TSH*	Thyroid Stimulating Hormone
TVUS	Transvaginal Ultrasound

U

U	Unit
UA	Urinalysis
UACR	Urine Albumin Creatinine Ratio
UCSD	University of California, San Diego
UCSF	University of California, San Francisco
UI	Urinary Incontinence
ULN	Upper Limit of Normal (page 16 primary care)
UPS	Uninterruptable Power Supply
URI*	Upper Respiratory Infection
U.S.	United States
USDA	United States Department of Agriculture
USMEC*	United States Medical Eligibility Criteria
USP	United States Pharmacopeia
USPSTF	United States Preventative Services Task Force
UPT*	Urine Pregnancy Test
UTI*	Urinary Tract Infection

V

VAERS	Vaccine Adverse Event Reporting System (A national vaccine safety surveillance program co-sponsored by the CDC & the FDA.)
VAIN	Vaginal Intraepithelial Neoplasia
VDRL*	Venereal Disease Research Lab (A blood test for syphilis developed by this lab in 1906. The lab is now part of the U.S. Public Health Service.)
VEA	Very Early Abortion
VIN	Vulvar Intraepithelial Neoplasia
VIS	Vaccine Information Sheet (from the CDC)
VPR	Vaginal-Perineal-Rectal (culture)
VTE*	Venous thromboembolic event or venous thromboembolism (A blood clot in a vein that can become life-threatening if it breaks away and lodges in the heart, lung, or brain.)
VVC	Vulvo-Vaginal Candidiasis
VZIG	Varicella Zoster Immune Globulin (An injection for passive immunization to Varicella Zoster given as soon after & preferably within 10 days of exposure to the virus.)
VZV	Varicella Zoster Virus (A herpes virus that causes Chickenpox [varicella] or shingles [herpes zoster]).

**cross-listed with ARMS abbreviation list*

W

WBC*	White Blood Count
WH	Women's Health
WHO*	World Health Organization
WNL*	Within Normal Limits
WPATH	World Professional Association for Transgender Health (A group promoting care, education, & research in transgender & transsexual health.)

X

XR	Extended Release

Y

Z

**cross-listed with ARMS abbreviation list*

(affiliate name and telephone number)

Date: _____

Dear _____,

Planned Parenthood got the result of your test from _____.
(date)

❑ **Your test shows that you have chlamydia.** (See information sheet.)
- ❑ You were treated at your visit. Make sure you take all your medicine.
- ❑ It is important that you call or come to Planned Parenthood to be treated.
- ❑ Your sex partner(s) needs to be treated.
- ❑ Come back to Planned Parenthood for a retest in 3 months.

❑ **Your test shows that you have gonorrhea.** (See information sheet.)
- ❑ You were treated at your visit. Make sure you take all your medicine.
- ❑ It is important that you call or come to Planned Parenthood to be treated.
- ❑ Your sex partner(s) needs to be treated.
- ❑ Come back to Planned Parenthood for a retest in 3 months.

❑ **Your test shows that you have herpes.** (See information sheet.)
- ❑ It is important that you call or come to Planned Parenthood to be treated.
- ❑ Make sure you finish the medicine that you got at your visit.

❑ **Your test shows that you have syphilis.** (See information sheet.)
- ❑ It is important that you call or come to Planned Parenthood to be treated.
- ❑ Your sex partner(s) need to be tested and may need treatment.

Treatment is important. It may prevent your infection from getting worse, help you to feel better, keep you from giving the infection to others, and in some cases, help you to stay healthy so you can get pregnant in the future.

❑ **Your test shows that you have a urinary tract infection.**
- ❑ You were treated at your visit. Make sure you take all your medicine.
- ❑ It is important that you call or come to Planned Parenthood to be treated.
- ❑ The urine test also shows that you need a different medicine to treat the infection.

It is important that you call Planned Parenthood at _____.

Treatment of a urinary tract infection is important. It may prevent you from getting a more serious infection in your kidneys.

❑ **Other** _____

Your health is important to us. We strongly encourage you to get the follow-up we recommend. We are happy to help you, but it is your responsibility. Please call us anytime and thank you for choosing Planned Parenthood.

List Planned Parenthood centers/numbers with checkboxes.

[Affiliate Code # and Revision Date]

(affiliate name and telephone number)

Date: _____

Dear _____,

On _____ Planned Parenthood performed your Pap / HPV test.
(date) (circle)

HPV Test	
Your test result(s)	**What your test result(s) mean**
□ HPV positive	HPV was found. HPV usually goes away on its own. If it doesn't go away on its own, over time it may cause changes on your cervix that can lead to cancer.
□ HPV negative	HPV was not found. A negative HPV test tells us that you are at lower risk for having problems.

Pap Test	
Your test result(s)	**What your test result(s) mean**
□ No result	The lab could not give any result.
□ Normal	No abnormal cells found.
□ Normal, but showed endometrial cells	Endometrial cells are normally found in the lining of the uterus (womb). You need more testing to find out if treatment is needed to prevent cancer.
□ Atypical squamous cells of undetermined significance □ (ASC-US)	Your test showed some changes to your cervix that may go away on their own. If they do not go away on their own, over time they may lead to cancer. You need more testing to find out if treatment is needed to prevent cancer.
□ Atypical squamous cells cannot exclude high grade squamous intraepithelial lesion (ASC-H)	Your test showed some changes to your cervix that may go away on their own. If they do not go away on their own, over time they may lead to cancer. You need more testing to find out if treatment is needed to prevent cancer.
□ Low grade squamous intraepithelial lesion (LSIL)	Your test showed some changes to your cervix that may go away on their own. If they do not go away on their own, over time they may lead to cancer. You need more testing to find out if treatment is needed to prevent cancer.
□ High grade squamous intraepithelial lesion (HSIL)	Your test showed some serious changes to your cervix. These changes could lead to cancer. You need more testing to find out if treatment is needed to prevent cancer.
□ Atypical Glandular Cells (AGC)	Your test showed serious changes to the inside of your uterus (womb) or cervix. You need more testing to find out if treatment is needed to prevent cancer.

You need the following test(s):
□ Colposcopy □ Endometrial biopsy □ Endocervical sampling **See information sheet included with this letter.**

Your health is important to us. We strongly encourage you to get the follow up we recommend. We are happy to help you but it is your responsibility.

Please call us to let us know you received this letter and to schedule an appointment. Feel free to call us any time you have questions.

Thank you for choosing Planned Parenthood.

List Planned Parenthood centers/numbers with checkboxes.

[Affiliate Code # and Revision Date]

(affiliate name and telephone number)

Date: _____

Dear _____,

On _____ Planned Parenthood performed your Pap / HPV test.
(date) (circle)

HPV Test			
Your test result(s)	**What your test result(s) mean**	**Follow-up tests recommended for you**	**Month/ year**
□ HPV positive	HPV was found. HPV usually goes away on its own. If it doesn't go away on its own, over time it may cause changes on your cervix that can lead to cancer.		
□ HPV negative	HPV was not found. A negative HPV test tells us that you are at lower risk for having problems.		

Pap Test			
Your test result(s)	**What your test result(s) mean**	**Follow-up tests recommended for you**	**Month/ year**
□ Normal	No abnormal cells found.	□ Pap and HPV in 12 months □ Pap in 3 years □ Pap and HPV in 3 years □ Pap and HPV in 5 years	
□ Normal	No abnormal cells found. But there were signs of an infection in your vagina. The attached information explains the infection(s).		
□ Normal, but not complete	The lab was not able to do a complete check. There were no problems seen but something in the test made it hard to read the results.	□ Pap in 12 months □ Pap and HPV in 12 months □ Pap and HPV in 3 years □ Other	
□ No result	The lab could not give any result. The Pap needs to be repeated.	□ Pap in 2 – 4 months	
□ Atypical squamous cells of undetermined significance (ASC-US)	Changes to your cervix that may go away on their own. If they do not go away on their own, over time they may lead to cancer.	□ Pap in 12 months □ Pap in 12 and 24 months □ Pap and HPV in 12 months □ Pap and HPV in 3 years □ Other	

Pap Test			
Your test result(s)	**What your test result(s) mean**	**Follow-up tests recommended for you**	**Month/ year**
□ Low grade squamous intraepithelial lesion (LSIL)	Changes to your cervix that may go away on their own. If they do not go away on their own, over time they may lead to cancer.	□ Pap in 12 months □ Pap in 12 and 24 months □ Pap and HPV in 12 months □ Other	

Your health is important to us. We strongly encourage you to get the follow up we recommend. We are happy to help you, but it is your responsibility.

Please feel free to call us any time and thank you for choosing Planned Parenthood.

List Planned Parenthood centers/ numbers with checkboxes.

[Affiliate Code # and Revision Date]

(affiliate name and telephone number)

Date _____

Dear _____,

Planned Parenthood cares about your health. This is a reminder to get the care we advised. If you have already done so, please let us know what happened.

INFECTION

❑ Treatment of a sexually transmitted infection (STI) called _____. Treatment is important. It may prevent your infection from getting worse, help you to feel better, keep you from giving the infection to others, and in some cases, help you to stay healthy so you can get pregnant in the future.

PAP/HPV PROBLEM

❑ Follow-up of an abnormal pap test and/or HPV test. We advised that you need a
- ❑ Repeat Pap test — due _____
- ❑ HPV test — due _____
- ❑ Colposcopy — due _____
- ❑ Other _____

The Pap test checks for changes to your cervix. The HPV test checks for the human papillomavirus (HPV), it usually goes away on its own. If HPV or the changes to your cervix do not go away on their own they can lead to cancer. Follow up is important to make sure you don't get cervical cancer.

BREAST PROBLEM

Follow-up of ❑ an abnormal breast exam or ❑ abnormal mammogram or ❑ incomplete mammogram or ❑ abnormal breast ultrasound

We advised that you need
- ❑ a repeat breast exam — due _____
- ❑ to see a specialist _____
- ❑ more tests — due _____

Follow-up is important to make sure you do not have breast cancer.

OTHER PROBLEMS

❑ Follow-up of _____
_____

Your health is important to us. We strongly encourage you to get the follow up we recommend. We are happy to help you but it is your responsibility.

Please feel free to call us any time and thank you for choosing Planned Parenthood.

List Planned Parenthood centers/numbers with checkboxes.

[Affiliate Code # and Revision Date]

(affiliate name and telephone number)

Date _____

Dear _____,

Planned Parenthood got the result of your test from _____
(date)

- □ Lab test _____
- □ Mammogram
- □ Ultrasound
- □ Other _____

Your result is:

□ **Normal**
Result is _____
□ You do not need any more tests.
□ Call Planned Parenthood to talk about your result.
□ Get a repeat test in _____

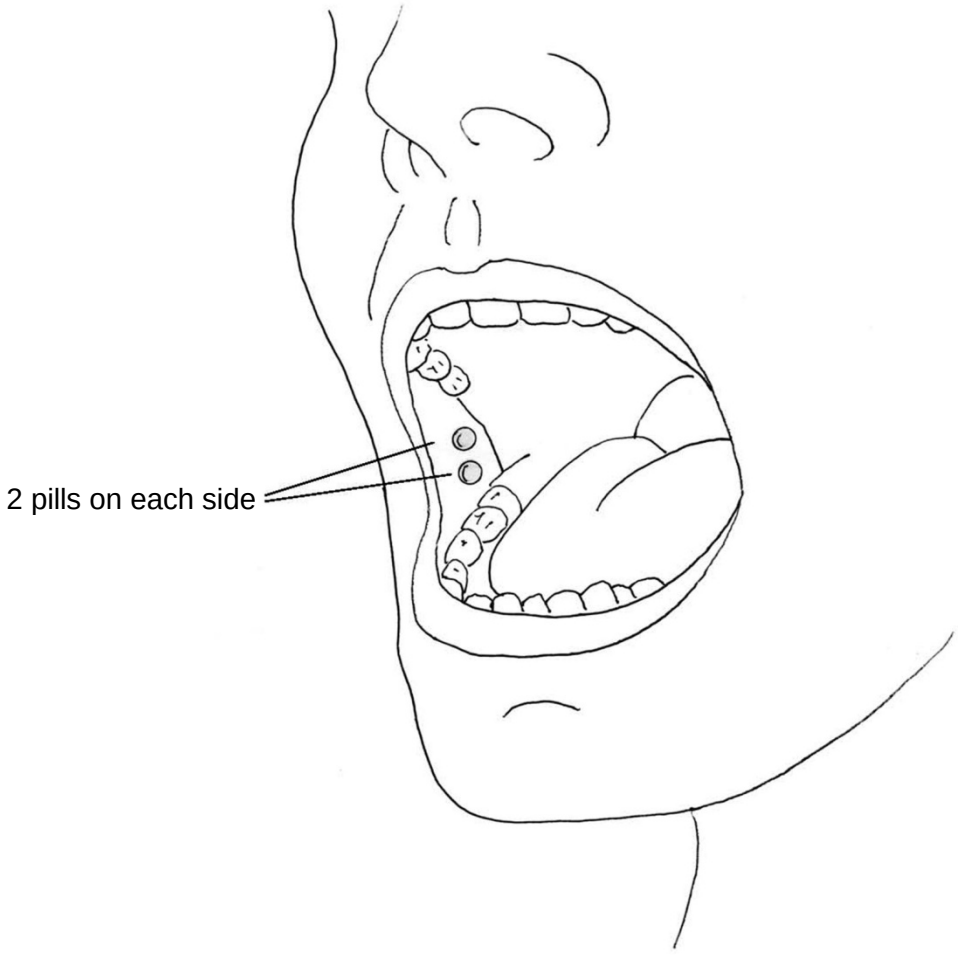
□ **Not Normal**
Result is _____
This means _____
_____
The follow-up is _____
_____
What could happen if you don't follow-up _____
_____
Please call Planned Parenthood at _____ to discuss your result.

□ **Other** _____
The follow-up is _____
What could happen if you don't follow-up _____
_____
Please call Planned Parenthood at _____ to talk about your tests.

Your health is important to us. We strongly encourage you to get the follow-up we recommend. We are happy to help, but it is your responsibility. Please call us anytime and thank you for choosing Planned Parenthood.

List Planned Parenthood centers/numbers with checkboxes.

[Affiliate Code # and Revision Date]



Abortion Options

	Abortion Pill	In-Clinic Abortion
How well does it work?	8 weeks or less: About 98 out of 100 times From 8 to 9 weeks: About 96 out of 100 times From 9 to 10 weeks: About 91 to 93 out of 100 times	It almost always works - over 99% of the time.
When can it be done?	Up to 10 weeks	Up to XX weeks
How does it happen?	▪ In the clinic, you take mifepristone. ▪ At home, you take misoprostol 24 to 48 hours later to pass the pregnancy tissue. ▪ Some people need a second dose of misoprostol. ▪ You have a follow-up ultrasound or blood draw about a week later to make sure it worked.	▪ In the clinic, your doctor or nurse will use gentle suction to remove the pregnancy. ▪ You will be in a recovery area until it's safe to go home, usually after 15 to 45 minutes. ▪ In most cases, no follow-up appointment is needed.
How long does it take?	Usually 24 hours or less, but it can take up to several days.	About 10 minutes.
How will I feel?	You'll start to have strong cramps and bleeding within 1 to 4 hours after taking the misoprostol. You may have cramping on and off for 1 or 2 more days. You may also have ▪ Fever of 99-100°F ▪ Chills ▪ Diarrhea ▪ Nausea or vomiting ▪ Headache ▪ Dizziness ▪ Back pain ▪ Tiredness	You may feel ▪ Mild to moderate cramping during and after the abortion. You may have cramping on and off for 1 or 2 more days.
What can I do for pain?	Pain medicine is available. Your doctor or nurse will discuss your choices with you.	
How much will I bleed? For how long?	Heavy bleeding with clots is common after taking misoprostol. Bleeding may continue on and off for 4 to 6 weeks.	Light or medium bleeding is common for 1 to 7 days. Bleeding may continue on and off for 4 to 6 weeks.
What are the benefits?	▪ It may feel more natural, like a miscarriage. ▪ Being at home may be more private and comfortable for you.	▪ It is over in a few minutes. ▪ You may have less bleeding than you would with the abortion pill. ▪ Clinic staff is there to support you.
What are the risks?	▪ If it doesn't work, you may need to have a suction procedure to complete the process.	▪ Possible injury to cervix, uterus or other organs. ▪ If it doesn't work, you may need to have a suction procedure to complete the process.
	For both procedures, risks include ▪ Pregnancy does not end ▪ Some of the pregnancy left in uterus ▪ Blood clots in uterus ▪ Heavy bleeding ▪ Infection ▪ Allergic reaction to medicines used ▪ Death	
How much does it cost?	▪ Cost ranges from XXX to XXX. ▪ State funding, private insurance and other funding sources may cover some of the costs.	▪ Cost ranges from XXX to XXX. ▪ State funding, private insurance and other funding sources may cover some of the costs.

How to Take the Pills for Your Abortion and What to Expect
BUCCAL

You will take 2 different medicines for your abortion.
- You will take mifepristone at the clinic on **DAY 1**.
- You will take misoprostol at home on **DAY 2 or 3**.

DAY 1

What will I do when I come to the clinic?
- You will swallow 1 **mifepristone** pill at the clinic.
- [INSERT AFFILIATE-SPECIFIC ANTIBIOTIC REGIMEN INSTRUCTIONS HERE]

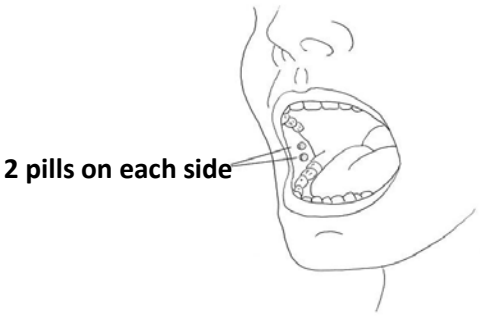
GETTING READY FOR DAY 2 or 3

You will bleed and have cramps after you take the **misoprostol**. Plan ahead before you take it.
- Choose a time when you can be private and rest for a while after you take it.
- Plan to have someone you trust on hand to help you out.
- Buy maxi pads, pain medicine, food, and anything else you think you will need.

DAY 2 or 3

How do I take the misoprostol?
You will take the misoprostol at home on **Day 2 or 3** (24-48 hours after taking the mifepristone).

Follow these steps:
- Take the anti-nausea pills, if we gave them to you, and pain medicine to prevent cramps. You can use ibuprofen. [INSERT AFFILIATE SPECIFIC INSTRUCTIONS HERE]. **Do NOT take aspirin, because it will make you bleed more**.
- Wait 30 minutes.
- Take the 4 **misoprostol** pills. Put 2 pills on one side of your mouth and the other 2 on the other side of your mouth. Wait 30 minutes for the pills to dissolve. After 30 minutes, swallow what is left of the pills. (See picture below).



What will happen to me after I take the misoprostol?

You'll start to have strong cramps and bleeding within 1 to 4 hours after taking the misoprostol. It can last for hours. It is heaviest when the pregnancy comes out. The pregnancy is very small. You may not see it. You might see it if you are more than 8 weeks (2 months) pregnant. At 8 weeks, the fetus is about ¼ to ½ inch long. Cramping and bleeding will slow down after it comes out.

What else do I need to know?

- Bleeding can be heavy. You may see large blood clots the size of a lemon.
- You may have nausea, vomiting, and diarrhea.
- You may also have mild fever, chills, dizziness, headache, back pain, and tiredness.

Your cramps may be strong. To feel better, you can

- Take your pain medicine.
- Put a hot water bottle or heating pad on your belly.
- Take a shower.
- Sit on the toilet.
- Have someone rub your back.

How will I feel after the pregnancy comes out?

Bleeding — It is normal to bleed. You may have little or no bleeding for a few days or weeks. Bleeding may stop and then start again. You may bleed like a normal menstrual period for 1 or 2 weeks. It should get lighter and lighter. Bleeding may continue on and off for 4 to 6 weeks. You should have your normal period again 4 to 8 weeks later.

Cramping — You will cramp less and less as the hours and days go by.

Fever and chills — You may have fever and chills the day you take the **misoprostol**. It is **NOT** normal to have a fever after that. Call us right away if you do. It could be a sign that you are getting an infection.

Nausea — This should go away in 1 or 2 days after you take the **misoprostol**.

Tiredness — You may feel tired for 1 or 2 days. You should be back to normal soon.

Breast changes — Tenderness should go away in a few days. You may leak a milky discharge. Wear a snug-fitting bra if you do. This should stop in 1 or 2 days.

What else do I need to know?

When can I return to my normal activities?
Plan on relaxing for the rest of the day. Most women return to their normal activities the next day, but do **NOT** do hard work or heavy exercise for several days.

Don't put anything in your vagina or have sex for 1 week after the procedure. You can get pregnant again within 2 weeks of the abortion, so you should start your birth control as you were told by the clinic staff. We can help you if you haven't chosen a method yet.

When your next period will come depends on the birth control method you use. If you are not using birth control, you should have a period within 8 weeks of the abortion. If you are not using birth control and you do not get a period within 8 weeks, call the clinic.

Should I use tampons or maxi pads?
Using maxi pads makes it easier to tell how much you are bleeding. You can use tampons when the heavy bleeding lets up.

What if I am breastfeeding?
Both misoprostol and mifepristone can pass into your breast milk in small amounts after you take it. These amounts shouldn't cause any problems for you or your baby. Tell your doctor or nurse if you're breastfeeding so you can work out the best plan together.

Why do I need a follow-up visit?
Follow-up is important so we can make sure that the pregnancy ended and that you are well. You were given instructions about when and where to follow-up. If you are unable to keep your appointment, please contact us to reschedule.

Call us right away at XXX-XXX-XXX **if you**

- Have a fever of 100.4°F or higher more than 24 hours after you've taken the misoprostol
- Have belly pain or cramps that don't get better with pain medicine
- Soak 2 maxi pads an hour for more than 2 hours
- Pass blood clots larger than the size of a lemon for more than 2 hours
- Are weak, have nausea, vomiting or diarrhea for more than 24 hours after taking misoprostol. All of these could be signs of serious infection.

How to Take the Pills for Your Abortion and What to Expect

ORAL

You will take 2 different medicines for your abortion.

- You will take mifepristone at the clinic on DAY 1.
- You will take misoprostol at home on DAY 2.

DAY 1

What will I do when I come to the clinic?

- You will swallow 1 **mifepristone** pill at the clinic.
- [INSERT AFFILIATE-SPECIFIC ANTIBIOTIC REGIMEN INSTRUCTIONS HERE]

GETTING READY FOR DAY 2

You will bleed and have cramps after you take the **misoprostol**. Plan ahead before you take it.

- Choose a time when you can be private and rest for a while after you take it.
- Plan to have someone you trust on hand to help you out.
- Buy maxi pads, pain medicine, food, and anything else you think you will need.

DAY 2

How do I take the misoprostol pills?

You will take the **misoprostol** at home on **Day 2** (24 hours after taking the mifepristone).

Follow these steps:

- Take the anti-nausea pills, if we gave them to you, and pain pills to prevent cramps. You can use ibuprofen. [INSERT AFFILIATE SPECIFIC INSTRUCTIONS HERE]. **Do NOT take aspirin, because it will make you bleed more.**
- Wait 30 minutes.
- Swallow 2 **misoprostol** pills, wait 2 hours, then swallow the next 2 **misoprostol** pills.

DAY 2

What will happen to me after I take the misoprostol?

You'll start to have strong cramps and bleeding within 1 to 4 hours after taking the misoprostol. It can last for hours. It is heaviest when the pregnancy comes out. The pregnancy is very small. You may not see it. You might see it if you are more than 8 weeks (2 months) pregnant. At 8 weeks, the fetus is about ¼ to ½ inch long. Cramping and bleeding will slow down after it comes out.

Things to know:

- Bleeding can be heavy. You may see large blood clots the size of a lemon.
- You may have nausea, vomiting, and diarrhea.
- You may also have mild fever, chills, dizziness, headache, back pain, and tiredness.

Your cramps may be strong. To feel better, you can

- Take your pain medicine.
- Put a hot water bottle or heating pad on your belly.
- Take a shower.
- Sit on the toilet.
- Have someone rub your back.

How will I feel after the pregnancy comes out?

Bleeding — It is normal to bleed. You may have little or no bleeding for a few days or weeks. Bleeding may stop and then start again. You may bleed like a normal menstrual period for 1 or 2 weeks. It should get lighter and lighter. Bleeding may continue on and off for 4 to 6 weeks. You should have your normal period again 4 to 8 weeks later.

Cramping — You will cramp less and less as the hours and days go by.

Fever and chills — You may have fever and chills the day you take the misoprostol pills. It is **NOT** normal to have a fever after that. Call us right away if you do. It could be a sign that you are getting an infection.

Nausea — This should go away in 1 or 2 days after you take the misoprostol.

Tiredness — You may feel tired for 1 or 2 days. You should be back to normal soon.

Breast changes — Tenderness should go away in a few days. You may leak a milky discharge. Wear a snug-fitting bra if you do. This should stop in 1 or 2 days.

What else do I need to know?

When can I return to my normal activities?
Plan on relaxing for the rest of the day. Most women return to their normal activities the next day, but do **NOT** do hard work or heavy exercise for several days.

Don't put anything in your vagina or have sex for 1 week after the procedure. You can get pregnant again within 2 weeks of the abortion, so you should start your birth control as you were told by the clinic staff. We can help you if you haven't chosen a method yet.

When your next period will come depends on the birth control method you use. If you are not using birth control, you should have a period within 8 weeks of the abortion. If you are not using birth control and you do not get a period within 8 weeks, call the clinic.

Should I use tampons or maxi pads?
Using maxi pads makes it easier to tell how much you are bleeding. You can use tampons when the heavy bleeding lets up.

What if I am breastfeeding?
Both misoprostol and mifepristone can pass into your breast milk in small amounts after you take it. These amounts shouldn't cause any problems for you or your baby. Tell your doctor or nurse if you're breastfeeding so you can work out the best plan together.

Why Do I Need a Follow-Up Visit?
Follow-up is important so we can make sure that the pregnancy ended and that you are well. You were given instructions about when and where to follow-up. If you are unable to keep your appointment, please contact us to reschedule.

Call us right away at XXX-XXX-XXX if you

- Have a fever of 100.4°F or higher more than 24 hours after you've taken the misoprostol
- Have belly pain or cramps that don't get better with pain medicine
- Soak 2 maxi pads an hour for more than 2 hours
- Pass blood clots larger than the size of a lemon for more than 2 hours
- Are weak, have nausea, vomiting or diarrhea for more than 24 hours after taking misoprostol. All of these could be signs of serious infection

Making Sure the In-Clinic Abortion is Complete

What needs to be done to make sure the in-clinic abortion is complete?

The doctor or nurse looked closely at the tissue that was removed from the uterus after the in-clinic abortion. Only a small amount was seen. More tests are needed to make sure the in-clinic abortion is complete.

Why was a small amount of tissue seen?

There are a few reasons why this might happen. It could be that

- The in-clinic abortion is complete and everything is okay but it was hard to see the pregnancy in the tissue that was removed.
- The test that showed you were pregnant was wrong and you were not pregnant.
- You were pregnant and aren't anymore but some of the pregnancy tissue was left inside the uterus. This may lead to heavy bleeding, infection, or both.
- You may have had a miscarriage.
- The in-clinic abortion did not end the pregnancy and you are still pregnant.
- The in-clinic abortion did not end the pregnancy, you are still pregnant, and the pregnancy may be outside the uterus – called ectopic pregnancy. An ectopic pregnancy can cause bleeding, which in some cases can lead to death. This requires immediate treatment that may include surgery.

What tests or treatment do I need?

So that we can be sure your in-clinic abortion is complete, we recommend:

- ☐ Another ultrasound
- ☐ 2 blood tests 48 to 72 hours apart to help us see if your pregnancy is growing normally, was a miscarriage, or is ectopic
- ☐ Sending the tissue that was removed from the uterus to a lab to be looked at under a microscope
- ☐ A more detailed ultrasound done outside of Planned Parenthood to get more information about your pregnancy
- ☐ A suction procedure
- ☐ Seeing a doctor outside of Planned Parenthood for more tests and/or treatment

Call us right away at XXX-XXX-XXXX if you

- Have belly pain or cramps that don't get better with pain medicine
- Soak 2 maxi pads an hour for more than 2 hours
- Faint
- Have shoulder pain

What to Expect After In-Clinic Abortion or Suction Procedure

When can I return to my normal activities?

Plan on relaxing for the rest of the day. Most women return to their normal activities the next day, but do **NOT** do hard work or heavy exercise for several days. Fill and take any prescriptions you may have been given for antibiotics, birth control, or other medicine.

Don't put anything in your vagina or have sex for 1 week after the procedure. You can get pregnant again within 2 weeks of the in-clinic abortion or suction procedure, so you should start your birth control as you were told by the clinic staff. We can help you if you haven't chosen a method yet.

Should I use tampons or maxi pads?

Using maxi pads makes it easier to tell how much you are bleeding. You can use tampons when the heavy bleeding lets up.

What else do I need to know?

Bleeding — Some vaginal bleeding is normal after an in-clinic abortion or suction procedure. It may be different from your period. It is normal to have no bleeding, spotting that lasts up to 6 weeks, heavy bleeding for a few days, or bleeding that stops and starts again.

Cramping — You may have cramps. Use a heating pad or hot water bottle, take pain medicine, and rest.

Breast Changes — Tenderness should go away in a few days. You may leak a milky discharge. Wear a snug-fitting bra if you do. This should stop in 1 or 2 days

Your next period — When your next period will come depends on the birth control method you use. If you are not using birth control, you should have a period within 8 weeks of the abortion or suction procedure. If you are not using birth control and you do not get a period within 8 weeks, call the clinic.

Call us right away at XXX-XXX-XXXX if you

- Have a fever of 100.4° F or higher
- Have belly pain or cramps that don't get better with pain medicine
- Soak 2 maxi pads an hour for more than 2 hours

Make an appointment to see us as soon as possible, or call the clinic if you

- Have a bad smelling vaginal discharge
- Still feel pregnant

Digoxin

(affiliate name and telephone number)

What is digoxin?

Digoxin is a common heart medicine. It can be used to stop the fetal heartbeat before an abortion. This causes the fetus to die.

Digoxin is given through a thin needle. The needle goes through your belly and into the fluid around the fetus or into the fetus itself. It can take from several minutes to 24 hours for digoxin to work. You will have the in-clinic abortion after the digoxin has had a chance to work.

Before getting digoxin, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits of digoxin?

- It decreases the risk of the doctor or nurse violating the federal abortion ban.
- It decreases the risk of a live birth.
- Some women are helped by knowing that the fetus died before the in-clinic abortion.
- Some experts believe it makes the in-clinic abortion easier to do.

How well does it work?

Digoxin will cause fetal death in about 90 to 92 of every 100 times it is given. If it doesn't work you may be given another dose of digoxin. It is likely that you will still be able to have the abortion completed on the scheduled day.

What are the risks of digoxin?

- **Going into labor** — The digoxin can cause labor before the in-clinic abortion.
- **Infection of the injection site or uterus** —Most infections can be treated with medicines.
- **Injury to other organs** — Very rarely, the injection may cause injury to organs in your belly.
- **Allergic reaction** — Some women may be allergic to digoxin.

What are the side effects of digoxin?

Side effects usually do not last long. They usually need little or no treatment.

- **Pain —** You may have some discomfort during the injection, which should go away quickly. You may be bruised at the site of the injection.
- **Other Complications of the Injection —** You may have contractions and leak clear or bloody liquid (amniotic fluid) from your vagina.
- **Other —** You may have nausea, vomiting, diarrhea, and belly pain.

Cramping is expected. It may be severe.

Besides digoxin, what other choices do I have?
You may choose not to have digoxin. This may mean you will be referred to another provider for your abortion.

What else do I need to know?
Digoxin is one step in the abortion process. You must be sure you want to end your pregnancy before receiving digoxin.

If digoxin does not cause fetal death and you decide to continue the pregnancy, it is not known if the medicine will harm the fetus. No guarantee can be made that the pregnancy or fetus will be normal.

Call us right away at XXX-XXX-XXXX if you
- Notice changes in your heartbeat (slow, fast, or irregular)
- Have blurry vision

Signature of Client (or person authorized to sign for client) Date

Relationship to Client: ☐ self ☐ parent ☐ legal guardian ☐ other

I witness that the client received this information, said it was read and understood, and there was an opportunity to ask questions.

Signature of Witness Date

In-Clinic Abortion

(affiliate name and telephone number)

[For affiliates in doctor only states, delete "or nurse" where ever it states "doctor or nurse".]

What is an in-clinic abortion?

The way an abortion is done depends on how long a person has been pregnant. This is figured out by counting from the first day of the last period or by ultrasound. There are 2 kinds of in-clinic abortion.

- **In-clinic suction abortion:** suction is used to take the pregnancy out of the uterus.
- **In-clinic D&E abortion:** both suction and surgical tools are used to take the pregnancy out of the uterus.

[Select the phrase below that is appropriate to your affiliate]

At Planned Parenthood [XXX], we offer both kinds of in-clinic abortion.

At Planned Parenthood [XXX], we only offer in-clinic suction abortion.

Before having an in-clinic abortion, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits of in-clinic abortion?

- It is a safe and effective way to end a pregnancy.

How well does in-clinic abortion work?

- It almost always works – over 99% of the time.

What are the risks of in-clinic abortion?

Abortion is very safe. But, there are risks with any medical procedure. Your risk may be higher if you had a C-section or other surgery on your uterus.

Risks of an in-clinic abortion are

- **The pregnancy doesn't end —** Sometimes the in-clinic abortion does not end the pregnancy. If the pregnancy is still in the uterus, you may need a suction procedure.
- **Incomplete abortion —** This means some of the pregnancy may be left inside the uterus. This may lead to heavy bleeding, infection, or both. If this happens, you may need a suction procedure, other tests or treatments.
- **Blood clots in the uterus —** Clots may cause cramping and belly pain. If this happens, you may need a suction procedure.
- **Heavy bleeding —** This may require treatment with medicine, a suction procedure, blood transfusion, and/or surgery — including possible hysterectomy (removal of the uterus).
- **Infection of the uterus —** Most infections can be treated with medicines. But, there is a small chance that you may need a suction procedure. You may have to go to the hospital, or even have other surgery to treat the infection.
- **Injury to the cervix (opening to the uterus) —** This may be treated with medicine or rarely with stitches.
- **Injury to the uterus or other organs —** A surgical tool may go through the wall of the uterus, which could damage organs inside the body like the intestines, bladder, or blood vessels. Treatment may mean just watching and waiting for a while or surgery on your belly. There is a small chance that hysterectomy (removal of the uterus)

may be needed. Afterwards, scars may develop inside the uterus, which may need to be treated.

- **Allergic reaction —** Some women may be allergic to the medicines that are used.
- **Death —** Death from an in-clinic abortion is very rare. The risk of death from an abortion goes up the longer you are pregnant. When an abortion is done when a woman is less than 20 weeks pregnant (about 4 ½ months), the risk of death from childbirth is higher than the risk of abortion. After 20 weeks of pregnancy, the risks are about the same.

What are the side effects of in-clinic abortion?

Side effects don't usually last long and don't need to be treated.

- Light or medium bleeding
- Cramping

Besides an in-clinic abortion, what other choices do I have?

If you are pregnant, you have 3 options to think about — abortion, adoption, and parenting.

If you choose abortion and are early enough in the pregnancy, you may be able to use the abortion pill.

We can talk about any of these options with you, and help you with whatever you decide to do.

What will be done to get me ready for the in-clinic abortion?

You will have some lab tests, an ultrasound to help tell how long you've been pregnant, and a brief physical exam.

Pain Medicine — We will tell you about pain medicines that can be used.

Opening your cervix — Your cervix may need to be opened before your abortion. If so, you will be given separate information about the medicine and/or steps that will be taken to open your cervix.

What will happen to me during the in-clinic abortion?

You will be given medicine to make you more comfortable. You may get medicine to numb your cervix.

After the pain medicine begins to work, your doctor or nurse will decide if your cervix is open enough. If your cervix needs to be opened more, your doctor or nurse will stretch it.

When your cervix is open enough, your uterus will be emptied with suction. A small plastic tube will be put into your uterus and connected to a hand-held or electric suction machine. Surgical tools may be put into the uterus through the cervix. The way it is done will depend on how long you've been pregnant.

You may feel cramping during and after the in-clinic abortion, as your uterus gets smaller. What has been removed will be looked at to help make sure the in-clinic abortion is finished.

What will happen to me after the in-clinic abortion?
You will spend time in a recovery area to rest. We will also watch to see if you are OK. You will be given instructions on what to expect, how to care for yourself and reasons to contact us. We will talk about birth control plans with you, unless this was already done.

Most people are ready to leave in about 15 to 45 minutes.

What else do I need to know?
Having a wide range of feelings is normal. Most women feel relieved and do not regret their decision. Others may feel sadness, guilt, or regret after an abortion, just as they may after having a baby. If your mood keeps you from doing the things you usually do each day, call us. We can help or send you to someone who can.

No promise can be made about the outcome of your in-clinic abortion. In the unlikely event that you need emergency medical care that cannot be provided at Planned Parenthood, you will be responsible for paying for it. This is the case even if Planned Parenthood sends you to a hospital because of a problem.

Your health is important to us. If you have any questions or concerns, please call us. We are happy to help you.

□ I am having an in-clinic suction abortion
□ I am having an in-clinic D&E abortion
[If you only offer one in-clinic abortion option, delete the procedure not offered.]

Signature of Client (or person authorized to sign for client) Date

Relationship to Client: ☐ self ☐ parent ☐ legal guardian ☐ other _____

I witness that the client received this information, said it was read and understood, and there was an opportunity to ask questions.

Signature of Witness Date

Opening the Cervix with Dilators and/or Pills

(affiliate name and telephone number)

How is the cervix opened?

Before an in-clinic abortion or suction procedure, the cervix needs to be opened. This can be done in 3 different ways.

1. **Pills** — There are 2 different kinds.
   - Misoprostol — taken 1 to 4 hours before. Your doctor or nurse may ask you to put the pills in your cheek or under your tongue, or they may put them in your vagina.
   - Mifepristone — swallowed the day of or day before.
2. **Dilators that expand over time** — These small objects, shaped like matchsticks, will slowly get bigger and open your cervix over time. A doctor or nurse will put them in the cervix the day of or day before. They may need to be put in more than once. They may also put gauze in your vagina.
3. **Dilating instruments** — These are made of metal or plastic. Your doctor or nurse may use them to gently open your cervix.

You may need both pills and dilators to open your cervix. Because each person is different, your doctor or nurse will tell you what you will need.

Before your cervix is opened, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What is the benefit of opening the cervix?

- Lowers the risk of injury to the uterus or cervix

What are the risks of opening the cervix?

- **Infection of the uterus —** Most infections can be treated with medicines.
- **Injury to the uterus or cervix —** This can happen when the dilators are put in or taken out.
- **Dilators can get stuck or may break**
- **Allergic reaction —** Some women may be allergic to the medicines or dilators used.
- **Going into labor —** Very rarely, the pills or dilators can cause labor before the in-clinic abortion.

What are the side effects?

Side effects usually do not last long. They usually need little or no treatment.

Common side effects of misoprostol include

- Fluid leaking from the vagina
- Nausea
- Vomiting
- Fever
- Diarrhea
- Headache
- Dizziness
- Back pain
- Tiredness

Bleeding and cramping are expected.

Besides having the cervix opened, what other choices do I have?

You may choose not to have your cervix opened. This may mean you will be referred to another provider for your abortion.

What else do I need to know if dilators are used to open the cervix?

- **DO NOT** put anything in your vagina (like douche, tampons, or vaginal sex).
- **DO NOT** take anything out of your vagina. If anything falls out of your vagina, tell us when you come back in.
- Call us if you are worried or if fluid is leaking from your vagina.
- If you have cramps, you may take ibuprofen.
- **DO NOT** take aspirin. It can make you bleed more during your abortion.

Call us right away at XXX-XXX-XXXX if you

- Have signs of labor — regular, strong contractions or severe cramping
- Have a fever of 100.4˚ F or more
- Have rupture of membranes — fluid leaking from the vagina
- Have belly pain or cramps that don't get better with pain medicine
- Soak 2 maxi pads an hour for more than 2 hours

Rho(D) Immune Globulin

(affiliate name and telephone number)

What is Rho(D) immune globulin and why do I need it?

You had a test to find out if your blood is Rh positive or Rh negative. You are Rh negative. Rh is a protein on the outside of red blood cells. Most people have it. People with Rh are called "Rh positive." People without it are called "Rh negative."

During pregnancy, blood cells from the fetus can enter your blood. If you are Rh negative and your fetus is Rh positive, your body can develop antibodies against Rh-positive blood. This does not harm you. But it can cause serious problems if you become pregnant again. The antibodies in your body can attack and destroy the blood of another Rh-positive fetus. It can give the fetus very bad anemia. It may also lead to many other serious problems.

Rho(D) immune globulin is a shot that can prevent you from developing antibodies against Rh-positive blood. That is why we recommend that you get it.

Before getting Rho(D) immune globulin, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits of Rho(D) immune globulin?

- It is a very safe and effective way to prevent you from developing antibodies against Rh-positive blood.

What are the risks of Rho(D) immune globulin?

- **Getting a virus such as hepatitis or HIV** – Because Rho(D) immune globulin is made from a part of blood there is a very small chance of getting a virus such as hepatitis or HIV from the shot. The people who donate the blood are carefully checked for these and other conditions. The medicine is tested for safety while it is being made and again afterwards. **There are no known cases in the U.S. of a woman getting a disease from this medicine.**
- **Having an allergic reaction** – Some women may be allergic to Rho(D) immune globulin.

What are the side effects of Rho(D) immune globulin?

Side effects are rare.

- You may have pain or swelling where you get the shot.
- You might get a slight fever.

Besides Rho(D) immune globulin, what are my other choices?

There is no other medicine to take instead. You could decide to do nothing. But you would be taking a chance. A fetus in any future pregnancy could develop very bad anemia.

What else do I need to know?
Even if you get the Rho(D) immune globulin, there is no guarantee that you won't have problems with a future pregnancy.

Your health is important to us. If you have any questions or concerns. We are happy to help you.

Second Dose of Misoprostol for a Continuing Pregnancy

(affiliate name and telephone number)

Why do I need a second dose of misoprostol?

You took the abortion pill to end your pregnancy. It did not work.

One way to end the pregnancy is to take the misoprostol pills again.

Before you take misoprostol again, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits of taking a second dose of misoprostol?

If the misoprostol pills work the second time, you won't need a suction procedure to end the pregnancy.

How well does it work?

Taking the second dose of misoprostol only works about 30 to 50 out of 100 times it is used. If the misoprostol does not work this time, you will need a suction procedure to end the pregnancy.

What are the risks of taking a second dose of misoprostol?

Using misoprostol is very safe. But, there are risks with any medical procedure. Your risk may be higher if you are not healthy.

Risks of taking a second dose of misoprostol are

- **The pregnancy doesn't end —** Sometimes the second dose of misoprostol does not end the pregnancy. If this happens, you can have a suction procedure to end the pregnancy.
- **Incomplete abortion —** This means some of the pregnancy may be left inside the uterus. This may lead to heavy bleeding, infection, or both. If this happens, you may need a suction procedure, other tests or treatments.
- **Blood clots in the uterus —** Clots may cause cramping and belly pain. If this happens, you may need a suction procedure.
- **Bleeding too much or too long —** This may require treatment with medicine, a suction procedure, or a blood transfusion.
- **Infection of the uterus —** Most infections can be treated with medicines. But, there is a small chance that you may need a suction procedure. You may have to go to the hospital, or even have other surgery to treat the infection.
- **Allergic reaction —** Some women are allergic to the medicines that are used.
- **Death —** Death from medication abortion is very rare. The risk of death from childbirth is much greater.

What are the side effects of misoprostol?

Side effects usually do not last long. They usually need little or no treatment.

- **Cramping is expected —** It will be the worst soon after you take the misoprostol. Milder cramps may last a day or 2 after that.
- **Bleeding is expected —** It will be heaviest soon after taking the misoprostol. You may bleed or spot for 4 to 6 weeks.
- **Fever —** Having a temperature of 99-100°F is okay.
- **Other —** It is common to have diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness.

Besides taking a second dose of misoprostol, what other choices do I have?

You have 2 other choices.

- You could have a suction procedure. It almost always works to end a pregnancy – over 99% of the time.
- You could choose to continue the pregnancy.

We can talk about any of these options with you, and help you with whatever you decide to do.

What else do I need to know?

After taking misoprostol a second time, you must make sure the medicines worked. This can be done by having an ultrasound at the clinic or by a blood test at the clinic or lab. [DELETE THE OPTION NOT AVAILABLE AT AFFILIATE.] We will tell you when and where to do this.

Misoprostol can cause serious birth defects if the pregnancy continues.

No promise can be made about the outcome of using misoprostol a second time. In the unlikely event that you need emergency medical care that cannot be provided at Planned Parenthood, you will be responsible for paying for it. This is the case even if Planned Parenthood sends you to another doctor or hospital because of a problem.

Your health is important to us. If you have any questions or concerns please call us. We are happy to help you.

Signature of Client (or person authorized to sign for client) Date

Relationship to Client: ☐ self ☐ parent ☐ legal guardian ☐ other

I witness that the client received this information, said it was read and understood, and there was an opportunity to ask questions.

Signature of Witness Date

Suction Procedure

(affiliate name and telephone number)

What is a suction procedure?
You had an abortion but it did not work or some of the pregnancy is still inside your uterus. A suction procedure is one way to end the pregnancy or remove what is left.

Before you have a suction procedure, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits of a suction procedure?
- It is a safe and effective way to empty the uterus.
- It may improve pain and/or bleeding.
- It may prevent or treat infection.

What are the risks of a suction procedure?
A suction procedure is very safe. But, there are risks with any medical procedure. Your risk may be higher if you had a C-section or other surgery on your uterus.

Risks of a suction procedure are
- **The pregnancy still doesn't end —** Sometimes the suction procedure does not end the pregnancy. If the pregnancy is still in the uterus, you may need another suction procedure.
- **Incomplete abortion —** This means some of the pregnancy may still be left inside the uterus. This may lead to heavy bleeding, infection, or both. If this happens, you may need another suction procedure, other tests or treatments.
- **Blood clots in the uterus —** Clots may cause cramping and belly pain. If this happens, you may need another suction procedure.
- **Heavy bleeding —** This may require treatment with medicine, a repeat suction procedure, blood transfusion, and/or surgery — including possible hysterectomy (removal of the uterus).
- **Infection of the uterus —** Most infections can be treated with medicines. But, there is a small chance that you may need another suction procedure. You may have to go to the hospital, or even have other surgery to treat the infection.
- **Injury to the cervix (opening to the uterus) —** This may be treated with medicine or rarely with stitches.
- **Injury to the uterus or other organs —** A surgical tool may go through the wall of the uterus, which could damage organs inside the body like the intestines, bladder, or blood vessels. Treatment may mean just watching and waiting for a while or surgery on your belly. There is a small chance that hysterectomy (removal of the uterus) may be needed. Afterwards, scars may develop inside the uterus, which may need to be treated.
- **Allergic reaction —** Some women are allergic to the medicines that are used.
- **Death —** Death from a suction procedure is very rare. The risk of death from childbirth is much greater.

What are the side effects of a suction procedure?
Side effects don't usually last long and don't need to be treated.
- Light or medium bleeding
- Cramping

Besides a suction procedure, what other options do I have?
You may be able to take pills. You can also decide to do nothing.

We can talk about any of these options with you, and help you with whatever you decide to do.

What will happen to me during a suction procedure?
You will be given medicine to make you more comfortable. You may get medicine to numb your cervix.

After the pain medicine begins to work, your doctor or nurse will decide if your cervix is open enough. If your cervix needs to be opened more, your doctor or nurse will stretch it.

When your cervix is open enough, your uterus will be emptied with suction. A small plastic tube will be put into your uterus and connected to a hand-held or electric suction machine. Surgical tools may be put into the uterus through the cervix. The way it is done will depend on how long you've been pregnant.

You may feel cramping during and after the suction procedure, as your uterus gets smaller. What has been removed will be looked at to make sure the procedure is finished.

What will happen to me after the suction procedure?
You will spend time in a recovery area for rest. We will also watch to see if you are OK. You will be given instructions on what to expect, how to care for yourself, and reasons to contact us. We will talk about birth control plans with you, unless this was already done.

Most people are ready to leave in about 15 to 45 minutes.

What else do I need to know?
No promise can be made about the outcome of your suction procedure. In the unlikely event that you need emergency medical care that cannot be provided at Planned Parenthood, you will be responsible for paying for it. This is the case even if Planned Parenthood sends you to a hospital because of a problem.

Your health is important to us. If you have any questions or concerns please call us. We are happy to help you.

Signature of Client (or person authorized to sign for client) Date

Relationship to Client: ☐ self ☐ parent ☐ legal guardian ☐ other

I witness that the client received this information, said it was read and understood, and there was an opportunity to ask questions.

Signature of Witness Date

Using the Abortion Pill

(affiliate name and telephone number)

What is the abortion pill and how do I take it?
"Abortion pill" is the popular name for using 2 medicines to end a pregnancy – mifepristone and misoprostol. Mifepristone is the first pill you will take and starts the abortion process. Pregnancy needs a hormone called progesterone to grow normally. Mifepristone blocks your body's own progesterone.

The second medicine, misoprostol, opens the cervix and makes the uterus contract. This empties the uterus and completes the process. The whole process is also called medication abortion.

There are a few different ways to take these medicines. We will talk to you about your choices.

Before you have an abortion, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits of the abortion pill?
It is a safe and effective way to end a pregnancy.

How well does the abortion pill work?
It depends how far along you are in the pregnancy. Some women need to take an extra dose of misoprostol.

8 weeks or less	About 98 out of 100 times
From 8 to 9 weeks	About 96 out of 100 times
From 9 to 10 weeks	About 91 to 93 out of 100 times

What are the risks of the abortion pill?
Using the abortion pill is very safe. But, there are risks with any medical procedure.

Risks of the abortion pill are

- **The pregnancy doesn't end —** Sometimes the medicines do not end the pregnancy. If this happens, you can take more medicine or have a suction procedure to complete the abortion.
- **Incomplete abortion —** This means some of the pregnancy may be left inside the uterus. This may lead to heavy bleeding, infection, or both. If this happens, you may need a suction procedure, other tests or treatments.
- **Blood clots in the uterus —** Clots may cause cramping and belly pain. If this happens, you may need a suction procedure.
- **Bleeding too much or too long —** This may require treatment with medicine, a suction procedure, or a blood transfusion.
- **Infection of the uterus —** Most infections can be treated with medicines. But, there is a small chance that you may need a suction procedure. You may have to go to the hospital, or even have other surgery to treat the infection.
- **Allergic reaction —** Some women are allergic to the medicines that are used.
- **Death —** Death from medication abortion is very rare. The risk of death from childbirth is much greater.

What are the side effects of the abortion pill?
Side effects usually do not last long. They usually need little or no treatment.

- **Cramping is expected** — It will be the worst soon after you take the misoprostol. Milder cramps may last a day or 2 after that.
- **Bleeding is expected** — It will be heaviest soon after you take the misoprostol. You may bleed or spot for 4 to 6 weeks after the abortion.
- **Fever** — Having a temperature of 99-100°F is okay.
- **Other** — It is common to have chills, diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness.

Besides taking the abortion pill, what other choices do I have?
If you are pregnant, you have 3 options to think about — abortion, adoption, and parenting.

There are 2 ways to have an abortion, the abortion pill and in-clinic abortion.

We can talk about any of these options with you, and help you with whatever you decide to do.

What else do I need to know?
After you take the abortion pill, you must make sure the medicines worked. This can be done by having an ultrasound at the clinic or by a blood test at the clinic or lab. [DELETE OPTION NOT AVAILABLE AT AFFILIATE.] We will tell you when and where to do this.

Misoprostol can cause serious birth defects if the pregnancy continues.

Having a wide range of feelings is normal. Most women feel relieved and do not regret their decision. Others may feel sadness, guilt, or regret after an abortion, just as they may after having a baby. If your mood keeps you from doing the things you usually do each day, call us. We can help or send you to someone who can.

We will also tell you other reasons to contact us.

No promise can be made about the outcome of your abortion. In the unlikely event that you need emergency medical care that cannot be provided at Planned Parenthood, you will be responsible for paying for it. This is the case even if Planned Parenthood sends you to another doctor or hospital because of a problem.

Your health is important to us. If you have any questions or concerns please call us. We are happy to help you.

Signature of Client (and person authorized to sign for client when required) Date

Relationship to Client: ☐ self ☐ parent ☐ legal guardian ☐ other _____

I witness that the client received this information, said it was read and understood, and there was an opportunity to ask questions.

Signature of Witness Date

When You Decide to Stop Your In-Clinic Abortion

(affiliate name and telephone number)

What will happen if I stop the in-clinic abortion?

To start the abortion, a doctor or nurse has already given you pills, put dilators in your cervix, or both. We will take out the pills and/or dilators. We cannot be sure

- your pregnancy will go normally
- your baby will be healthy when he/she is born
- you will be healthy

Many women do go on to have a healthy baby.

Before you stop your in-clinic abortion, you need to know the most common risks. We are happy to answer any questions you have.

What are the risks of stopping the in-clinic abortion?

- Your cervix may already be open and you can get an infection of the uterus. Most infections can be treated with medicine.
- You could have a miscarriage.
- The pregnancy may continue but you could have premature (early) labor. Babies born prematurely (too early) are at risk for many problems including death.

What are the risks of taking out the dilators?

- Injury to the uterus or cervix

What are the risks of misoprostol?

- Misoprostol can cause birth defects. You may not know until after you deliver.

What else do I need to know?

We recommend you take prenatal vitamins and make an appointment for prenatal care as soon as possible. Make sure you tell the doctor or nurse that you had pills or dilators to start an abortion.

Your health is important to us. If you have any questions or concerns, please call us. We are happy to help you.

Signature of Client (or person authorized to sign for client) Date

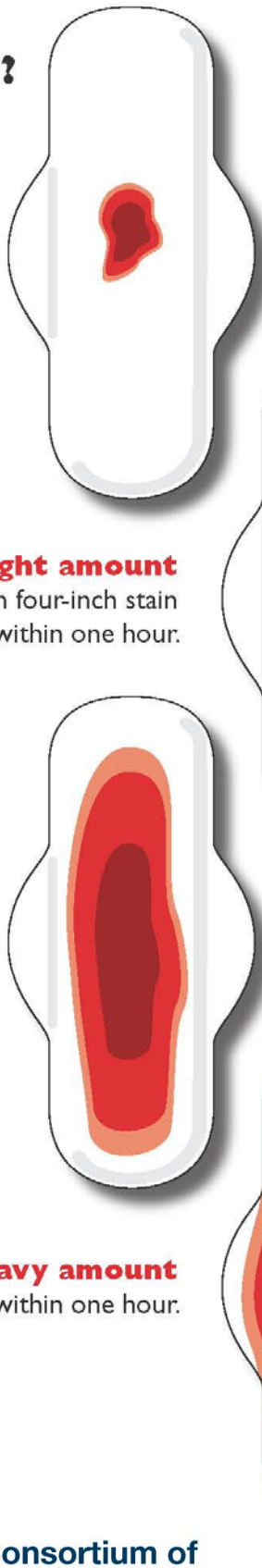
Relationship to Client: ☐ self ☐ parent ☐ legal guardian ☐ other

I witness that the client received this information, said it was read and understood, and there was an opportunity to ask questions.

Signature of Witness Date

HOW MUCH AM I BLEEDING?

¿CUANTO ESTOY SANGRANDO?



Scant amount
Blood only on tissue when wiped or less than one-inch stain on maxi pad within one hour.

Cantidad muy escasa
Solo hay sangre en el papel sanitario cuando se limpia, o tiene manchas que miden menos de una pulgada en una toalla sanitaria tamaño maxi en menos de una hora.

Light amount
Less than four-inch stain on maxi pad within one hour.

Poca cantidad
Manchas que miden menos de 4 pulgadas en una toalla sanitaria tamaño maxi en menos de una hora.

Moderate amount
Less than six-inch stain on maxi pad within one hour.

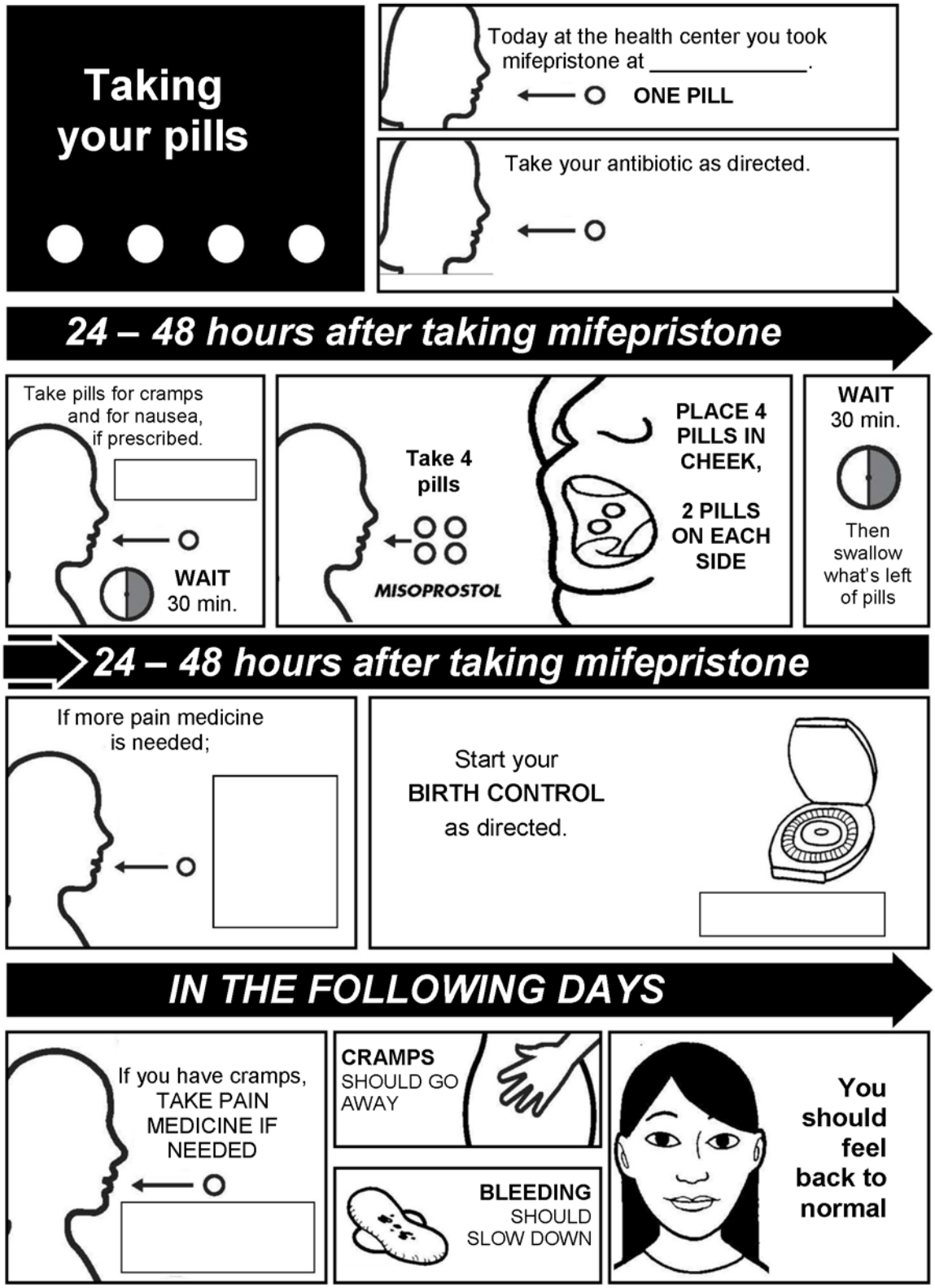
Cantidad moderada
Manchas que miden menos de 6 pulgadas en una toalla sanitaria tamaño maxi en menos de una hora.

Heavy amount
Saturated maxi pad within one hour.

Cantidad muy fuerte
Una toalla sanitaria tamaño maxi completamente saturada en una hora.

Planned Parenthood® Care. No matter what. | CAPS Consortium of Abortion Providers

Courtesy of PP Western Washington



Planned Parenthood® Care. No matter what. | CAPS Consortium of Abortion Providers

Sample Offsite Information and Treatment Form May 2007
(affiliate name, address and telephone number)

THIS PATIENT IS UNDERGOING AN ELECTIVE STAGED TERMINATION OF PREGNANCY

Patient Name _____

Address _____

Phone Number (Home) _____ (Hotel) _____

Age _____ G _____ P _____ SAB _____ TAB _____

Vaginal Delivery _____ Cesarean Section _____

Hgb _____ on _____ (date) Rh _____ on _____(date)

Gestational Age by Ultrasound _____ on _____ (date)

First Day of laminaria _____ (date) Number of laminaria _____

Second Day of laminaria _____ (date) Number of laminaria _____

Digoxin infusion, 1 mg intra-amniotic _____ or 1 mg intra-fetal _____ on _____(date)

_____
Signature

Dear Health Care Provider:

Please fill in the following information and fax it to us at **(XXX) XXX-XXXX** or mail it to us at **[affiliate address]**. Thank you.

The patient received the following treatment at our facility:

_____
_____
_____
_____

IF YOU HAVE AN EMERGENCY

You may call at any time if you have questions or if you think you have a problem.

CALL US AT [affiliate emergency number]

SAMPLE PROTOCOL IN-CLINIC ABORTION CARE FOR DIABETIC CLIENTS

Chapter 0 Table of Contents

0.1 PRE-ABORTION

0.1.1 Medical Screening and Evaluation

I. History should be obtained at the time of appointment scheduling or, if indicated, at a visit prior to the day of the procedure. Clinician(s) performing procedure and providing sedation (if applicable) **must** review client medical record to determine eligibility for in-clinic abortion.
II. Targeted medical history **must** include:
    A. Type and duration of diabetes
    B. Medications
III. Physical Examination — as indicated
IV. Laboratory — see Procedure Day, below

0.1.2 Information for Preoperative Care and Scheduling

I. Clients should be advised to
    A. consult with their usual primary diabetes care provider prior to procedure regarding operative and post-procedural management, if possible
    B. bring medications and all diabetic supplies to clinic on day of procedure
II. Schedule diabetic clients as first procedure of day.
III. Instructions for medication use
    A. If client was seen by primary diabetes care provider and given medication instructions, those should be followed.
    B. If not seen by primary diabetes care provider
        1. Oral hypoglycemic agents or non-insulin injectables
            a. If not NPO – continue medication
            b. If NPO – do not take medication on morning of procedure
        2. Insulin
            a. Day prior to procedure - use usual dose until NPO
            b. Morning of procedure
            c. If not NPO
                i. usual AM dose
                ii. short-acting correction boluses for hyperglycemia may be used

✓ FYI — Insulin Administration in Clinic

d. If NPO
   i. Half of morning dose of intermediate-acting insulin only should be injected in the morning prior to surgery
   ii. Client should be done with procedure in time to eat lunch
   iii. Clients with insulin-dependent type 2 diabetes may delay morning insulin and take with breakfast immediately after the procedure or administer AM short-acting insulin only and no intermediate-acting insulin with lunch.
   iv. Short-acting correction boluses for hyperglycemia may be used (see FYI — Insulin Administration in Clinic, below), otherwise do not give short acting insulin for clients who are NPO.

0.1.3 Procedure Day

I. Check client's blood glucose upon arrival, and at least q4 hours while at facility, especially if NPO, and more frequently if hypoglycemia or hyperglycemia suspected.
   A. Perioperative blood glucose levels – values of 100-180 mg/dL are optimal
      1. If blood glucose < 70 mg/dL
         a. For NPO clients, administer ½ amp D50.
         b. For clients able to eat, give 15 grams of carbohydrates as glucose (4 oz juice, 4 glucose tablets, 2 sugar packets).
         c. Reassess and repeat treatment q15 minutes until blood glucose is ≥70 mg/dL.
      2. If blood glucose >180 mg/dL
         a. Consider insulin administration with the goal of achieving blood glucose <180mg/dL prior to procedure (see FYI — Insulin Administration in Clinic).
         b. Must not provide abortion if blood glucose >240 mg/dL
II. If client took AM anti-hypoglycemics other than described as acceptable regimens in FYI — A Guide to Anti-diabetic Agents, below, must change PO status to avoid hypoglycemia.
III. For clients who use insulin
   A. Clients with Type 1 diabetes must not be without insulin (see FYI — A Guide to Anti-diabetic Agents, below). Basal coverage for insulin needs with long-acting insulin, CSII, or half dose intermediate-acting insulin are appropriate management options.
   B. Clients who utilize CSII outpatient therapy may be candidates for self-management in the clinic provided they have mental and physical capacity to do so.
   C. If client comes to clinic and has not taken AM insulin, refer to preoperative insulin instructions above and FYI — Insulin Administration in Clinic for guidance.

0.2 POST-PROCEDURE MANAGEMENT

0.2.1 Managing Blood Glucose Prior to Discharge

I. Continue checking blood glucose q4 hours after procedure until discharge.
II. Must check blood glucose prior to discharge
   A. If <70mg/dL, follow 15/15 rule (see above).
   B. If 70-179 mg/dL, routine discharge.
   C. If ≥180mg/dL in post-operative setting and
      1. no suspicion for DKA, client may be discharged after advising to notify usual diabetes provider for same day diabetes management consultation.
      2. suspicious for DKA, if no usual provider or if provider unavailable, advise client to present for urgent care.

0.2.2 Resumption of Anti-diabetic Agents

I. First Trimester Termination
   A. Oral Agents - Resume oral anti-diabetic agents once tolerating POs.
   B. Insulin - Resume insulin regimen once client tolerating POs per primary diabetes care provider instructions or as follows:
      1. Immediate resumption of usual dosing for those who:
         a. were not NPO
         b. utilize CSII therapy
         c. use qmeal short-acting insulin with basal analogue (long-acting)
         d. did not take AM short acting-insulin and will be eating breakfast and lunch
         e. took AM intermediate insulin only and will be eating lunch.
      2. Administer short-acting insulin only from usual breakfast dose at lunch for clients with Type 2 diabetes who did not take AM insulin but are now eating lunch or those who did not plan to eat breakfast that will now be eating breakfast and lunch. Resume usual routine at dinner.
II. Mid-Trimester Termination
   A. Clients should be encouraged to speak with their primary diabetes care provider regarding medical management after pregnancy is terminated.
   B. If clients have not received instruction from their primary diabetes care provider
      1. Resume as above (first trimester termination) if adjustments had not been made from pre-pregnancy/first trimester regimen.

2. Resume pre-pregnancy or first trimester regimen if known.
3. Consider decreasing insulin by 30% if insulin was increased in second trimester of pregnancy but previous doses unknown. (Gabbe, 2003)

0.3 ADDITIONAL INFORMATION

0.3.a. Table: For Your Information

Section	Topic	Detail
	Insulin Administration in Clinic	It is sometimes impractical to delay performing an abortion procedure (i.e. laminaria already placed day prior and client presents for procedure, client at gestational limit and may not return for procedure for another day, travel considerations) due to hyperglycemia. Certain clients may be eligible for diabetes self-management in the clinic at the discretion of the clinician performing the procedure if the clients have mental and physical capacity (ADA 2012). For clients who did not administer long-acting or 1/2 dose of intermediate-acting insulin in the morning prior to procedure or for those resuming PO status, self-administration in clinic will avoid hyperglycemia later. Those with type 1 diabetes **must** not be without basal insulin. For those clients who experience transient hyperglycemia in the clinical setting, it may be beneficial to administer a correction bolus of subcutaneous short-acting insulin prior to or following the abortion procedure. ▪ In this event, client may use her usual correction bolus to correct to a goal of fingerstick blood glucose 140-180mg/dL. ▪ For clients who do not have a standard correction bolus dose, consider using the "1800 rule" formula: 1800/ total daily dose = mg/dL that 1 unit of insulin will lower client's glucose level (Rhodes, 2005). ▪ Example: Client has glucose of 280mg/dL and usually takes a total of 30 units of insulin per day. If she administers 1 unit of short acting insulin, this will decrease her blood glucose by 60mg/dL. Thus, she can take 2 units of short acting insulin with the goal to lower her blood glucose to 160mg/dL. Procedure may be performed in 30 minutes — 2 hours if repeat fingerstick glucose <240mg/dL and DKA is not suspected. In the setting of suspected DKA, clients **must** be referred for emergency care.

Section	Topic	Detail
	A Guide to Anti-diabetic Agents	**Common insulin regimens**

Insulin type	Onset of action	Peak effect	Duration of action
Short-acting (*except when used in CSII or as a correction bolus for hyperglycemia, short-acting insulin or formulations containing short-acting insulin are not appropriate for preoperative clients who are NPO)			
lispro, aspart, glulisine	5 to 15 min	45 to 75 min	2 to 4 h
Regular	About 30 min	2 to 4 h	5 to 8 h
Intermediate-Acting			
NPH	About 2 h	4 to 12 h	18 to 28 h
Long-acting			
glargine	About 2 h	No peak	20 to >24 h

Non-insulin anti-diabetic regimens

* May proceed with procedure where client is NPO and did not take AM anti-diabetic agents (Kahn 2011)

*When referring to medications listed below are additional precautions for prolonged hold of anti-diabetic agents (if does not cause hyperglycemia) and medications which are unlikely to cause hypoglycemia thus clinician performing procedure may use discretion to perform procedure if medication inadvertently administered.

Classification	Generic Name	Precautions
Binguanides	metformin	Unlikely to cause hypoglycemia. Can induce lactic acidosis.
Meglitinides	repaglinide, nateglinide	Can lead to hypoglycemia. Hold when NPO.
Sulfonylureas	glyburide, glipizide, glimepride	Can lead to hypoglycemia. Hold when NPO.
Thiazolidinedione	pioglitizone,	Unlikely to cause hypoglycemia.

Section	Topic	Detail

	rosiglitazone	Can cause fluid retention and liver toxicity. Consider hold several days prior to planned surgery.
Alpha-glucosidase inhibitor	acarbose, miglitol	Works as a starch blocker. If hypoglycemia develops, only treat with glucose tablets or nonfat milk, glucagon, or IV D50. Do not use juice or other food items.
GLP-1 agonist	exenatide	Delay gastric motility. May increase arterial blood pressure and heart rate.
DPP-4 inhibitors (incretin enhancers)	linagliptin, sitagliptin, saxagliptin, vildagliptin	Unlikely to cause hypoglycemia. Effects on postprandial glycemia. May increase arterial blood pressure and heart rate.

(Meneghini 2009), (Kahn 2011), (Luna 2001), (Petznick 2011), Rhodes 2005

Routine hCG Telephone Contact

_____ _____
Client name chart number

Date, time and phone number where client agrees to be contacted:

_____

hCG results

1st hCG result _____ date done _____

2nd hCG result_____ date done _____

1st call date _____ 2nd attempt _____ 3rd attempt _____

Lab work results: (20% or less of original)
(2nd hCG result divided by original hCG result x 100 = %) Yes No

Phone interview

How do you feel? _____

Have your pregnancy symptoms resolved? _____

Are you still bleeding? Yes No If yes, amount, timing, severity?_____

_____

Current complaints — fever, pain, etc._____

Assessment/Plan

___ complete abortion ___ release from care
___ unable to confirm abortion completion ___ follow-up required

Comments
_____
_____
_____

Clinician Signature _____ Date _____

Client Name:_____Phone: _____

Date:_____Time:_____Call initiated by: _____

Gestational Age:_____Type of Abortion: Surgical ____ Medication

Date of visit: _____

Date Mifepristone taken:_____Date Misoprostol taken:_____ N/A: _ _____

Major Problem / Complaint:_____

Symptom	**NO**	**YES**	**Amount/Severity**	**Duration**	**Additional Notes or Comments**
Temperature					
Bleeding			Pads/hour:		
Pain			Location:		
Clotting			Size:		
Fainting/Dizziness					
If medication AB: Client believes pregnancy aborted					
Nausea/Vomiting					
Diarrhea					
Allergic Reaction					
Other					

On Call Notes: _____
_____

Advised:
___rest/take it easy ___heating pad/hot water bottle ___Ibuprofen/Tylenol as directed
___massage uterus ___monitor # of pads used ___med instructions reviewed
___take temp, call if over 100^{o} ___ other_____

Plan:
___call in 2 hrs if no improvement ___if symptoms persist, call back
___If client has not had F/U, advised to keep F/U appt.
___return to center _____ ___refer to MD ___refer to ER
Other (describe):_____
_____

Clinician Signature: _____Staff Signature: _____

Notes:_____

When to call us

AFTER USING THE PILLS AT HOME

CRAMPING and BLEEDING are normal

Some women bleed a little

Some women bleed more than a period

Some clots may be as big as a lemon

IF YOU ARE SOAKING more than 2 MAXIPADS per hour

FOR MORE THAN 2 HOURS in a row

CALL US

IF YOU HAVE **SEVERE CRAMPS** AND **PAIN PILLS** don't help

CALL US

YOU MAY ALSO HAVE SOME SIDE EFFECTS

Nausea
Vomiting
Diarrhea
Dizziness

IF ANY OF THESE LAST MORE THAN 24 *hours*

CALL US

If you are feeling worried and think you need to go to the ER,

CALL US

FEVER AND CHILLS ARE NORMAL on the day you take MISOPROSTOL

BUT IF YOU STILL HAVE

FEVER OR **CHILLS**

24 HOURS after taking MISOPROSTOL

CALL US

IF YOU **FEEL SICK** OR ARE IN A **LOT OF PAIN** AFTER THE MISOPROSTOL DAY:

CALL US AT:

Planned Parenthood® Care. No matter what. | CAPS Consortium of Abortion Providers

What to Expect After Sedation

When can I return to my normal activities?

Plan on relaxing for the rest of the day. After sedation it can take up to 24 hours for the medicines to wear off completely. You may feel sleepy when you leave the clinic. This is normal.

Eating and Drinking

- Drink small amounts of clear liquids such as water, soda or apple juice.
- Avoid foods that are sweet, spicy, rich, or hard to digest for the first few hours.
- Eat more foods as your body can tolerate.
- If you feel nauseated, don't eat or drink anything for 1 hour, then try drinking a clear liquid.
- Do not drink alcohol for 24 hours after you leave the clinic or while you are taking a prescription pain medicine.

Activity - the sedation may affect your judgment, coordination and reaction time. For at least 24 hours after sedation, we recommend you

- Do not drive, operate heavy machinery or make any important decisions
- Make sure a responsible adult is with you

Call us right away at XXX-XXX-XXXX **if**

- You have nausea and vomiting that doesn't get better within 24 hours
- Your IV site becomes hot, red or swollen

Sedation – Deep

(affiliate name and telephone number)

[Note to affiliates — You may also list the specific medications used with the potential benefits, risks, and side effects related to each. DELETE THIS STATEMENT.]

What is sedation?
Sedation is medicine to make you more relaxed during a surgery or procedure. There are many kinds. Deep sedation is one kind.

What is deep sedation?
Deep sedation will make you fall asleep. You will have little or no memory of the surgery or procedure later on. The medicine is given directly into your vein. You may be given oxygen to breathe.

Before you choose to have sedation, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits of deep sedation?
- It is safe.
- It will put you to sleep.
- It will keep you from remembering parts of the procedure later on.

What are the risks of deep sedation?
Although the medicines used for deep sedation are safe, there are problems that can occur. You may have swelling at the injection site (phlebitis). You may need help with breathing. This could happen because of
- The types of medicine you are given
- Your health
- Any drugs or medicine you took
- A reaction you may have to the medicines

Major problems that can happen include
- Allergic reaction to the medicines
- Damage to or failure of the heart, lungs, liver, kidneys, and/or brain
- Loss of consciousness
- Death

What are the side effects of deep sedation?
Side effects usually do not last long. They usually need little or no treatment.
- Dizziness
- Nausea and vomiting

Besides deep sedation, what other choices do I have?
There are many kinds of sedation. You may choose to have no sedation, or to be referred elsewhere for another kind. We can talk about any of these options with you, and help you with whatever you decide to do.

What else do I need to know?
If you have problems during or after sedation, you may be sent to a hospital or emergency room. This is rare. We will tell you how to contact us if you have any questions or problems.

We will tell you reasons to contact us.

The medicine can last for several hours. **Do not drive**, operate heavy machinery, or make important decisions for at least 24 hours after sedation. You must leave the health center with a responsible adult who will drive or ride other transportation with you.

Signature of Client (or person authorized to sign for client) Date

Relationship to Client: ☐ self ☐ parent ☐ legal guardian ☐ other

I witness that the client received this information, said it was read and understood, and there was an opportunity to ask questions.

Signature of Witness Date

Sedation – Minimal and Moderate

(affiliate name and telephone number)

[Note to affiliates — You may also list the specific medications used with the potential benefits, risks, and side effects related to each. DELETE THIS STATEMENT.]

What is sedation?
Sedation is medicine to make you more relaxed during a surgery or procedure. There are many kinds. Minimal and moderate sedation are two kinds.

What is minimal sedation?
Minimal sedation may make you feel more relaxed but it won't put you to sleep. The medicine is swallowed or injected into a muscle.

What is moderate sedation?
Moderate sedation may make you feel more relaxed and you may fall asleep. The medicine is given directly into your vein.

Before you choose to have sedation, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits of minimal sedation?
- It is safe.
- It may make you feel more relaxed.

What are the risks of minimal sedation?
Although the medicines used for minimal sedation are safe, there are problems that can occur. You may have swelling at the injection site (phlebitis). You may become sleepier than expected. This could happen because of
- The types of medicine you are given
- Your health
- Any drugs or medicine you took
- A reaction you may have to the medicines

Major problems that can happen include
- Allergic reaction to the medicine

What are the side effects of minimal sedation?
Side effects usually do not last long. They usually need little or no treatment.
- Dizziness

What are the benefits of moderate sedation?
- It is safe.
- It may make you feel more relaxed.
- It may keep you from remembering parts of the surgery or procedure later on.

What are the risks of moderate sedation?
Although the medicines used for moderate sedation are safe, there are problems that can occur. You may have swelling at the injection site (phlebitis). You may become sleepier than expected or need help with breathing. This could happen because of
- The types of medicine you are given

- Your health
- Any drugs or medicine you took
- A reaction you may have to the medicines

Major problems that can happen include
- Allergic reaction to the medicines
- Damage to or failure of the heart, lungs, liver, kidneys, and/or brain
- Loss of consciousness
- Death

What are the side effects of moderate sedation?
Side effects usually do not last long. They usually need little or no treatment.
- Dizziness
- Nausea and vomiting

Besides minimal and moderate sedation, what other choices do I have?
There are many kinds of sedation. You may choose to have no sedation, or to be referred elsewhere for another kind. We can talk about any of these options with you, and help you with whatever you decide to do.

What else do I need to know?
If you have problems during or after sedation, you may be sent to a hospital or emergency room. This is rare. We will tell you how to contact us if you have any questions or problems.

We will tell you reasons to contact us.

The medicine can last for several hours. **Do not drive**, operate heavy machinery, or make important decisions for at least 24 hours after sedation. You must leave the health center with a responsible adult who will drive or ride other transportation with you**.**

I am choosing
☐Minimal Sedation ☐Moderate Sedation

Signature of Client (or person authorized to sign for client) Date

Relationship to Client: □ self □ parent □ legal guardian □ other _____

I witness that the client received this information, said it was read and understood, and there was an opportunity to ask questions.

Signature of Witness Date

Sedation - Minimal

(affiliate name and telephone number)

[Note to affiliates — You may also list the specific medications used with the potential benefits, risks and side effects related to each. DELETE THIS STATEMENT.]

What is sedation?
Sedation is medicine to make you more relaxed during a surgery or procedure. There are many kinds. Minimal sedation is one kind.

What is minimal sedation?
Minimal sedation may make you feel more relaxed but it won't put you to sleep. The medicine is swallowed or injected into a muscle.

Before you choose to have sedation, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits of minimal sedation?
- It is safe.
- It may make you more relaxed.

What are the risks of minimal sedation?
Although the medicines used for minimal sedation are safe, there are problems that can occur. You may have swelling at the injection site (phlebitis). You may become sleepier than expected. This could happen because of
- The types of medicine you are given
- Your health
- Any drugs or medicine you took
- A reaction you may have to the medicines

Major problems that can happen include
- Allergic reaction to the medicine

What are the side effects of minimal sedation?
Side effects usually do not last long. They usually need little or no treatment.
- Dizziness

Besides minimal sedation, what other choices do I have?
There are many kinds of sedation. You may choose to have no sedation, or to be referred elsewhere for another kind. We can talk about any of these options with you, and help you with whatever you decide to do.

What else do I need to know?
If you have problems during or after sedation, you may be sent to a hospital or emergency room. This is rare. We will tell you how to contact us if you have any questions or problems.

We will tell you reasons to contact us.

The medicine can last for several hours. **Do not drive**, operate heavy machinery, or make important decisions for at least 24 hours after sedation. You must leave the health center with a responsible adult who will drive or ride other transportation with you.

Signature of Client (or person authorized to sign for client) Date

Relationship to Client: □ self □ parent □ legal guardian □ other

I witness that the client received this information, said it was read and understood, and there was an opportunity to ask questions.

Signature of Witness Date

Sedation –Moderate and Deep

(affiliate name and telephone number)

[Note to affiliates — You may also list the specific medications used with the potential benefits, risks, and side effects related to each. DELETE THIS STATEMENT.]

What is sedation?
Sedation is medicine to make you more relaxed during a surgery or procedure. There are many kinds. Moderate and deep sedation are two kinds. The medicine is given directly into your vein.

What is moderate sedation?
Moderate sedation may make you feel more relaxed and you may fall asleep.

What is deep sedation?
Deep sedation will make you fall asleep. You will have little or no memory of the surgery or procedure later on. You may be given oxygen to breathe.

Before you choose to have sedation, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits of moderate sedation?
- It is safe.
- It may make you feel more relaxed.
- It may keep you from remembering parts of the surgery or procedure later on.

What are the benefits of deep sedation?
- It is safe.
- It will put you to sleep.
- It will keep you from remembering parts of the procedure or surgery later on.

The risks and side effects of moderate and deep sedation are very similar.

What are the risks of moderate and deep sedation?
Although the medicines used for moderate and deep sedation are safe, there are problems that can occur. You may have swelling at the injection site (phlebitis). You may become sleepier than expected or need help with breathing. This could happen because of
- The types of medicine you are given
- Your health
- Any drugs or medicine you took
- A reaction you may have to the medicines

Major problems that can happen include
- Allergic reaction to the medicines
- Damage to or failure of the heart, lungs, liver, kidneys, and/or brain
- Loss of consciousness
- Death

What are the side effects of moderate and deep sedation?
Side effects usually do not last long. They usually need little or no treatment.
- Dizziness
- Nausea and vomiting

Besides moderate or deep sedation, what other choices do I have?
There are many kinds of sedation. You may choose to have no sedation, or to be referred elsewhere for another kind. We can talk about any of these options with you, and help you with whatever you decide to do.

What else do I need to know?
If you have problems during or after sedation, you may be sent to a hospital or emergency room. This is rare. We will tell you how to contact us if you have any questions or problems.

We will tell you reasons to contact us.

The medicine can last for several hours. **Do not drive**, operate heavy machinery, or make important decisions for at least 24 hours after sedation. You must leave the health center with a responsible adult who will drive or ride other transportation with you**.**

I am choosing
☐Moderate Sedation ☐Deep Sedation

Signature of Client (or person authorized to sign for client) Date

Relationship to Client: □ self □ parent □ legal guardian □ other _____

I witness that the client received this information, said it was read and understood, and there was an opportunity to ask questions.

Signature of Witness Date

Sedation – Moderate

(affiliate name and telephone number)

[Note to affiliates — You may also list the specific medications used with the potential benefits, risks, and side effects related to each. DELETE THIS STATEMENT.]

What is sedation?
Sedation is medicine to make you more relaxed during a surgery or procedure. There are many kinds. Moderate sedation is one kind.

What is moderate sedation?
Moderate sedation may make you feel more relaxed and you may fall asleep. The medicine is given directly into your vein.

Before you choose to have sedation, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits of moderate sedation?
- It is safe.
- It may make you feel more relaxed.
- It may keep you from remembering parts of the surgery or procedure later on.

What are the risks of moderate sedation?
Although the medicines used for moderate sedation are safe, there are problems that can occur. You may have swelling at the injection site (phlebitis). You may become sleepier than expected or need help with breathing. This could happen because of
- The types of medicine you are given
- Your health
- Any drugs or medicine you took
- A reaction you may have to the medicines

Major problems that can happen include
- Allergic reaction to the medicines
- Damage to or failure of the heart, lungs, liver, kidneys, and/or brain
- Loss of consciousness
- Death

What are the side effects of moderate sedation?
Side effects usually do not last long. They usually need little or no treatment.
- Dizziness
- Nausea and vomiting

Besides moderate sedation, what other choices do I have?
There are many kinds of sedation. You may choose to have no sedation, or to be referred elsewhere for another kind. We can talk about any of these options with you, and help you with whatever you decide to do.

What else do I need to know?
If you have problems during or after sedation, you may be sent to a hospital or emergency room. This is rare. We will tell you how to contact us if you have any questions or problems.

We will tell you reasons to contact us.

The medicine can last for several hours. **Do not drive**, operate heavy machinery, or make important decisions for at least 24 hours after sedation. You must leave the health center with a responsible adult who will drive or ride other transportation with you**.**

Signature of Client (or person authorized to sign for client) Date

Relationship to Client: □ self □ parent □ legal guardian □ other

I witness that the client received this information, said it was read and understood, and there was an opportunity to ask questions.

Signature of Witness Date

BRSQ-1

	No	Yes
a. Have you had breast or ovarian cancer?		
b. Has a blood relative had breast or ovarian cancer?		
▪ If answer to BOTH questions is NO, recommend average risk screening. ▪ If answer to BRSQ-1, Question a is YES, continue to BRSQ-2a. ▪ If answer to BRSQ-1, Question b is YES, continue to BRSQ-2b.		

BRSQ-2a – For clinician to complete if response to BRSQ-1, Question a is Yes.

	No	Yes	Don't know
1. Was the client's breast or ovarian cancer diagnosed before age 50?			
2. Was the client's breast cancer triple negative (ER, PR, HER2/neu negative)? (Triple negative breast cancers lack estrogen [ER], progesterone [PR], and HER2/neu receptors.)			
3. Does the client have a history of 2 primary breast cancers (2 independently identified breast cancers)?			
4. Does the client have a personal history of breast cancer AND a blood relative with ovarian cancer or breast cancer ≤ 50 years old?			
5. Does the client have a personal history of breast cancer AND a family history of 2 or more blood relatives with breast cancer and/or pancreatic cancer on the same side of the family?			
6. Has the client had both breast and ovarian cancer?			
7. If the client has had breast cancer, has she had any of the following cancers: thyroid, sarcoma, endometrial, pancreatic, brain, or stomach?			
If answer to **ANY** of the questions is **YES**, recommend genetic counseling. If the client answered **NO or DON'T KNOW** to **ALL** of the questions, she should follow average risk screening recommendations.			

BRSQ-2b – For clinician to complete if response to BRSQ-1, Question b is YES

	No	Yes	Don't know
1. Does the client have 3 or more breast cancers or 2 or more ovarian cancers on the same side of the family (maternal or paternal)?			
2. Does the client have a blood relative with breast cancer <45 years old?			
3. Does the client have a blood relative with ovarian cancer ≤ 50 years old?			
4. Does the client have a relative with male breast cancer?			
5. Does the client have a known breast cancer susceptibility gene (e.g. BRCA) in her family?			
If answer to **ANY** of the questions is **YES**, recommend genetic counseling. If the client answered **NO or DON'T KNOW** to **ALL** of the questions, she should follow average risk screening recommendations.			

(affiliate name and telephone number)

At your visit we found

- □ a lump in your breast
- □ breast discharge
- □ that you have pain in your breast that isn't going away
- □ information that means that you may have a higher risk of getting breast cancer than most women

You need to

- □ see a breast specialist. This is someone who has special training to check on breast problems.
- □ have a mammogram, ultrasound, or MRI of your breast. These are tests that take a picture of your breasts to look for changes that are not normal.
- □ see a genetic counselor. This is someone who has special training to figure out your risk of getting breast cancer.

If you are taking hormones for menopause and you do not get the follow-up we recommend within three months, we may not be able to refill your prescription.

Your health is important to us. We strongly encourage you to get the follow-up we recommend. We are happy to help you, but it is your responsibility. Please call us anytime and thank you for choosing Planned Parenthood.

Breast Engorgement and Mastitis

If you have breast engorgement and

are breastfeeding:

- nurse your baby often
- use a breast pump to get the milk flowing just before you nurse
- gently massage the firm areas of your breast while nursing
- wear a well-fitting bra
- take frequent warm showers or baths or put warm packs on your breasts. This will help them feel better and help your milk flow

are not breastfeeding:

- touch your breasts as little as possible until you feel better
- wear a tight fitting bra or wrap your breasts to bind them
- take over-the-counter pain medicine like ibuprofen.
- put ice packs on your breasts

Call the clinic if

- your breasts become warm to the touch.
- you get pain or a burning sensation in your breast(s) all the time.
- the skin of one or both of your breasts is red.
- you feel sick.
- you have a fever of 101° F or higher.

If you have mastitis (infection in the breast tissue)

- continue to breastfeed
- use a breast pump or nurse the breast that has mastitis every 2-3 hours by nursing or pumping
- rest as much as possible
- take over-the-counter pain medicine like ibuprofen
- put warm packs or a heating pad on the breast that has mastitis
- drink plenty of fluids
- use a breast pump if your nipples are cracked

Call the clinic if you're not

- feeling better 2 days after starting the medicine we give you
- completely better after finishing all the medicine we give you

Breast Health – What you Can Do

What can I do to help keep my breasts healthy?

There are several things you can do that we know can lower your risk of breast cancer. Most of these things are also good for your overall health:

- Stay at a healthy weight
- Get regular exercise — 4 or more hours a week is best.
- Avoid tobacco — Smoking increases the risk of breast and many other cancers.
- Limit alcohol — The more you drink, the higher your risk of breast cancer. If you do drink alcohol, 1 drink per day is a good limit.
- Know your environment — Some chemicals and harmful things around you in your daily life can affect your breasts. This includes some foods, cosmetics, plastics, and household products. Ask your doctor or nurse for more information.
- Breastfeed — Women who breastfeed their children are less likely to develop breast cancer.
- Discuss breast screening with your doctor or nurse

What should I be doing for breast cancer screening?

It is important to follow your doctor or nurse's recommendations for breast screening. Breast screening is based on both your age and your risk level (things like family history of breast cancer). Your recommended screening might include

- self-breast awareness (knowing what your breasts feel like and letting your doctor or nurse know if there is a change)
- clinical breast exam (an exam done by your doctor or nurse)
- breast imaging (special x-rays or other ways to "see" inside the breast)
- genetic counseling (meeting with someone who has special training to figure out your risk of getting breast cancer)

Though breast screening cannot prevent breast cancer, it can help to find breast cancer earlier, when it is easier to treat and more curable. If you don't get the recommended breast screening and you have breast cancer it might not be found at the earliest possible stage.

You can find out more about your risk for getting breast cancer by answering the questions on page 2.

Breast Cancer Risk Screening Questionnaire (BRSQ)		
	No	Yes
Have you had breast or ovarian cancer?		
Has a blood relative had breast or ovarian cancer?		

If you answer No to both questions, your risk for breast cancer is just like most women. You should

- get to know what your breasts feel like and call your doctor or nurse if there is a change (This is called breast self-awareness or BSA.)
- have a breast exam done by your doctor or nurse every 1-3 years from age 21-39, then every year from age 40 on
- have a mammogram once a year, starting at age 40

If you answer Yes to either question, you should talk to your doctor or nurse.
If you don't know, you should try to find out the answers by talking to your family members.

Breast Cyst Aspiration

(affiliate name and telephone number)

What is a breast cyst aspiration?
A cyst is a kind of breast lump that is filled with fluid. In breast cyst aspiration, a small needle is used to remove fluid. Cysts are common. Simple cysts are rarely cancer.

How is breast cyst aspiration done?
It is done in the clinic. The doctor or nurse will clean your skin in the area over the lump. Then she or he will insert a small needle through your skin into the cyst and drain the fluid. You may be offered medicine to numb your skin before the needle is put in.

What happens after the procedure?
You can go home the same day. You may feel bruising or soreness in the area that was drained:

- If the cyst goes away after clear fluid is drained, you will not likely need any more tests. You should return for routine breast exams.
- If bloody fluid is drained from the cyst, the fluid will be sent to the lab to find out what it is. And you will be referred to a breast doctor outside of Planned Parenthood.
- If clear fluid is drained from the cyst, but the cyst doesn't go away, you will need more tests. You will be referred to a breast doctor outside of Planned Parenthood.
- If no fluid is drained, you will need more tests. These might be ordered by Planned Parenthood. You may be referred to a breast doctor outside of Planned Parenthood.

What are the risks?
You may get a bruise where the needle goes in. Very rarely, you may get an infection where the needle goes in.

Warning Signs — Call the health center if you have

- very bad swelling or pain, bleeding, redness, or warmth around where the needle went in
- fever of 100.4°F or higher

Further Treatment
After the procedure, you may be asked to come back to the clinic for a follow-up visit. You may be referred to a breast doctor. You will be responsible for getting and paying for that care. If your fluid was sent to the lab, your doctor or nurse will discuss your results with you.

Affiliate Name and Address

EMERGENCY TELEPHONE NUMBER XXX-XXX-XXXX

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

Pap and HPV Tests

What is a Pap test?
A **Pap test** looks for changes on your cervix that might become cancer if not treated. The cervix is the opening of the uterus (womb).

What is an HPV test?
An **HPV test** looks for human papillomavirus (HPV).

What is HPV?
HPV is a very common virus that infects both men and women.

How does someone get HPV?
You can get HPV by skin touching skin, most often during sex.

What does HPV do?
There are many different kinds of HPV.

- Most HPV infections go away on their own and do not cause any health problems.
- Some types of HPV cause genital warts.
- Some types of HPV can cause changes on the cervix that might become cancer if not treated.

Which test(s) do I need and when?

If you are…	You should get a…
21 to 24 years old	Pap test every 3 years
25 to 29 years old	Pap test every 3 years OR HPV test every 3 years
30 to 65 years old	Pap test every 3 years OR HPV test every 3 years OR Pap and HPV test ("co-testing") every 5 years
Older than 65	You may not need tests anymore. Ask your doctor or nurse.

Some women may need to get tested more often, like women who've had changes to their cervix before, have a weak immune system, or if their mother took a medicine called DES during pregnancy.

Why should I get tested?
Getting regular tests will help find changes early enough so that they can be treated and cervical cancer can be prevented.

I got the HPV vaccine, do I still need to get tested?
Yes. The vaccine prevents most types of HPV linked to cervical cancer, but not all.

Shouldn't I get a tested every year?
No. It can take many years for cervical cancer to grow – more than 10 years. So getting tested every year doesn't lower your risk of cervical cancer and can even lead to having tests or procedures that can harm you more than help you.

Colposcopy and Biopsy

(affiliate name and telephone number)

What Is a Colposcopy?
Colposcopy is a way to get a close-up view of the cervix — the opening to the womb. The nurse or doctor will use a colposcope to do it. It is like binoculars on a stand with a bright light. It doesn't touch your body.

When Should Colposcopy Be Done?
It should be done on a day when you do not have your period or the bleeding is light.

How Do They Do a Colposcopy?
You lay down in the same way you would for a Pap test. We will put a speculum into your vagina. After that, we will wash your cervix with vinegar. This makes it easier for us to see any parts that are not normal. Then, the nurse or doctor looks for them through the colposcope. It takes about 5-10 minutes.

What Does a Colposcopy Feel Like?
- You may feel pressure when we put the speculum in.
- Y ou may feel a little burning when we wash the cervix with vinegar.

What Is a Biopsy?
Sometimes, the cervix will look normal. If a part of it doesn't, the nurse or doctor will pinch a tiny sample off of it and send it to a lab. This is called a biopsy. Often, a woman will need more than one biopsy.

How Do They Do a Biopsy?
There are two types of biopsy. One is taken from the outside of the cervix. Another is taken from the inside of the opening of the cervix. We send the sample to a lab. A doctor there will test them. The lab sends the doctor's test results back to Planned Parenthood. We use the results to decide if you need more tests or treatment.

What Does a Biopsy Feel Like?
- You may feel a pinch if we take a biopsy from the outside of the cervix. It may be slight or sharp.
- You may feel cramps if we take a biopsy from inside the opening of the cervix. They may be mild or severe.
- Most women feel little or no cramps afterwards.

You may have a little spotting or bleeding for a few days after a biopsy. You may have a dark discharge from the vagina for a few days. It is caused by a medicine that we may put on the area of the biopsy.

Why Have a Colposcopy?
A colposcopy may be done when you have
- a Pap test that is not normal
- a positive HPV test (HPV is the human papilloma virus)
- an area on the cervix that does not look normal
- certain other medical problems

Colposcopy and biopsy give more information than other tests. If a Pap or HPV test shows that there may be a problem, a colposcopy and/or biopsy can tell us more.

Risks
It is rare to have problems after a biopsy. You might have
- heavy bleeding that needs to be treated in the clinic, an emergency room, or the hospital
- an infection that needs to be treated

Colposcopy and biopsy are like many other tests. They can sometimes give a wrong result.

Other Choices
There is no other test that will give you and your nurse or doctor the same information as a colposcopy and biopsy.

After Colposcopy
- If you *don't* have a biopsy, you can start having vaginal sex whenever you want.
- If you *do* have a biopsy, wait about three days to allow the cervix to heal before having vaginal sex.
- Take your medicines as usual. This includes your birth control.
- You may shower or bathe as soon as you want.
- You may use a tampon, unless you are told otherwise at the time of the colposcopy.

WARNING SIGNS — Call the clinic if you have
- bleeding that's heavier than spotting — unless you think it's your period
- severe pain in the lower part of your belly
- fever or chills
- heavy, yellow, or bad-smelling discharge from your vagina

Further Treatment
Sometimes colposcopy and biopsy results show that you don't need treatment right away. Sometimes they show that you will need more tests later. If you need treatment, you can usually get it at Planned Parenthood. If not, we will help you make an appointment with another doctor.

affiliate name and address

EMERGENCY TELEPHONE NUMBER XXX-XXX-XXXX

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

Cryotherapy

(Affiliate Name and Telephone Number)

Before having cryotherapy, you need to know the possible benefits, risks, and alternatives. We have listed them here for you. We are happy to answer any questions you have.

What is cryotherapy?

Cryotherapy is a treatment for abnormal cells of the cervix. It is done by applying a very cold chemical to the cervix with an instrument called a cryoprobe. The cells on the surface of the cervix are frozen. This allows new normal cells to grow back later in the same area.

How is cryotherapy done?

The client lies in the same position used for having a Pap test. A speculum is inserted to view the vagina and cervix. The clinician places the cryoprobe into the vagina and gently holds it to the cervix for a few minutes. This causes the cells of the cervix to freeze. Usually the freezing is done twice, stopping for a few minutes in between.

What does cryotherapy feel like?

Even though the instrument is very cold, most women will not feel very cold inside their vagina during the procedure. Most women feel pelvic pressure and menstrual-like cramps during cryotherapy. A few women notice no discomfort at all.

Reasons for Cryotherapy

Cryotherapy may be recommended for several reasons. Usually, it is used to treat abnormal cervical cells that have been identified through biopsy. Sometimes it is used to treat other abnormalities on the cervix or vagina, such as warts.

Benefits

In most cases, cryotherapy cures abnormal cells so that the problem does not come back.

Risks

Most women do not have any serious side effects after cryotherapy. Rarely, however, problems can occur. These include fainting, flare-up of pelvic infection, freeze burns in the vagina, and heavy bleeding.

In a small number of cases, the treatment does not completely cure the problem. This can be more of a risk if the abnormal cells are deep in the cervical canal and the freezing does not reach them. In these cases it may be necessary to treat again with cryotherapy or with another treatment.

No treatment is one hundred percent effective. Planned Parenthood cannot guarantee the success of the treatment. The risk that this treatment will fail to cure the cervical problem is about 10 to 15 percent. If not cured, the abnormal cells could progress to a more serious condition or to cervical cancer. That's why it is very important for you to keep all of your appointments for follow-up exams and tests.

Alternatives

There are other treatments for abnormal cervical cells. The cells can be destroyed with laser or removed with an electric cutting loop ("LEEP" procedure) or by surgery.

In some cases if the abnormality is mild, it is possible to just continue to check the problem carefully with more Pap tests. The problem could stay the same, get worse, or go away on its own. Treatment may be needed later. Or no treatment may be needed, if the problem goes away on its own. Your clinician can discuss what the best plan is for you.

After Cryotherapy
All women will have a watery discharge that can last from a few days to several weeks. This discharge may be extremely heavy and can be blood-tinged. Because of the heavy loss of water from the freezing of tissue, you should be sure to drink lots of fluids.

[Your clinician may advise you not to have intercourse and not to use tampons for several weeks.][1]

Warning Signs — Call the clinic if you have
- heavy bleeding
- severe abdominal pain
- foul smell vaginal discharge
- fever (temperature of 100.4º or higher), chills, or other discomforts that concern you

Affiliate Name and Address

EMERGENCY TELEPHONE NUMBER XXX-XXX-XXXX

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

[1]Insert an explanation of your affiliate policy here.

LEEP – Loop Electrosurgical Excision Procedure

(affiliate name and telephone number)

Before having a LEEP, you need to know the possible benefits, risks and alternatives. We have listed them here for you. We are happy to answer any questions you have.

What is LEEP?

LEEP is the abbreviation for loop electrosurgical excision procedure. It is a treatment for abnormal cells on the cervix. A small electrical wire loop is used to remove the area of the cervix where there are abnormal cells.

How is LEEP done?

LEEP can be done in a clinic or doctor's office. The patient lies in the same position used for having a Pap test. A speculum is inserted to view the cervix and vagina. Numbing medication is applied or injected into the cervix. The clinician inserts a small instrument with an electrical wire loop into the vagina. The clinician uses the wire to quickly remove a small area of cervical tissue. The procedure takes about 10 minutes.

The tissue is sent to a lab to be examined under microscope for diagnosis. The findings are sent to Planned Parenthood.

What does LEEP feel like?

The woman does not feel cutting or heat from the loop. Some women experience mild discomfort or cramping. Most don't feel anything.

Benefits

LEEP is an effective treatment for abnormal cervical cells. Treatment with LEEP can remove abnormal cells that are deep in the cervical canal. Because a tissue sample is taken during the treatment, your clinician will get added information from the lab about the abnormal tissue. This will aid in planning follow-up care.

Risks

Most women do not experience serious problems from LEEP. Very rarely, however, serious problems occur. These include

- damage to other pelvic organs or the vaginal walls
- pelvic infection that needs treatment — This is more of a risk if you have sex before the cervix heals.
- heavy bleeding that may require a return visit to the office — This happens in about one out of 100 cases.
- reaction to local anesthetic
- possible increased risk of preterm birth in future pregnancies

In a small number of cases, LEEP does not completely cure the problem. It may have to be repeated later, or another treatment may be needed. Planned Parenthood cannot guarantee the success of the treatment. The risk that this treatment will fail to cure the problem is about 10 percent. If not cured, the abnormal cells could progress to a more serious condition or to cervical cancer. That's why it is very important for you to keep all of your appointments for follow-up exams and tests.

Alternatives

In some cases, the problem can be cured with cryotherapy (freezing of the tissue). But this is not possible in all cases. Also, cryotherapy does not provide tissue samples for lab diagnosis. In some cases, the problem can be treated with surgery in an operating room. Your clinician can discuss what the best plan is in your case.

After the Procedure

After treatment, you may experience mild cramping for up to 24 hours. You probably will have a watery vaginal discharge for several weeks. This discharge may be heavy for a few days or may be mixed with a little blood. The discharge may have an odor. If this happens, wash the labia (lips) off with plain water several times a day for a few days.

To speed healing and prevent infection, follow these instructions:

- If needed, use sanitary pads, not tampons, for *three weeks*.[1]
- Don't have intercourse for *three weeks*[1], unless your doctor recommends otherwise.
- Don't douche for at least *three weeks*[1].
- Use oral pain relievers, such as Tylenol® or Advil®, for cramps.

Warning Signs — Call the clinic if you have any questions or any unusual or unexpected symptoms, such as

- unusual vaginal bleeding, or bleeding heavier than the heaviest day of your period
- foul smelling vaginal discharge
- fever (temperature of 100.4º or higher), chills, or abdominal pain

It is very important to have follow-up care. More frequent visits to your provider will be needed for a while. Be sure you understand your instructions and your schedule of follow-up exams and tests.

Affiliate Name and Address

EMERGENCY TELEPHONE NUMBER XXX-XXX-XXXX

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

[1] Fill in an alternate number, based upon affiliate policy.

Before and After Your Hysteroscopic Tubal Sterilization (Hts)

Your appointment is on _____.

BEFORE YOUR APPOINTMENT

- Use birth control or don't have sex until your appointment, and until we tell you your tubes are blocked. Talk to your doctor or nurse about your birth control plan.
  - □ Condoms - use them every time you have sex until we tell you your tubes are blocked.
  - □ Implant – it will be removed after we know your tubes are blocked.
  - □ IUD - it will be removed at the time of your HTS. You should start using another kind of birth control at least 7 days before the procedure and keep using it until we tell you your tubes are blocked.
  - □ Pills or Patch – use it until we tell you your tubes are blocked.
  - □ Ring - keep it in for your HTS. The doctor performing your HTS will remove and replace your ring at the time of the procedure.
- Tell us if you have had any unprotected sex in the 2 weeks before your HTS appointment.
- Call us if your period starts early.
- Take only medications that were approved by your doctor or nurse, as instructed.
- Make sure you have ibuprofen or acetaminophen at home before your appointment.
- Plan to be at the clinic at least XXX hours.

AFTER YOUR HTS

You may have some symptoms for a few days:

- lightheaded or nausea
- watery discharge for 1 to 2 days
- Spotting or light bleeding for up to a week
- mild cramping and/or a backache for a few days

INSTRUCTIONS

- Go home and rest. You may do your normal activities as soon as you feel well enough, usually within 1 to 2 days.
- If you have nausea, eat small meals and drink a lot of fluids.
- If you have pain or discomfort, pain medicine such as ibuprofen or acetaminophen taken every 4 to 6 hours should help. A heating pad put on your belly may be helpful too.
- You may have sex as soon as you're ready.

GETTING YOUR HSG

You must get a HSG (hysterosalpingogram) 3 months after your HTS. This test will tell us if your tubes are blocked and you are sterile. Schedule your HSG, bring the referral form to your appointment, and we will notify you of your test results.

Warning Signs — Call the clinic right away if you have

- heavy bleeding or bleeding lasts for more than a week
- severe cramping that is getting worse or does not improve with medication.
- fever (over 100.4°F).
- foul smelling vaginal discharge.
- symptoms of pregnancy such as breast tenderness or nausea or if your period is more than 5 days late.

What if I have an emergency?

Call us immediately at XXX-XXX-XXXX, go to the nearest emergency room, or call 911.

Before and After Your Transabdomnal Tubal Sterilization (Tubal)

Your appointment is on _____.

BEFORE YOUR APPOINTMENT

- Use birth control or don't have sex until your appointment.
  - □ Condoms - use them every time you have sex until your appointment.
  - □ Implant – it will be removed during or after your tubal.
  - □ IUD - it will be removed either at the time of your tubal or afterwards.
  - □ Pill or Patch – use it until your tubal.
  - □ Ring - keep it in for your tubal.
- Tell us if you have had any unprotected sex in the 2 weeks before your appointment.
- Take only medications that were approved by your doctor or nurse, as instructed.
- Do not eat or drink after _____.
- DO NOT use any alcohol or drugs for 24 hours before your appointment.
- Wear loose, comfortable clothing on the day of your appointment.
- Plan to be at the clinic or hospital at least XXX hours.
- Bring someone who can drive you home.

AFTER YOUR APPOINTMENT

You may have some symptoms for a few days.

- Shoulder pain from the gas that was pumped into your belly. Lying down can help you feel better if this happens.
- Bloating
- Mild cramps
- Discharge or bleeding from your vagina
- Lightheaded or nausea
- Scratchy or sore throat

Instructions

- Go home and rest. Start your normal activities as soon as you feel well enough, usually in a few days.
- Take acetaminophen (Tylenol) or ibuprofen (Motrin) for pain, as directed by your doctor or nurse.
- Keep your incision areas clean and dry for a few days. Follow the instructions you were given about bathing and how to take care of your dressing.
- Avoid baths, sitting in hot tubs, and swimming until your skin has healed.
- Avoid heavy lifting for 1 week. Your doctor or nurse can tell you when to return to specific activities.

Warning Signs — Call the clinic right away if you have

- drainage, bleeding, redness, or swelling at any incision area
- pain that is getting worse or does not improve with medication
- fever (over 100.4°F)
- vomiting or nausea that doesn't stop
- dizziness or fainting spells
- symptoms of pregnancy such as breast tenderness, nausea, or if your period is more than 5 days late

What if I have an emergency?

Call us immediately at XXX-XXX-XXXX, go to the nearest emergency room or call 911.

Before and After Your Vasectomy

Your appointment is on _____.

BEFORE YOUR VASECTOMY

Instructions

- Take a shower or bath the morning of your vasectomy; wash penis and scrotum well.
- Trim or shave any hair from the front side of your scrotum.
- Eat a light meal before you come to the clinic.
- DO NOT use any alcohol or drugs for 24 hours before your vasectomy.
- Plan to be at the clinic for at least XXX hours.
- Plan to do no physical work or heavy exercise for 2 days after your procedure.

What to Bring

- Close-fitting jockey style briefs, jock strap, or athletic supporter.
- Someone to drive you home.

AFTER YOUR VASECTOMY

You may have some pain, swelling and bruising in the scrotal area. Call the clinic right away if you have severe pain or a lot of swelling.

Instructions

- After your vasectomy go home and rest. You may be able to do your normal activities in 2 or 3 days. Do not do physical work or heavy exercise for at least 2 days.
- Wear a jock strap or other support for 2 days while awake and asleep. After that, wear it for as long as it makes you feel more comfortable.
- If you have stitches, they will dissolve and do not need to be taken out.
- Do not pull, rub, or irritate the area.
- If you have pain or discomfort, pain medicine such as ibuprofen or acetaminophen taken every 4 to 6 hours should help.
- You may have sex after 1 week. Stop if it is uncomfortable.
- You can still get your partner pregnant right after the surgery. Most men will not be sterile until after 12 weeks (3 months). You must use another method of birth control until then. The only way to know for sure that you are sterile is to have a sperm check. You **must** bring us a sample of your semen for testing after 12 weeks.

Warning Signs — Call the clinic right away if you have

- fever (over 100.4 ºF)
- blood or pus coming from the site of the incision
- bad pain or swelling

What if I have an emergency?
Call us immediately at XXX-XXX-XXXX, go to the nearest emergency room or call 911.

HSG (Hysterosalpingogram)

What is an HSG?
HSG stands for hysterosalpingogram. It is an X-ray test. It takes pictures of the inside of your uterus and tubes after a dye is injected through your cervix.

Why do I need to get an HSG?
Your doctor or nurse has recommended an HSG for one of two reasons:

- You are trying to get pregnant. The test will tell us whether your tubes are blocked (if they are blocked sperm cannot reach an egg to cause pregnancy) and if the inside of your uterus is shaped normally.
- You have had a procedure called hysteroscopic tubal sterilization (HTS). The HSG is needed to tell us if your tubes are blocked and you are sterile.

Where do I go to get the HSG?
We do not do it at Planned Parenthood. You will go to a radiology or imaging center for the test. We will give you a referral form and a list of places you can go to for your HSG.

You need to make the appointment to have an HSG and bring the referral form with you to your appointment. We will notify you of your HSG results.

When should I get the HSG?
If you are having sex and you're not using birth control — like the pill or shot —you need to have the test in the first 2 weeks after your period. Be sure to bring the referral form with you when you go for the HSG.

- If you're trying to get pregnant, your doctor or nurse will tell you when to get the HSG.
- You should have it done 3 months after a hysteroscopic tubal sterilization.

How is the HSG done?

- You will lie on your back as you would for a Pap test.
- The doctor will put a speculum into your vagina to see your cervix.
- Your cervix will be washed with antibacterial soap.
- A numbing medication may be applied.
- The doctor will pass a narrow tube through the opening of the cervix into the uterus.
- A small amount of dye will be injected into the uterus through the tube. The doctor will watch on a screen as the uterus and tubes fill with dye.
- X-ray pictures will be taken.

If you're trying to get pregnant and have had or may have had a pelvic infection in the past, or if your tubes are blocked at the time of the x-ray (and you have not had a hysteroscopic procedure), you may be given an antibiotic to take for a few days before and/or after the HSG.

What will the HSG feel like?
You may feel some cramping when the dye is injected. After the test, you may feel the dye leaking out of your vagina. It is sticky.

Be sure to tell the doctor doing the HSG if you:
- have ever had an allergic reaction to X-ray dye
- have had a recent pelvic infection
- think you could be pregnant

What are the benefits of HSG?
HSG is one of the easiest ways to find out if the inside of your uterus is normal and if your tubes are open or blocked.

What are the side effects of HSG?
You may have
- mild to moderate lower belly (pelvic) cramping
- light vaginal bleeding

An over-the-counter pain medicine such as ibuprofen (Advil) or acetaminophen (Tylenol) may help if you have cramping. You can take it before the test. **Do not** take aspirin because it can make you bleed more. If these problems continue, call us for instructions.

What are the risks and WARNING SIGNS?

Call the radiology/imaging center right away or go to your local emergency room if any of these things happen to you:
- You get a rash, swelling, or have trouble breathing — you may be having an allergic reaction to the dye.
- You get lower abdominal (belly) pain, a temperature of 100.4° F or higher, unusual vaginal discharge or odor — you may be having a pelvic infection. This is very rare if there is no history of infection.

Hysteroscopic Tubal Sterilization (HTS)

(affiliate name and telephone number)

What is Hysteroscopic Tubal Sterilization (HTS)?

HTS is a method of birth control that is meant to be permanent. In HTS, a tiny insert is put into the opening of each of the fallopian tubes. They are the tubes that carry eggs from your ovaries to your uterus. After the procedure, your body will make scar tissue in the tubes. The scar tissue will close the tubes. This will block sperm from joining with your eggs. This process takes 3 to 6 months in most women.

How well does HTS work?

For every 1,000 women who have HTS, fewer than 3 will become pregnant. (No method of birth control is perfect.)

There is a chance that the inserts cannot be put in, they are in the wrong place, or they slip out. If this happens, you may need a second procedure or need to choose another type of birth control.

HTS is intended to be permanent. If you decide later you wish to get pregnant, it is not possible for the tubes to be reopened. You must be certain you will never want to be pregnant again before you choose HTS.

Before having HTS, you need to know the most common benefits, side effects, other options, risks, and what to expect with HTS. We are happy to answer any questions you have.

What are the benefits of HTS?

- No cutting is needed.
- You won't have a scar.
- We won't need to make you sleep. (No general anesthesia.) But you may choose Local numbing medicine is used.
- You should be able to return to work and other normal activities within 1 to 2 days — or even the same day.
- HTS has no hormones.

What are the side effects of HTS?

During HTS, and for a short time after, you may have

- pain and/or cramping, like strong menstrual cramps
- mild nausea or vomiting
- fainting or lightheadedness
- vaginal discharge, it can be clear or like a light menstrual period, for about 3 days

Rarely, in the first year after HTS, you may have pain

- during sex
- in your belly or your back

What are my other options?

There are other birth control methods and other types of sterilization. We will discuss these options with you to help you make the best decision for yourself.

What are the risks of HTS?

- **Perforation —** Rarely, instruments make a hole in the uterus or tubes while the inserts are being placed. This can cause bleeding, which is rarely life-threatening.
- **Pregnancy —** There is a small chance that you could get pregnant. You should see your doctor or nurse right away if this happens. We need to make sure you do not have a pregnancy in your tubes. This could be life-threatening.

Other rare risks include

- Before the procedure - already being pregnant at the time HTS is done
- During the procedure - too much fluid build-up in your bloodstream
- After the procedure
  - infection
  - changes in menstrual cycle
  - pelvic/back pain
  - regret about having the procedure — regret is greater for women who are younger than 30 years old and for those who have never had a child

Risks with medical procedures that you may need in the future

- Certain procedures or surgeries can damage inserts and/or cause injury to the area around the inserts.
- If you have *in vitro* fertilization after HTS, the fertilized egg may not be able to implant properly.

How will HTS be done?

- You will lie on your back as you would for a Pap test. We will put a speculum in your vagina.
- Before we start, we will numb your cervix. We will also give you medicine, such as ibuprofen (Advil) or acetaminophen (Tylenol). You may be offered other medicine for pain.
- Your doctor will put a small, tube-like camera into your vagina and through the cervix (opening to the uterus). It is called a hysteroscope or scope.
- Fluid moving through the scope will help the doctor see the openings of your tubes inside your uterus.
- The doctor will put the inserts in the opening of the tubes.

What does it feel like to have HTS?

You may have mild to moderate pain while the inserts are being placed. The medicine we give helps most women. If you need more medicine, we will discuss which options may work best for you.

What will I need to do after HTS?

- You will need to stay in the recovery room at least 15 minutes, or until you and the doctor feel you are ready to leave.
- After 3 months, you will need to have an HSG. It is a special x-ray to tell us if your tubes are closed. This will tell us whether or not you are still able to get pregnant.
- **You must use another method of birth control until we know that your tubes are closed**, otherwise, there is a risk you could become pregnant.

What else do I need to know?
Sterilization protects against pregnancy, but does not protect against sexually transmitted infections. Always use a condom for protection against infection.

You should carry the patient ID card with you, and tell your doctors and nurses that you had HTS.

What if I have an EMERGENCY?
Call the health center right away at XXX-XXX-XXXX, go to your local emergency room, or call 911 if any of these things happen to you:

- You get a rash, swelling, or have trouble breathing — you may be having an allergic reaction to the inserts.
- You get lower abdominal (belly) pain, a temperature of 100.4° F or higher, unusual vaginal discharge or odor — you may be having a pelvic infection.

Call us if you have any health problems or concerns about HTS.

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

Transabdominal Tubal Sterilization

(affiliate name and telephone number)

Before having a transabdominal tubal sterilization, you need to know the possible benefits, side effects, risks, and warning signs. We have listed them here for you to read. We are happy to answer any questions you have.

Transabdominal tubal sterilization is a method of birth control that is intended to be permanent. It blocks the fallopian tubes that carry the eggs from the ovaries to the uterus. If the procedure is successful, it is very unlikely that you will be able to become pregnant. In rare instances, the fallopian tubes reconnect on their own. If this happens, pregnancy can occur in the uterus or in the fallopian tubes. In about one out of 100 cases, the tubes cannot be blocked because of extensive scarring around the fallopian tubes or technical problems with the operation.

BENEFITS

- Transabdominal tubal sterilization is highly effective. Effectiveness depends on the type of transabdominal tubal sterilization that is done. Overall, 5 in 1,000 women report a pregnancy in the first year after transabdominal tubal sterilization.
- It is intended to provide permanent birth control.
- No periodic heath care visits are needed for contraception following sterilization.
- Some couples enjoy intercourse more because they are relieved of worries about unintended pregnancy.
- Nothing needs to be done daily, monthly, yearly, or just before intercourse to prevent unintended pregnancy.
- No hormones are involved.

RISKS

- **Reaction to general anesthesia —** Reaction to anesthesia can be nearly eliminated if a *local* anesthetic combined with sedatives is used. Some women, however, may be allergic to certain local anesthetics and/or to other medications. Certain medicines or drugs, including street drugs, may cause dangerous reactions during anesthesia. It is important to tell your clinician about any drugs or medication that you are taking. What you report will be kept in confidence.
- **Serious injury —** This is rare, but may require surgery. Rare injuries may occur with the laparoscope, which is a viewing instrument inserted through an incision near the navel. Rarely, it may damage the intestines, bladder, or blood vessels. Rare injuries may occur with electrocautery — an instrument that uses electric current to cut and seal the tubes. Rarely, it burns the intestines or other abdominal structures.
- **Method failure —** In the rare instance that pregnancy occurs after transabdominal tubal sterilization, there is an increased risk of ectopic (tubal) pregnancy. Ectopic pregnancies can be removed with medication, but sometimes require surgery.

No guarantee can be made about the outcome of the procedure. It is important that you understand its benefits, possible risks, and complications. You will be responsible for paying for emergency medical care that cannot be provided by Planned Parenthood — even in the unlikely event that Planned Parenthood refers you to a hospital because of a complication.

Sterilization does not protect against sexually transmitted infection. If you or your partner have other sex partners, use a latex or female condom to reduce the risk of infection.

Transabdominal tubal sterilization is intended to be permanent. Reversing a transabdominal tubal sterilization is usually very difficult and costly. It is often unsuccessful and pregnancy may not be possible. A woman **must** be certain she wants no future pregnancies before she chooses this method.

Planned Parenthood will continue to provide you with high quality medical care if you decide not to be sterilized at any time before the procedure. You will not lose any benefits that you are entitled to from programs or projects receiving federal funds if you decide not to be sterilized.

Affiliate Name and Address

EMERGENCY TELEPHONE NUMBER XXX-XXXX

Client Signature Date

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature Date

Vasectomy

(affiliate name and telephone number)

What is Vasectomy?
Vasectomy is a kind of birth control for men. It works by blocking the tubes that carry sperm to the penis so it keeps sperm out of semen. Semen is ejaculated, but it cannot cause pregnancy. It takes about 3 months before it works.

Vasectomy is one of the most effective methods of birth control. There is a small risk that it won't work. When men have their semen tested after vasectomy, there is less than 1 pregnancy per 2000 couples.

Vasectomy is meant to be permanent. Reversing it is difficult, expensive and often doesn't work. A man must be certain that he does not want to cause any pregnancies before he chooses this method.

What are the benefits of vasectomy?
It is a highly effective method of birth control for men who do not want more children.
It is safe and convenient. It allows a man to take responsibility for birth control. It may increase the enjoyment and frequency of sex.

What other choices do I have?
There are other methods of birth control that can be used by you and your partner(s). The only other method that is intended to be permanent is sterilization for the woman.

What are the risks of vasectomy?
- **Infection** in the skin, tubes, or testicles – Treatment with antibiotics, or very rarely, surgery, may be needed.
- **Bleeding** – You may notice blood from the place the skin was cut and this usually stops on its own.
- **Hematoma** — bleeding under the skin that may cause swelling or bruising. It usually goes away on its own. It may need medical treatment or surgery.
- **Spermatic Granuloma** — swelling caused by leakage of sperm from the tube that usually clears on its own. It may need to be drained.
- **Pain** —Very rarely, there may be bad pain in the scrotum or testicles that lasts for months or years.

What will happen to me during my vasectomy?
Vasectomy is done in the clinic. We may give you medicine to help you relax. The doctor will clean the scrotum. Numbing medicine will then be given in the area. The doctor or nurse will make 1 or 2 small holes or cuts in the skin of the scrotum and find both tubes that carry sperm to the penis to cut or block them. A small section of each tube may be removed.

What will happen to me after my vasectomy?
You can go home the same day. You may have some pain, swelling and/or bruising in the area. This is normal.

Warning Signs — Call the health center if you have
- fever (over 100.4° F)
- blood or pus coming from the site of the incision
- bad pain or swelling

(continued on page 2)

You **must** bring in a semen sample 12 weeks after your vasectomy. It needs to be tested to make sure that you are sterile. You are considered sterile when there are no sperm in the sample or only a small amount of sperm that doesn't move. You need to use another method of birth control until we tell you that you are sterile. Very rarely a second vasectomy is needed when the first vasectomy does not make you sterile.

What else do I need to know?

- Vasectomy protects against pregnancy, but does not protect you from sexually transmitted infections (STIs). Always use a condom for protection against infection.
- Vasectomy does not cause any change in sexual performance, pleasure, sensation, interest, desire, satisfaction, ability to have an erection or to ejaculate, or amount of semen.

It is very important that you understand this information. We are happy to answer your questions.

What if I have an emergency?

Call us immediately at XXX-XXX-XXXX, go to the nearest emergency room, or call 911.

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

After Insertion of the Implant

Remember

- For a few days, you may notice tenderness and swelling of the skin around the implant.
- Bruising and color change of the skin around the implant may last for a week or two.
- Try not to bump or rub the area for three to five days.
- Keep the area clean and dry. Keep the pressure bandage on for 24 hours.
- If a band-aid was put on the insertion site, leave it on for three days.
- You can return to normal activities right away, but do not lift heavy objects for a few days.
- After healing
  - do not worry about bumping the area
  - you may touch or wash the area as usual

Return to the health center

- as instructed by health center staff for follow-up
- as instructed by health center staff for periodic health screening

Call the health center if you

- have questions about the implant
- think you might be pregnant
- want the implant removed
- think the implant has come out
- have
  - a delayed menstrual period after having regular periods
  - unusually heavy vaginal bleeding
  - arm pain
  - opus or bleeding at the insertion site
  - unusual pain or swelling in the legs or arms
  - shortness of breath
  - sudden severe headaches
  - migraine aura — gradual onset, yet short-term visual experience of arcing, bright, flashing zig-zag lines
  - severe pain in the stomach or abdomen
  - yellowing of the skin or whites of the eyes
  - a new lump in your breast
- have other questions or problems

If you develop sharp or crushing chest pain or coughing blood, sudden partial or complete loss of vision, or other severe symptoms, call 911 or go to the nearest emergency room.

After Taking Out The Implant

After the Implant has been taken out — There are a few things to remember after the implant has been taken out:

- For a few days, you may notice tenderness and swelling of the skin around the implant.
- Bruising and color change of the skin may last for a week or two.
- Try not to bump the area for 3 to 5 days.
- Keep the area clean and dry.
- Keep the pressure bandage on for 24 hours.
- Keep the small tape or band-aid on for 3 days.
- You can return to normal activities right away.
- After healing, you can touch or wash the area as usual.

Remember — If you do not want to get pregnant at this time, you must use another birth control method immediately. Otherwise, you could get pregnant right away.

Call the health center if you have

- pus, redness, swelling or bleeding at the removal site
- arm pain that doesn't go away after a few weeks
- any other questions or problems

Condoms and Female Condoms

What are condoms and female condoms?

Condoms and female condoms are barriers. They

- prevent pregnancy by keeping sperm from entering the vagina and joining with an egg.
- reduce the risk of sexually transmitted infections (STIs), including HIV, by preventing contact with blood and sexual fluids and covering some skin. They can be used with vaginal, anal, and oral sex.

Condoms fit over a penis**.** They are made of latex, polyurethane, or animal tissue (lambskin). Of 100 women whose partners use condoms, about 15 will become pregnant in the first year of typical use. Some condoms are coated with spermicide.

Female condoms fit into the vagina**.** They also cover part of the vulva. They are made of polyurethane or another type of plastic called nitrile. Of 100 women who use female condoms, 21 will become pregnant in the first year.

Should I use spermicide with condoms?

Spermicides contain a chemical that kills sperm and this can help prevent pregnancy. They include gels, creams, film, foam, sponges, and suppositories that are inserted into the vagina. Some male condoms may contain spermicide.

Vaginal spermicides and condoms with spermicide are not recommended to prevent STIs. Nonoxynyl-9 is the active ingredient in most spermicides made in the US. Using it many times a day may irritate tissue in the vagina or anus. This can increase the risk of getting HIV or other STIs.

How do I use condoms?

Before putting on:

- Store condoms in a cool, dry place away from direct sunlight.
- Check the expiration date before using.
- Tear the condom package carefully – without using your teeth – to open.
- If the condom looks damaged, discolored, or brittle, do not use.
- Add a drop of lubricant inside the condom for extra pleasure, if you like.

To put on:

- Pull back the foreskin, unless circumcised, before rolling on the condom.
- Leave about a half-inch of space at the tip to collect semen.
- Pinch the air out of the tip with one hand while placing it on the penis.
- Unroll the condom over the penis with the other hand.
- Roll it all the way down to the base of the penis.
- Smooth out any air bubbles to prevent breaks.
- Lubricate the outside of the condom with water-based lubricant only, if you like.

To take off:

- Pull the penis out before it softens.
- Hold the condom against the base of the penis while you pull out.
- Throw the condom away in the trash.

How do I use female condoms?

To insert:

- Put lubricant on the outside of the closed end.
- Find a comfortable position, like standing with one foot on a chair, squatting, or sitting on the edge of a chair.
- Squeeze together the sides of the inside ring (at the closed end of the condom) and put into the vagina, like you would a tampon.
- Push the inner ring into the vagina as far as it can go.
- Pull out your finger and let the outer ring hand about an inch outside the vagina.

To remove:

- Squeeze and twist the outer ring to keep semen inside the pouch.
- Gently pull it out of the vagina or anus.
- Throw it away in the trash.

What else can I do to make condoms or female condoms work better?

- Use them every time you have sex.
- Put it in place before the penis, or mouth, goes in or near the vagina, or anus.
- Use water-based lubricants with vaginal and anal sex. This may increase sensitivity and help prevent tears. Oils such as baby oil and Vaseline can make condoms and dams break.
- Use a condom or dam only once.
- Do not “double up” (use 2 condoms, or male and female condoms together) as this increases the risk of breakage.
- Read and follow the instructions that come with the condoms you use.

What should I do if the condom breaks or falls off?

Emergency contraception (EC) can reduce the risk of pregnancy when accidents happen. If the condom breaks or falls off during sex, consider taking EC. EC includes the insertion of a copper IUC (Cu IUC) and “morning after” pill(s). All work best when started as soon as possible, within 5 days of unprotected sex.

Let us know if you have any questions. We are happy to help you.

Fertility Awareness-Based Birth Control Methods (FAM)

Fertility Awareness-Based Methods (FAM) allow you to figure out which days every month you are at risk of pregnancy (called fertile days). To avoid pregnancy, you cannot have sex on those days or you can use a barrier method of birth control (like condoms). If you want to be become pregnant you should have sex on your fertile days.

There are different kinds of FAM, like

- counting the days of your menstrual cycle on a calendar
- taking your temperature every morning
- checking

How do I use FAM?

Each method has different instructions. If you decide to use FAM, ask your doctor or nurse for detailed information and instructions for the method(s) you want to use. Here are some details to help you get started.

- **Rhythm method** — To use this method, you need to count the days in your last 6 menstrual cycles. This helps to figure out when you are fertile (and when having sex has a risk of pregnancy).
  - The first day of the cycle is the day your period starts.
  - To figure out the number of days in one of your cycles, you need to count the number of days from the first day that your period starts to the first day that your next period starts.
  - Once you have these numbers, you need to do a little math:
    - Subtract 18 from the number of days in the ***shortest*** cycle you counted. (For example, if your last 6 cycles were anywhere from 26 to 30 days long, then your shortest cycle was 26 days. 26 minus 18 equals eight.)
    - Subtract 11 from the number of days in the ***longest*** cycle you counted. (Using the same example, the longest cycle was 30 days. 30 minus 11 equals 19.)
    - Those two numbers are the beginning and ending days of the fertile period. So, in the example, the fertile period starts Day 8 of the cycle, and ends Day 19. On those days of every menstrual cycle, you shouldn't have sex or you should use a barrier method (like a condom) when you do have sex to avoid getting pregnant.

- **Standard Days Method** — This method is for women with menstrual cycles that are between 26 and 32 days long – never longer or shorter. You should avoid sex or use a barrier method between Days 8 and 19 of the menstrual cycle. Some women use a product called Cycle Beads to help them keep track of cycle days for this method.

- **Basal Body Temperature (BBT) method** — For this method, you have to take your own temperature every single morning, before getting out of bed. You should write the temperature on a graph, and follow the instructions to figure out when you have ovulated. Your clinic may have graph paper for this, or you can get graphs on the internet. For the best protection against pregnancy using BBT, you should avoid unprotected sex from the first day of each menstrual cycle until you have ovulated.

- **Cervical mucus (or secretion) methods** — These methods require you to touch your cervical mucus. The mucus changes at different times of the menstrual cycle. Around the time of ovulation, the mucus can be wet, stretchy, and slippery. Other times, it may feel drier or thicker, or you may not really notice any at all. The look and feel of the mucus helps you to figure out when to avoid unprotected sex. The Billings Ovulation Method is one example of these methods.

- **Symptothermal method** — This means using more than one FAM at once to reduce the chances of getting pregnant. It could mean using a cervical mucus method with BBT, for example.

How well does FAM work?

If a couple uses FAM perfectly for a year, about **5 out of 100 women** will get pregnant. But in real life, where it is hard to use FAM correctly all the time, **between 10 and 20 out of 100 women** using FAM will get pregnant in a year. This is a higher pregnancy rate than most hormonal birth control methods.

FAM may not work for you if you

- don't want to keep track of your fertile days
- can't avoid sex or use another method of birth control for at least 10 days during each menstrual cycle
- take medicines that makes it hard for you to figure out your fertile days
- have irregular periods
- have a partner who isn't cooperative
- are breastfeeding

Where do I go for more information about FAM?

- Rhythm Method: http://www.mayoclinic.com/health/rhythm-method/MY01003
- Standard Days Method: http://www.plannedparenthood.org/health-topics/birth-control/fam-standard-days-method-22141.htm
- Cycle Beads: http://www.cyclebeads.com/
- BBT: http://www.mayoclinic.com/health/basal-body-temperature/MY01002
- Cervical Mucus Methods:
  - The Billing Ovulation Method: www.woomb.org
  - The Creighton Model: www.creightonmodel.com
  - General information: http://www.mayoclinic.com/health/cervical-mucus-method/MY01004
- Symptothermal Method: http://www.fertilityuk.org

How to Use the Cervical Cap

If you use a cervical cap to prevent pregnancy, be sure to read the package insert first. The information may be different from ours. Let us know if you have questions.

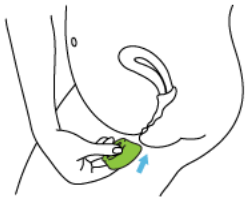
Do not leave your cap in for more than 2 days.

To put it in:

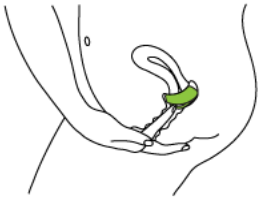
1. Put ¼ teaspoon of spermicide in the cup and spread a thin layer on the flat part of the brim.

2. Put ½ teaspoon in the groove between the brim and the dome.

3. Spread it in a thin layer on the brim of the cap.
4. Find a comfortable position, like standing with one foot on a chair or squatting.
5. Separate the lips of your vulva with one hand.
6. Squeeze the rim of the cap with your other hand and insert “dome side” and strap down, long brim entering first.



7. Push the cap deeply into the vagina.



8. Once in place, make sure your cervix is covered.

To take it out:

1. Squat down. Using your fingers, push against the dome to break suction.

2. Hook your finger under the strap and pull the cap down and out gently.

Taking care of your cap.

- Wash with mild soap and warm water after every use.
- Allow it to air dry.
- Don't use powder on it.
- Don't use oil-based lubricants – like Vaseline or cold cream – with the cap – they can damage silicone and latex.
- Store it away from heat.
- Check it regularly by holding it up to the light. Light will shine through weak spots or holes. Or, fill it with water and look for leaks.
- Stop using your cap if you find holes, weak spots, cracks, or wrinkles and talk to your doctor or nurse about a replacement. In the meantime, use another form of birth control or don't have sex.
- Have your fit checked by your doctor or nurse every year, after significant weight change (+/- 10 pounds), or pregnancy.

What else can you do to help your cap work better?

- Use the cap every time you have vaginal sex.
- Insert it before you feel aroused.
- Always use with spermicide cream or jelly.
- Add more cream or jelly before every time you have sex.
- Always leave the diaphragm or cap in place for at least 6 hours after the last time you had sex.

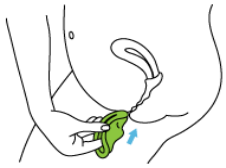
How to Use the Diaphragm

If you use a diaphragm to prevent pregnancy, be sure to read the package insert first. The information may be different from ours. Let us know if you have questions.

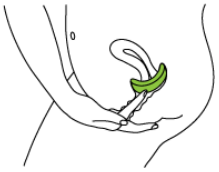
Do not leave your diaphragm in for more than 1 day.

To put it in:

1. Apply spermicide according to package directions.
2. Find a comfortable position, like standing with one foot on a chair or squatting.
3. Separate the lips of your vulva with one hand.
4. Fold diaphragm with your other hand and insert into your vagina “dome side” down. For Caya, insert the edge with the removal dome last.



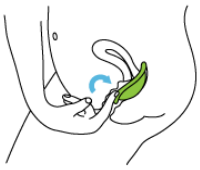
5. Push the diaphragm as far up and back in your vagina as possible.



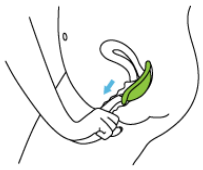
6. Tuck front edge in place behind your pubic bone.
7. Once in place, make sure cervix is covered.

To take it out

1. For Milex, hook a finger over the top of the rim to break the suction. For Caya, hook a finger into the removal dome and pull to break the suction.



2. Pull the diaphragm down and out gently.



Taking care of your diaphragm.

- Wash with mild soap and warm water after every use.
- Allow it to air dry.
- Don't use powder on it.
- Don't use oil-based lubricants – like Vaseline or cold cream – with the diaphragm – they can damage silicone and latex.
- Store it away from heat.
- Check it regularly by holding it up to the light. Light will shine through weak spots or holes. Or, fill it with water and look for leaks.
- Stop using your diaphragm if you find holes, weak spots, cracks, or wrinkles and talk to your doctor or nurse about a replacement. In the meantime, use another form of birth control or don't have sex.
- For Milex, have your fit checked by your doctor or nurse if you lose or gain 10 pounds or more or if you were pregnant.

What else can you do to help your diaphragm work better?

- Use the diaphragm every time you have vaginal sex.
- Insert it before you feel aroused.
- Always use with spermicide cream or jelly.
- Add more cream or jelly before every time you have sex.
- Always leave the diaphragm in place for at least 6 hours after the last time you had sex.

How to Use the Patch

How do I put on the patch?

Tear open the pouch along the top and side. Peel the foil open and make it flat. Take the patch and plastic layer off the foil. Peel *one half* of the clear layer of plastic away from the patch. Be careful not to touch the sticky part. Put the sticky half of the patch on clean dry skin. Remove the other half of the plastic, and press the whole patch to your skin. Hold in place with the palm of your hand for 10 seconds.

Where do I put the patch?

Put the patch onto clean, dry skin on your belly, upper outer arm, buttocks, or back. — **DO NOT put it on your breasts**.

When can I start the patch?

- You can start during the first 5 days of your period. You don't need to use backup birth control – like condoms — if you do.
- You can start any other time during your cycle. But you will not be protected from getting pregnant until after 7 days. So use backup birth control or don't have sex for the first 7 days.

When should I change the patch?

- Each patch is worn for one week. Put on a new patch each week for 3 weeks in a row. Then you have one week with no patch. Change the patch on the same day each week — your "patch change day." Do not put on a patch for the 4th week. That is when you will get your period.
- Other _____

What do I do with the patch after I take it off?

Be sure to fold each used patch in half to stick it to itself. Put it in a plastic bag, seal it, and throw it away. Used patches still contain hormones. Sealing it up protects the hormones from getting in the soil and water. Do not flush patches down the toilet.

Will the patch fall off?

The patch is made to stay in place while swimming, taking saunas, using whirlpools, or sweating. Check your patch every day to make sure it is sticking. Rarely, the patch can loosen or come off the skin.

Don't try to put a patch back on if

- it isn't sticky any more
- it gets stuck to itself or something else
- it's loose or has fallen off — unless it's been less than 1 day

Never use tape or anything else to keep the patch in place. If it doesn't stick to your skin by itself, it won't work. If a patch won't stick any more, put on a new patch right away.

What if the patch falls off or I forget to change it?		
What happened?	**What should I do?**	**Do I need to use back-up birth control or not have sex?**
The patch got loose or fell off and it has been less than 2 days.	Put the patch back on. If it won't stick or you don't have it, put on a new patch right away. Your "patch change day" will stay the same.	No.
The patch got loose or fell off, and it has been more than 2 days, or I don't know how long it has been off.	Start a new, 4-week cycle by putting on a new patch right away. This is your new "patch change day."	**Yes, for 7 days.**
I forgot to put on a new patch at the end of my patch-free week.	Put on the first patch of your new cycle as soon as you remember. This becomes your new "patch change day."	**Yes, for 7 days.**
I forgot to change my patch in the third week. (1 or 2 days since I should have changed it)	Put on a new patch as soon as your remember. Put on your next patch on your normal "patch change day."	No.
I forgot to change my patch in the third week. (More than 2 days since I should have changed it)	Put on a new patch as soon as you remember. This starts a new, 4-week cycle. You have a new "patch change day."	**Yes, for 7 days.**
I forgot to remove my patch at the end of a patch cycle.	Take the patch off as soon as your remember. Start your next cycle on your normal "patch change day."	No.

Can I get pregnant if I forget to change my patch?

Yes, it depends on the timing. You may want to take emergency contraception. If you have no period in 2-4 weeks, you should consider doing a pregnancy test. Call the clinic, our staff will help you.

How do I store the patch?

Keep the patch at room temperature out of direct sunlight. Don't store it in the refrigerator or freezer. Keep patches sealed in their pouches. Put them on as soon as you remove them from the pouch.

Emergency Contraception (EC)

Accidents happen. That's why we have EC to prevent pregnancy after unprotected sex. It can be started up to five days after unprotected sex.

When do I start my pills?

You may start your pills on any of the following days:

- today
- the first day of your period
- the first Sunday after your period begins (if your period begins on Sunday, start that day).

Your doctor or nurse can also help you figure out which will work best for you.

Will my pills work right away?

Not always. If you start your pills

- within 5 days of the start of your period, you do not need back up birth control.
- after the first 5 days of your period, use back up birth control – like condoms – or no sex for the first 7 days of your pill pack.
- after taking levonorgestrel emergency contraception (LNG EC), use back up birth control or no sex for 7 days.
- after taking ulipristal acetate emergency contraception (UPA), use back up birth control or no sex for 14 days.

How do I take my pills?

It's up to you if you want to have a period or not.

If you want to have a period every month

- Swallow one pill every day, as close to the same time as possible. Take all hormone pills first, finish with reminder pills, then start a new pack. Taking pills this way will give you a period about every 4 weeks.
- It's okay to skip your reminder pills. There's no hormone in them, so skipping them won't make your pills less effective.

If you want to choose when you have a period

- Take the first 3 weeks of hormone pills. After taking the last hormone pill, skip the reminder pills and start a new pack the next day. Continue taking only the hormone pills to avoid having your period.
- When you're ready to have a period, and after you've been on the hormone pills at least 3 weeks, take the reminder pills for up to 7 days at a time.

If you don't want to get a period,

- Only take the hormone pills in each pack with no break between packs.

What do I do if I miss pills?

If you miss pills or start your pack late it may not work as well. The chance of getting pregnant depends on when and how many pills you missed. Once it's been more than 1 day since the time you should have taken it, the pill is considered missed.

What happened?	When in the pill pack?	What should I do?	Do I need to use back-up birth control or not have sex?
I took 1 hormone pill late. (Less than 1 day since I should have taken my pill.)	Anytime.	▪ Take the late pill as soon as possible. ▪ Take the rest of your pills at the usual time. ▪ This means you may take 2 pills in 1 day.	No.
I missed 1 hormone pill. (One to less than 2 days since I should have taken my pill.)	Anytime.	▪ Take the missed pill as soon as possible. ▪ Take the rest of your pills at the usual time. ▪ This means you may take 2 pills in 1 day.	No.
I missed 2 or more hormone pills in a row. (2 or more days since I should have taken a pill)	Week 1 or 2	▪ Take the most recent missed pill as soon as possible. ▪ Throw away any other missed pills. ▪ Keep taking the remaining pills in your pack, even if you take 2 pills in 1 day.	**Yes, for 7 days.**
I missed 2 or more hormone pills in a row. (2 or more days since I should have taken a pill)	Week 3	▪ Take the most recent missed pill as soon as possible. ▪ Throw away any other missed pills. ▪ Finish the rest of the hormone pills in your pack, then start a new pack the next day. This means you will skip the reminder pills.	**Yes, for 7 days.**
I missed reminder pills. (It doesn't matter how many.)	Week 4	▪ Throw away. ▪ Take the next reminder pill at your usual time.	No.

Emergency Contraception (EC)

Accidents happen. That's why it's important to remember that EC can reduce the risk of pregnancy. If you missed pills and have had unprotected sex in the last 5 days, consider taking EC. EC includes the insertion of a copper IUC (Cu IUC) and "morning after" pill(s). All work best when started as soon as possible, within 5 days of unprotected sex.

How to Use the Ring

Where do I put the ring? How do I put it in and take it out?
Put the ring into your vagina. It's easy to do. Use your fingers to bring the sides of the ring together and gently push it into your vagina. If you can't feel it when you walk, you've got it in right.

To take the ring out, hook your finger through the ring and pull gently. Put the used ring in the foil pouch and throw it away. Used rings still contain hormones. The foil pouch protects the hormones from getting into the soil and water. Do not flush the ring down the toilet.

When can I start the ring?
- **You can start during** the first 5 days of your period. You don't need to use backup birth control if you do.
- **You can start** any other time during your cycle. But you will not be protected from getting pregnant until after 7 days. So use backup birth control – like condoms – or don't have sex for the first 7 days.

When should I change the ring?
There are different ways to use the ring:
- Change your ring once a month. Whatever day you start the ring becomes your change day. On your change day, you take out the old ring and put in the new one. You may have some bleeding or spotting. You will probably not get regular periods.
- Keep your ring in place for 3 weeks, take a ring-free break for 7 days, and then put in a new ring. You should get your period during the ring-free break. It is normal to be still bleeding – usually spotting – when it is time to put in your new ring.
- Other _____

The Ring and Sex
It's best to keep your ring in your vagina during sex. If it bothers you, move it around until it feels comfortable. You can come in to the clinic to have us check for proper placement if you have any questions. If for some reason you decide to take the ring out during sex, make sure you
- Don't leave it out for more than 2 days.
- Rinse it in cool water and put it back in after sex.

Can I use vaginal medicine or lubricants when I'm using the ring? Yes.

What if the ring falls out or I forget to change it?		
What happened?	**What should I do?**	**Do I need to use back-up birth control or not have sex?**
The ring fell out or I took it out of my vagina and it has been less than 2 days?	Wash it in cool water and put it back in as soon as possible but within 2 days.	No.
The ring is out of my vagina for more than 2 days, and it's not my ring-free week?	Wash it in cool water and put it back in.	**Yes, for 7 days.**
I forgot to put in a new ring at the end of my ring-free week?	Put in a new ring as soon as you remember.	**Yes, for 7 days.**
I forgot to change my ring on my change-day?	Take out the old ring and put in a new one as soon as you remember.	**Yes, for 7 days.**

Can I get pregnant if I forget to change my ring or leave it out of my vagina by mistake?
Yes, it depends on the timing. You may want to take emergency contraception. If you have no period in 2 to 4 weeks, you should consider doing a pregnancy test. Call the health center — our staff will help you.

How do I store the ring?
Unused rings can be stored at room temperature out of direct sunlight for up to 4 months (16 weeks). Refrigerate any rings that will not be used within 4 months. Read the storage advice on the package.

Emergency Contraception (EC)
Accidents happen. That's why we have EC to prevent pregnancy after unprotected sex. It can be started up to 5 days after unprotected sex.

Pregnancy with an Intrauterine Contraceptive (IUC) in Place

You are pregnant with an IUC in place. Before you decide whether or not to have your IUC removed, be sure you understand the problems that can occur. We have also listed the warning signs to watch for. We are happy to answer your questions.

When you are pregnant with an IUC in place, our best medical advice is to have it removed, if possible. It is best done as soon as you know you're pregnant.

Being pregnant with an IUC in place increases the risk of
- ectopic (tubal) pregnancy
- dangerous pelvic infection
- early pregnancy loss — miscarriage
- early labor and delivery

Ectopic Pregnancy
A pregnancy for a woman with an IUC is more likely to be ectopic than it is for a woman who doesn't have one. Ectopic pregnancy can be a life-threatening condition.

Warning Signs — Get medical care right away if you have
- irregular vaginal bleeding
- pain in the abdomen or shoulder
- sudden weakness or fainting

You may need an operation if you have an ectopic pregnancy.

Miscarriage and Infection
An early pregnancy is one that is less than 12 weeks along. About 15–20 out of 100 of them end in miscarriage. The risk stays about the same if an IUC is removed early in the pregnancy. But the risk increases to about 50 out of 100 if the IUC is not removed.

A severe infection can develop during pregnancy with an IUC in place. It can affect the uterus, tubes, and ovaries. It can begin with flu-like symptoms — tired and achy feelings. But it can get worse so quickly that a woman can become very ill in just a matter of hours. Rarely, it can also lead to death.

Warning Signs — Get medical care right away if you have
- pelvic pain, cramping, or tenderness in the abdomen
- fever or chills
- flu-like symptoms — tired and achy muscle feelings
- bleeding from the vagina
- passing blood clots or clumps of tissue
- unusual discharge from the vagina

Removing the IUC
If possible, the IUC should be removed as soon as you know you are pregnant. If the IUC string can be seen at the opening of the cervix, then your clinician can usually gently remove it. You have three choices:

1. If you choose to remove the IUC and want to continue the pregnancy	Sometimes, taking out an IUC early in pregnancy can cause bleeding and may start a miscarriage. But the chance of miscarriage is worse for a woman who leaves the IUC in. If the IUC is left in, there is also a risk of infection. Watch for the warning signs of miscarriage and infection if you have your IUC removed. Report any signs to your clinician right away.
2. If you choose to end your pregnancy	You can have an IUC taken out during a surgical abortion. Be sure to tell the clinician doing the abortion that an IUC is in place. The clinician can make sure it is removed. The clinician can also check the uterus carefully if the IUC is not found.
3. If you choose to continue the pregnancy but not remove the IUC	The IUC will stay in the uterus for the duration of the pregnancy. There is no evidence that leaving it in will cause birth defects. But there are risks: ▪ Infection may develop. ▪ The bag of waters may break too soon. This is called premature rupture of the membranes. ▪ Labor and deliver may also happen too soon. These problems would put you, your pregnancy, and your baby at risk for complications. Watch for warning signs of miscarriage and infection. The clinician can check to see if the IUC comes out at delivery. If it doesn't, the clinician can try to remove it. But it may be difficult to locate the IUC because the uterus is so big at this time. If so, arrangements can be made to remove the IUC at the postpartum visit.

OUR RECOMMENDATION
Our best medical advice is for you to have the IUC removed, if possible, as soon as you know you're pregnant.

Planned Parenthood will not be responsible for anything that happens if you do not take our advice. Our staff and employees will not be responsible, either. You will be completely responsible for whatever happens if you decide to leave the IUC in place.

If you decide to leave the IUC in place
- Get medical care right away, for abortion or prenatal care, with a doctor at a clinic of your choice.
- Get emergency care right away if you have any warning signs of ectopic pregnancy, infection, or miscarriage. They are listed above.

Referrals — We may refer you for further diagnosis or treatment. You will be responsible for getting the care and paying for it — even if we refer you to a hospital because of a complication.

Diaphragm and Cervical Cap

(affiliate name and telephone number)

What are the diaphragm and cervical cap?

The diaphragm and the cervical cap are inserted into the vagina to prevent pregnancy:

- **Diaphragm** — made of latex or silicone. Shaped like a dome.
- **Cervical Cap** — made of silicone. Shaped like a sailor's cap.

Your doctor or nurse can prescribe them for you. They are called barrier methods because they block sperm from entering the uterus.

They work by covering the cervix. They keep sperm from joining with an egg. They are used with a spermicide cream or jelly. It stops sperm from moving.

How well do barriers work?

- **Diaphragm** — For every 100 women who always use the diaphragm as directed, about 6 will get pregnant in a year. For every 100 women who don't always use it as directed, about 12 will get pregnant in a year.

- **Cervical Cap** — For every 100 women who use the cap and were never pregnant or never had a vaginal delivery, about 14 will get pregnant in a year. For every 100 women who use the cap and have had a vaginal birth, about 29 will get pregnant in a year.

What are the benefits of a diaphragm and a cervical cap?

They are a safe way to prevent pregnancy. They have no hormones.

Besides a diaphragm or cervical cap, what other choices do I have?

There are many other methods of birth control. We will offer you information about them and answer your questions.

How do I use the diaphragm or cap?

Your doctor or nurse will give you instructions. If you decide to use a diaphragm or cap — Read the package insert that comes with it. The information may be different from ours.

What are the risks of barrier methods?

- Nonoxynol-9 (N-9) is the active ingredient in most spermicides. Using N-9 many times a day may irritate the vagina or anus. This can increase the risk of getting HIV or other sexually transmitted infections (STIs).
- Some people may be allergic to the latex, silicone, or spermicide.
- Women may have an increased chance of getting bladder infections with the diaphragm.

Warning Signs — Call the clinic if you have

- discomfort while the diaphragm or cap is in place
- itching or irritation in the vagina
- unusual discharge from the vagina
- frequent bladder infections
- redness or swelling of the vulva/vagina
- signs of toxic shock syndrome — which is very rare. If you have any of these symptoms, remove the device and contact us right away:
  - sudden high fever
  - a sunburn-type rash
  - diarrhea or vomiting
  - sore throat, aching muscles and joints
  - dizziness, faintness, weakness

What else do I need to know?

These methods protect against pregnancy, but do not protect against sexually transmitted infections (STIs). Always use a condom for protection against infection.

Take care of your health — Don't forget to get regular check-ups and screening for sexually transmitted infections and cancer.

Let us know if you have questions. We are happy to help you.

The Shot - DMPA

(affiliate name and telephone number)

The shot is made of the hormone **progestin**. It is like the hormone made by a woman's body. This hormone keeps you from getting pregnant:

- It keeps eggs from leaving the ovaries.
- It makes cervical mucus thicker. This keeps sperm from getting to the eggs.

How do I take the shot?

You get the shot at the clinic about every 12 weeks. There are two types:

- One is injected into the muscle. It has a higher dose of hormone.
- The other is injected into the tissue just under the skin. It has a lower dose of hormone.

How well does the shot work?

- For every 100 women who get each shot on time for a year, only 1 will get pregnant.
- For every 100 women who do not always get the shot on time, about 6 will get pregnant.

There's nothing you have to do before sex to make the shot work.

The shot does not protect you from sexually transmitted infections — It **does** protect you from

- cancer of the uterus
- pregnancy in the tubes

What are the side effects of the shot? — You may have

- nausea (feeling sick to your stomach) — usually clears up in 2 or 3 months
- sore breasts — usually clears up in 2 or 3 months
  headaches
- weight gain — some women gain a lot of weight on the shot
- depression
- hair loss or hair gain on face or body
- slight bruising where the shot was given
- very rarely, a small, permanent dent in the skin where the shot was given
- a delay of 9–10 months in being able to get pregnant after stopping the shot

What will happen to my period when I use the shot?

Most women have some change in their periods, including bleeding more days than usual, spotting between periods, or no periods. This is most common during the first year. After 12 months, about half of all women using the shot stop getting their periods. Sometimes, unusual bleeding can be a sign of pregnancy. After stopping the shot, it can take several months for your period to return.

If you get side effects from the shot, there is no way to stop them. They may continue and you may need treatment until the shot wears off.

Risks of the Shot

- **The shot and bone thinning —** Women who use the shot may have temporary bone thinning. It increases the longer they use it. Bone growth begins again when women stop using the shot. It's likely that most women will get all their bone mass back– except older women who have reached menopause. Because the bone thinning is temporary, it is unlikely that it will lead to a greater risk of bone fracture much later in life, but further studies are needed. To protect your bones, stop smoking, limit your alcohol, get regular exercise and get extra calcium, either through your diet or by using calcium and vitamin D supplements.
- Women who use the shot have a slightly greater risk of rare serious problems than women who don't use the shot. Her risks go up if she
  - is older than 35
  - smokes
  - has diabetes (sugar)
  - has high blood pressure
  - has high cholesterol
  - has had a stroke, heart attack, or angina

Women with certain health problems can't use the shot. Talk with your doctor or nurse about your risks and health problems. It will help you to decide if the shot is right for you. You may need special tests or extra visits to the clinic.

If you decide to use the shot for longer than two years, talk to your doctor or nurse about the risks and benefits of continuing.

Warning Signs — Call the clinic right away if you have

- a new lump in your breast
- yellowing of the skin or eyes
- signs of pregnancy
- severe depression
- unusually heavy bleeding from the vagina
- migraine with aura — seeing bright, flashing zigzags, usually before a very bad headache
- pus, pain for many days, or bleeding where you were given the shot

If you decide to take the shot — Read the package insert that comes with it. The information may be different from ours. Let us know if you have questions.

What about other methods of birth control? — There are many other methods of birth control. We will offer you information about them and answer your questions.

Take care of your health — Don't forget to get regular checkups and screening for sexually transmitted infections and cancer.

Use of Hormone Birth Control by Women with Special Conditions

(affiliate name and telephone number)

For Users of the Pill, Patch, or Ring

You have special risk factors that may increase your chance of getting serious problems while using the pill, patch or ring. These special risk factors are

☐ breast mass. If the mass is cancer, using the pill, patch or ring could cause the cancer to spread or make it more difficult to treat. It is very important that you go for the testing we recommended.

☐ diabetes (sugar)

☐ high blood pressure

Diabetes and high blood pressure increase your risk for heart disease. So do

- being 35 or older
- cigarette smoking
- high cholesterol
- having a father or brother with heart disease before age 55 and/or a mother or sister with heart disease before age 65

☐ at least two risk factors for heart disease

☐ blood clot in past

☐ other _____

Be sure you understand the information we have given you. We are happy to answer your questions.

For Users of POPs or the Implant

You have special risk factors that may increase your chance of getting serious problems while using POPs or the implant. These special risk factors are

☐ breast mass. If the mass is cancer, using POPS or the implant could cause the cancer to spread or make it more difficult to treat. It is very important that you go for the testing we recommended.

☐ systemic lupus erythematosus (SLE) and you have antiphospholipid antibodies (or if you don't know) you need to know that

- The hormone in the POPS or the implant could increase your risk of getting serious blood clots which could cause damage to your lungs, your heart, or your brain.

Be sure you understand the information we have given you. We are happy to answer your questions.

For Users of DMPA (Depo Provera, the Shot)

You have special risk factors that may increase your chance of getting serious problems while using DMPA. These special risk factors are

☐ breast mass. If the mass is cancer, using DMPA could cause the cancer to spread or make it more difficult to treat. It is very important that you go for the testing we recommended.

☐ stroke

☐ heart attack or angina

☐ vascular disease

☐ high blood pressure
High blood pressure increases your risk for heart disease. So do

- being age 35 or older
- cigarette smoking
- diabetes (sugar)
- high cholesterol
- having a father or brother with heart disease before age 55 and/or a mother or sister with heart disease before age 65

☐ at least two risk factors for heart disease

☐ osteoporosis (thin bones)

☐ fragility fractures (broken bones because bones are weak)

☐ systemic lupus erythematosus (SLE) and you have antiphospholipid antibodies (or if you don't know) or you have a very low number of platelets (severe thrombocytopenia)

- Using DMPA could increase your risk of getting serious blood clots which could cause damage to your lungs, your heart, or your brain. Or could lead to extra heavy bleeding.

☐ other _____

Be sure you understand the information we have given you. We are happy to answer your questions.

Single Rod Implant

(affiliate name and telephone number)

The implant goes under the skin of your arm. It is a thin, matchstick-sized rod. It is made of plastic and the hormone progestin. It is like the hormone made by a woman's body. This hormone keeps you from getting pregnant.

- It keeps eggs from leaving the ovaries.
- It makes cervical mucus thicker. This keeps sperm from getting to the eggs.

FYI — How is the Implant Put In and Taken Out?

- The implant is put under the skin of your arm by your doctor or nurse. The skin of your upper arm is made numb with a shot of numbing medicine (local anesthesia [an-iss-thea-zha]). Then the rod is placed just under the skin through a needle. It takes a few minutes.
- The best time to have the implant put in is when you are sure you are not pregnant. You may be told to use a backup method of birth control for 7 days after your implant is put in.
- The implant can be taken out any time you want. It must be removed by a doctor or nurse. It takes longer to take out the rod than to put it in. It may be harder to take out the rod than to put it in.

How Well Does the Implant Work?

- For every 100 women who use the implant for a year, only 1 will get pregnant.
- It is good for 3 years.

There's nothing you have to do before sex to make the implant work. Being able to get pregnant comes back quickly after removing the implant.

FYI — Drug Interactions

- The implant may not work quite as well for women who are taking certain other medicines, including herbals like St. John's wort and some that are used for TB, seizures, mental disorders, or HIV/AIDS.
- The implant may affect the other medicines you take. Always tell your doctor or nurse about your medicines.

The implant does not protect you from sexually transmitted infections.

It does protect you from

- pregnancy in the tubes
- bad cramps

What are the Side Effects of the Implant?

You may have

- nausea (feeling sick to your stomach) — usually clears up in 2 or 3 months
- sore breasts — usually clears up in 2 or 3 months
- headache
- irregular bleeding — including early or late periods, spotting between periods, or no periods
- weight gain
- soreness, bruising, or swelling for a few days after the implant is put in

What are the Risks of the Implant?

- You may get
- rarely, arm pain for longer than a few days
- rarely, an infection or pain in the arm that needs medicine
- a scar on your arm where the implant goes in

FYI — What Will Happen to my Period When I'm Using the Implant?
Most women have a change in their periods, including bleeding more days than usual, spotting between periods, bleeding more heavily or lighter, no periods, or more than one of these changes. Your periods may not come on a regular schedule. You may not be able to predict when your bleeding will happen.

Women with certain health problems can't use the implant. Talk with your doctor or nurse about your risks and health problems. It will help you to decide if the implant is right for you. You may need special tests or extra visits to the clinic.

Warning Signs — Call the clinic right away if you have

- pus, bleeding, increased redness, or pain where the implant was inserted
- any concerns about the location of the implant
- yellowing of the skin or eyes
- a new lump in the breast
- signs of pregnancy
- bleeding from the vagina for many, many days

If You Decide to Use the Implant — Read the package insert that comes with it. The information may be different than ours. Let us know if you have questions.

What About Other Methods of Birth Control? — There are many other methods of birth control. We will offer you information about them and answer your questions.

Take Care of your Health — Don't forget to get regular check-ups and screening for sexually transmitted infections and cancer.

Affiliate Name and Address
EMERGENCY TELEPHONE NUMBER XXX-XXX-XXXX

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

Continued Use of IUC Beyond Recommended Removal Date

(affiliate name and telephone number)

The removal date for your IUC is _____. You have decided not to have your IUC removed.

It is possible that your IUC may no longer work for birth control. Keeping your IUC beyond the recommended removal date might cause other problems as well.

Warning Signs — Get medical care right away if you

- cannot find the IUC string
- have signs of pregnancy
- have unusual vaginal bleeding
- have unusual vaginal discharge
- have pain during sex
- have unusual pelvic pain, cramping or soreness in your abdomen
- have been exposed to gonorrhea, chlamydia, or other sexually transmitted infections
- develop unexplained fever or chills
- feel part of the IUC at the cervix

There are many other methods of birth control. We will offer you information about them and answer your questions.

Intrauterine Contraceptives (IUCs)

(affiliate name and telephone number)

IUCs are small, T-shaped pieces of plastic. — They are put into the uterus. There are two types:

- **Copper IUC** has copper.
- **Levonorgestrel IUC (LNG IUC)** has a hormone like the progesterone made by a woman's body.

How does the IUC work? — Both work mainly by affecting the way sperm move so they can't join with an egg. For some women, LNG IUC may prevent the egg from leaving the ovary. This keeps sperm from getting to the eggs. LNG IUC may also thicken a woman's cervical mucus. The mucus blocks sperm and keeps it from joining with an egg.

The Copper IUC can also be used as emergency contraception (EC) when put in within 5 days of unprotected sex.

How well does the IUC work?

For every 100 women who use the IUC, fewer than 1 will get pregnant each year.

Depending on when in your cycle the IUC is inserted, you may need to use a backup method until the IUC begins to work. There's nothing you have to do before sex to make it work. Being able to get pregnant comes back quickly after removing the IUC. The Copper IUC is good for 12 years. LNG IUCs are good for 3 or 5 years depending on which one you choose.

How well does Copper IUC work as EC?

It is the EC that works the best. It reduces the risk of pregnancy by more than 99% when put in within 5 days of unprotected sex.

How is the IUC put in? — We will examine you and put a speculum into your vagina. Your doctor or nurse will hold your cervix with an instrument. The IUC will be put into the opening in your cervix and into the uterus. You may feel cramping. A short length of plastic "string" will hang down into your vagina. You can check the string to make sure that the IUC is still in place.

Before the IUC is put in, you may be offered medicine to help open your cervix. You may also be given medicine to numb the cervix.

Advantages of IUCs

LNG IUC

- fewer menstrual cramps
- lighter periods / less blood loss — often periods stop after a few months
- less anemia (iron poor blood)

Copper IUC

- no hormones
- can be used for emergency contraception

What are the side effects of the IUC? — You may have

- mild to moderate pain when the IUC is put in
- cramping or backache for a few days
- irregular periods or spotting between periods in the first 3 –6 months
- heavier periods and worse menstrual cramps — with Copper IUC

The IUC does not protect you from sexually transmitted infections (STIs).

Risks of using the IUC

Perforation — Very rarely, the IUC could make a hole in your uterus when it is being put in. It could be pushed through the wall of the uterus. This is called perforation. It could damage your internal organs. Surgery is often needed to remove the IUC.

Expulsion — Occasionally, the IUC will slip out of the uterus. This is called expulsion. You can become pregnant if it happens. The IUC must be removed if it comes out part way.

Pregnancy — There is a small chance that you could get pregnant. You should see your doctor or nurse right away if this happens. Your IUC needs to be removed. And we need to make sure you do not have a pregnancy in your tubes. This could lead to serious health problems.

Infection — Your chance of getting a pelvic infection (PID) from an IUC is only increased in the first 3 weeks after the IUC is put in. If you get PID — whether or not you have an IUC — you need to get treatment right away. If PID is not treated, it may be harder to get pregnant in the future.

Women with certain health problems can't use the IUC. Talk to your doctor or nurse about your risks and health problems. Your doctor or nurse will examine you and help you decide if the IUC is right for you. You may need special tests or extra visits to the clinic.

Warning Signs — Call the clinic right away if you

- notice any change in the length of the string or can feel part of the IUC
- have ongoing pain or bleeding with intercourse
- have signs of pregnancy
- have unprotected sex with someone who has an STI
- have unusual pain, cramping, or soreness in your lower belly or stomach
- have unusual vaginal discharge
- have unexplained fever or chills
- have bleeding from the vagina that is heavier than usual
- have trouble breathing

If you decide to get an IUC — Read the package insert that comes with it. The information may be different from ours. Let us know if you have questions.

How is the IUC removed? – Having your IUC taken out or replaced is usually very simple. Your doctor or nurse will do it for you by gently pulling on the IUC strings. Rarely, if the IUC doesn't come out easily, a surgical tool may be needed to take out your IUC. Very rarely, surgery may be needed.

What about other methods of birth control? — There are many other methods of birth control. We will offer you information about them and answer your questions.

What about other methods of EC? — There are EC pills such as levonorgestrel EC (LNG EC) and ulipristal acetate (UPA) that you can use. You can also choose to wait and see if you become pregnant. We are happy to discuss all your options with you.

Take care of your health — Don't forget to get regular checkups and screening for STIs and cancer.

What if I have an emergency?
Call us immediately at XXX-XXX-XXXX, go to the nearest emergency room, or call 911.

Client Signature Date

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature Date

IUC Removal - Missing String

(affiliate name and telephone number)

Your IUC string is missing. It is not visible or within easy grasp at the opening of your cervix. We have done an ultrasound that showed the IUC is still in your uterus. Because your IUC is in place, there is no medical reason to remove it.

You want us to remove your IUC, anyway. You can change your mind at any time about having your IUC taken out — as long as it has not expired.

How will the IUC be removed?

Your doctor or nurse will put a speculum into your vagina. An instrument will be placed into the opening in your cervix and into your uterus. If possible, the instrument will be used to grasp the IUC and pull it out. This removal could lead to

- an infection of the uterus that may make it harder for you to get pregnant in the future
- putting a hole in the wall of the uterus — called perforation (You may need surgery to repair that.)

You will be given referrals for further treatment if needed. You will be responsible for getting and paying for that care. You have been told how to get care in the case of an emergency.

Affiliate Name and Address

EMERGENCY TELEPHONE NUMBER XXX-XXX-XXXX

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

Use of Intrauterine Contraceptives (IUC) by Women with Special Conditions

(affiliate name and telephone number)

You have a condition that can increase the risk of getting a serious problem while using a Paragard, Mirena, or Skyla IUC.

If you have chosen Paragard and you have

- systemic lupus erythematosus (SLE) and you have a very low number of platelets (severe thrombocytopenia), you need to know that
  - Using a Paragard with this condition could lead to extra heavy bleeding.

If you have chosen Mirena or Skyla and you have

- systemic lupus erythematosus (SLE) and you have antiphospholipid antibodies (or if you don't know), you need to know that
  - The hormone in Mirena and Skyla could increase your risk of getting serious blood clots which could cause damage to your lungs, your heart, or your brain.
- an undiagnosed breast mass, you need to know that
  - If the mass is cancer, using Mirena or Skyla could cause the cancer to spread or make it more difficult to treat. It is very important that you go for the testing we recommended.

Be sure you understand the information we have given you. We are happy to answer your questions.

The Pill — Birth Control Pills / The Patch / The Ring

(affiliate name and telephone number)

What are the pill, the patch, and the ring?

These are birth control methods made of the hormones **estrogen** and **progestin**. They are like hormones made by a woman's body. They keep you from getting pregnant in 2 ways:

- They keep eggs from leaving the ovaries.
- They make cervical mucus thicker. This keeps sperm from getting to the eggs.

How well do they work?

- For every 100 women who use the pill, patch or ring perfectly for a year, only 1 will get pregnant.
- Women who don't use the pill, patch, or ring perfectly don't get the best results. This includes women who forget to take the pill every day, or change their patch every week, or change their ring every month. About 9 out of 100 will get pregnant in a year.

What are the benefits of the pill, patch, and ring?

There's nothing you have to do before sex to make these methods work. Being able to get pregnant comes back quickly after stopping.

These methods can protect you from

- Acne
- Bone thinning
- Cancer of the ovaries
- Cancer of the uterus
- Cysts in the breasts and ovaries
- Bad cramps
- Heavy periods
- Serious infection in the ovaries, tubes, and uterus
- Irregular periods
- Anemia (Iron poor blood)
- Pregnancy in the tubes
- PMS

What are the side effects?

You may have headaches or symptoms that usually clear up in 2 or 3 months. These include

- nausea (feeling sick to your stomach)
- sore breasts
- spotting between periods

Also

- Some women using the patch notice sore skin where the patch goes on.
- Some women using the ring notice more vaginal wetness.

If You use pills — Some women take a hormone pill every day to keep from getting their periods. It is normal for them to have spotting or bleeding the first 6 months between periods. It may get less over time. Some stop having any bleeding at all. This is normal and will not harm your body. But it's a good idea to get tested if you think you might be pregnant.

If you use the ring — Many women have spotting between periods the first 2 or 3 months on the ring. This usually stops. Some women use the ring every day without a ring-free break to keep from getting their periods. It is normal for them to have spotting or bleeding the first 6 months. It may get less over time. Some stop having any bleeding at all. This is normal and will not harm your body. But it's a good idea to get tested if you think you might be pregnant.

What are my other choices?
There are many other methods of birth control. We will offer you information about them and answer your questions.

Can I use the pill, patch or ring?
Women with certain health problems can't use the pill, patch, or ring. Talk with your doctor or nurse about your risks and health problems. It will help you to decide if the pill is right for you. You may need special tests or extra visits to the clinic.

What are the risks of the pill, patch, or ring?
Women on the pill, patch, or ring have a slightly higher risk of rare serious problems than women who are not. Death occurs in very rare cases. The problems are

- Blood clots that start in the legs and go to the lungs
- Heart attack
- Liver tumors
- Stroke

Serious problems are more likely from being pregnant than they are from using the pill, patch, or ring. The more a woman is at risk for heart disease and stroke, the greater her chances of having certain serious health problems with these methods. Her risks go up if she

- is older than 35
- smokes
- has diabetes (sugar)
- has a family history of blood clots
- has high blood pressure
- has high cholesterol
- is very overweight

Some studies show that women who use the patch have a higher risk of blood clots in the legs than women who use the ring or certain birth control pills. Other studies do not.

Warning signs of these very rare serious problems include

- sudden back/jaw pain along with nausea, sweating or trouble breathing
- chest pain or discomfort
- achy soreness in the leg
- trouble breathing
- severe pain in the belly or stomach

Call the clinic if you experience any of the warning signs listed or get any of the following:

- a sudden very bad headache
- headaches that are different, worse, or happen more often than usual
- aura – seeing bright, flashing zigzags, usually before a very bad headache
- yellowing of the skin or eyes
- a new lump in the breast
- signs of pregnancy

Once you choose a method — Read the package insert that comes with it. The information may be different than ours. Let us know if you have questions.

How do I use the pill, patch, and ring?

- **Pill** — You take 1 each day.
- **Patch** — You put 1 patch on every week for 3 weeks in a row. Then there is a patch-free week.
- **Ring** – You put the ring in your vagina. You will have choices about when to put it in and take it out. Your doctor or nurse will help you decide which way is best for you. See the instructions we give you.

What else do I need to know?

All of these methods

- may not work quite as well for women who are taking certain other medicines, including herbals like St. John's wort and some that are used for TB, seizures, mental disorders, or HIV/AIDS
- may affect other medicines you take. Always tell your doctor or nurse about your medicines
- protect against pregnancy, but do not protect you from sexually transmitted infections (STIs). Always use a condom for protection against infection.

The pill and the patch may not work quite as well for women who are overweight.

Take care of your health — Don't forget to get regular checkups and screening for STIs and cancer.

(affiliate name and telephone number)

The POP is made of the hormone **progestin**. It is like the hormone made by a woman's body. This hormone keeps you from getting pregnant:

- It keeps eggs from leaving the ovaries.
- It makes cervical mucus thicker. This keeps sperm from getting to the eggs.

How do I take POPs?

Take 1 progestin only pill each day. All pills in the pack have hormones. Start a new pack the day after you finish the old pack. There are no "off" days.

Take your POP at the same time each day. If you take your pill more than 3 hours late, use a back-up birth control — like a latex condom and/or spermicide — for 48 hours.

How well do POPs work?

- For every 100 women who take the progestin pill every day for a year, only 1 will get pregnant.
- For every 100 women who do not take the progestin pill every day for a year, about 9 will get pregnant.

There's nothing you have to do before sex to make POPs work. Being able to get pregnant comes back quickly after stopping POPs.

POPs may not work quite as well for women who are taking certain other medicines including herbals like St. John's wort and some that are used for TB, seizures, mental disorders, or HIV/AIDS.

POPs may affect the other medicines you take. Always tell your health care provider about your medicines.

POPs do not protect you from sexually transmitted infections. — They **do** protect you from

- pregnancy in the tubes
- bad cramps
- heavy periods

What are the side effects of POPs? — You may have

- nausea (feeling sick to your stomach) — usually clears up in 2 or 3 months
- sore breasts — usually clears up in 2 or 3 months
- headaches
- irregular bleeding — including early or late periods, spotting between periods or no periods

Women with certain health problems can't use POPs. Talk with your doctor or nurse about your risks and health problems. It will help you decide if POPs is right for you. You may need special tests or extra visits to the clinic.

Warning Signs — Call the clinic right away if you have

- yellowing of the skin or eyes
- a new lump in the breast
- signs of pregnancy
- bleeding

If you decide to take POPs — Read the package insert that comes with your pack. The information may be different from ours. Let us know if you have questions.

What about other methods of birth control? — There are many other methods of birth control. We will offer you information about them and answer your questions.

Take care of your health. — Don't forget to get regular check-ups and screening for sexually transmitted infections and cancer.

Preparing Your Cervix With Misoprostol

(affiliate name and telephone number)

What is misoprostol?

Misoprostol is a kind of hormone called a prostaglandin. Its brand name is Cytotec. It is used before some procedures to help open the cervix and make them easier to do. Some of the procedures are

- putting in an IUC
- taking a uterine biopsy
- doing hysteroscopy

How do I take the misoprostol?

There are several ways. It can be swallowed, put under the tongue, inside the cheek, or in the vagina.

Your nurse or doctor will tell you how to take it. You may also be told to take ibuprofen (Advil) or acetaminophen (Tylenol).

[Affiliates may add specific regimen / instructions here.]

What are the benefits?

It can make it easier to perform the procedure.

What are the risks?

Very rarely, a woman may be allergic to misoprostol.

What are the side effects?

Possible side effects include

- nausea and vomiting
- fever, hot flushes, or chills
- diarrhea
- headache

What if I don't want the misoprostol?

You can have your procedure without using misoprostol. If your cervix is too tight to put in an IUC, the doctor or nurse can try using dilators to help open your cervix.

Misoprostol may cause birth defects or miscarriage. It must not be used if you are pregnant or think that you may be pregnant.

Taking Out The Implant

(affiliate name and telephone number)

To remove the implant from your arm, medicine will be put in the skin to numb the area. A tiny cut will be made in the skin, and the implant will be removed through it.

It can be harder to take out than to put in. You may get a scar.

Rarely, a woman will have arm pain that continues after the implant is removed. Rarely, you may need medicine for pain or infection. Very rarely, the implant may break into pieces while it is being taken out. This would make taking it out more difficult.

A new implant can be put in right after taking out the old one. Let your doctor or nurse know if you would like to have another one put in.

It is important that you understand this information. We will be happy to answer any questions you have.

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

Most Effective

Less than 1 pregnancy per 100 women in a year

2-12 pregnancies per 100 women in a year

18 or more pregnancies per 100 women in a year

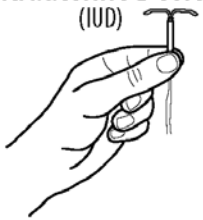
Least Effective

Reversible

Implant

0.05 %*

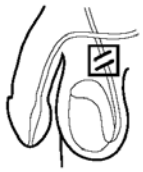
Intrauterine Device (IUD)



LNG - 0.2 % Copper T - 0.8 %

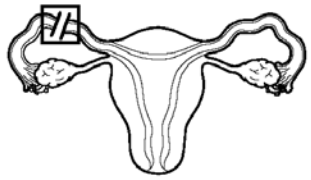
Permanent

Male Sterilization (Vasectomy)



0.15 %

Female Sterilization (Abdominal, Laparoscopic, Hysteroscopic)

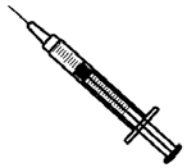


0.5 %

LAM (Breast feeding)

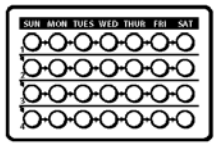
2 %

Shot



6 %

Pill



9 %

Patch

9 %

Ring

9 %

Diaphragm

12 %

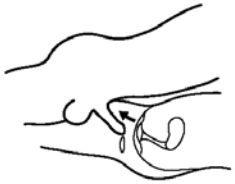
Male Condom

18 %

Female Condom

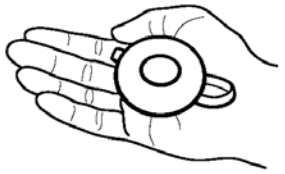
21 %

Withdrawal



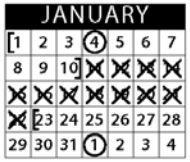
22 %

Sponge



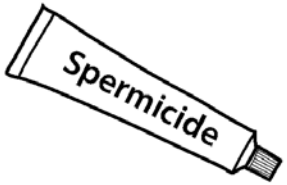
24 % if given birth
12 % if never given birth

Fertility-Awareness Based Methods



24 %

Spermicide



28 %

Cervical Cap

29 % if given birth
14% if never given birth

* The percentages indicate the number out of every 100 women who experienced an unintended pregnancy **within the first year of** typical use of each contraceptive method.

How to make your birth control most effective

After procedure, little or nothing to do or remember.

Vasectomy and hysteroscopic sterilization: Use another method for **first 3 months.**

LAM (for 6 months) breast feed often, day and night.

Shot: Get repeat shots on time.

Pills: Take a pill each day.

Patch, Ring: Keep in place, change on time.

Diaphragm: Use correctly every time you have sex.

Condoms, sponge, withdrawl spermicides, cervical cap: Use correctly every time you have sex.

Fertility awareness-based methods: Abstain or use condoms on fertile days. Newest methods (Standard Days Method and TwoDay Method) may be the easiest to use and consequently more **effective.**

(Adapted from the CDC 2014)

Emergency Contraception (EC)

(affiliate name and telephone number)

What is EC?

Emergency contraception can prevent pregnancy after unprotected sex. It is also known as emergency birth control, backup birth control or the morning-after pill. EC should be used as soon as possible up to 5 days after unprotected sex.

There are two types of EC:

- Copper Intrauterine Contraceptive (Copper IUC) – a small, T-shaped piece of plastic containing copper that is put into the uterus. The Copper IUC can also be used for continued birth control.
- EC pills – one type of EC pill is made of ulipristal acetate (UPA). Another type of EC pill is made of one of the hormones made by a woman's body – progestin (Progestin EC).

How well does EC work?

The Copper IUC is the most effective method – it reduces the risk of pregnancy by more than 99 percent if it's put in within 5 days of unprotected sex.

UPA reduces the risk of pregnancy up to 85 percent and works just as well on any day you take it up to 5 days after unprotected sex. But if you are very overweight, it may not work at all.

Progestin EC reduces the risk of pregnancy by 75-89 percent if you take it within the first 3 days after sex. It is less effective the more time that passes and may not work 4 or 5 days after sex. Also, if you are overweight, it may not work as well. If you are very overweight, it won't work at all.

How does EC work?

The Copper IUC works mainly by affecting the way sperm move so they can't join with an egg.

Both types of EC pills work by keeping a woman's ovaries from releasing eggs (ovulation).

Pregnancy cannot happen if egg and sperm don't meet.

When should I use EC?

Take it as soon as possible. Use EC every time you have unprotected sex.

You can ask for EC when you need it, or you can get EC pills before. Getting it before will let you take it as soon as possible if you ever need it.

How do I decide which type of EC is best for me?

Some things to think about are

- whether you want the most effective EC – the Copper IUC is best if you also want a highly effective method of birth control – the Copper IUC may be left in place to use for birth control for up to 12 years
- when you had unprotected sex
  - the Copper IUC is best and can work for up to 5 days after unprotected sex UPA is the next best and can work for up to 5 days
  - Progestin EC will work best in the first 3 days

(continued on next page)

- your weight
  - the Copper IUC is the best choice no matter how much you weigh
  - UPA is the next best option if you are overweight
- if you are breastfeeding
  - the Copper IUC and Progestin EC are safe
  - use UPA only if you are willing to pump and throw away your milk for 36 hours

What are the side effects of EC pills?
Possible side effects go away quickly. They include

- dizziness, headaches, breast tenderness
- nausea
- belly pain or period cramps
- bleeding between periods

EC pills can affect your next period. It could be early or late, lighter or heavier, or shorter or longer. Or it could be the same as usual.

EC pills will not end a pregnancy. Don't use it if you are already pregnant. If you're not sure, you may want to have a pregnancy test but even if you are pregnant, or if you become pregnant after taking EC pills, there is no proof that it will harm the pregnancy.

What are my other choices?
You can choose to wait and see if you become pregnant. We are happy to discuss all your options with you.

We are happy to talk with you about your birth control choices if you do not want to become pregnant right now.

If you decide to take EC pills — Read the package insert that comes with your pill(s). The information may be different from ours. Let us know if you have questions.

Instructions for using EC pills
[INSERT APPROPRIATE EC REGIMEN(S) HERE.]

Some women feel sick to their stomachs after taking EC pills. If you are concerned about that

- do not take the pills on an empty stomach
- take over-the-counter nausea medicine about an hour before the EC pills

Call the health center if you

- have questions
- think you have a problem or that you might be pregnant
- miss your period

Hot Flashes

What are hot flashes?
Most women describe a hot flash as a sudden hot feeling that spreads all over the body. You may feel sweaty as well. It is more common on the upper body (arms and chest) and face. It usually lasts from 1 to 5 minutes.

Will I always have hot flashes?
No. Most women have hot flashes for 6 months to 2 years. Rarely, some women may have them for 10 years or longer.

What can I do to make hot flashes better?
While nothing will "cure" hot flashes, there are some things you can do to feel better.

The following are some changes you can make in your everyday life:

- Keep your body as cool as possible – dress in layers of natural fabrics that breathe, use a fan, and sleep in a cool room.
- Maintain a healthy weight.
- Don't smoke.
- Exercise regularly.
- Reduce stress.

There are also herbal medicines you can get without a prescription. They include

- isoflavones such as soy and red clover
- black cohosh
- dong quai
- ginseng
- evening primrose oil

Of the herbal medicines listed, isoflavones and black cohosh are the only two that are likely to help. All of the herbal medicines listed have side effects and risks — just like other medicines you get with a prescription. Be sure to tell your doctor or nurse if you are taking any herbal medicines, and make sure you understand the side effects and risks.

Are there prescription medicines I can take to help hot flashes?
Menopausal Hormone Therapy (MHT) is the most effective therapy for hot flashes. Some women can't use hormones or don't want to use them. Some medicines commonly used to treat depression, sleeping problems and seizures have also been found to help treat hot flashes.

Your doctor or nurse can talk to you more about these medicines and their risks and benefits.

Menopause and Perimenopause

What is Menopause?
Menopause is the point when your periods stop forever. Your ovaries stop making the hormones estrogen and progesterone and you cannot get pregnant. It usually happens on its own around age 51, but it can be sooner or later. Menopause can also happen because of certain surgeries, such as hysterectomy (removal of the uterus and ovaries), medical conditions, or medicines.

What is perimenopause?
Perimenopause is the time leading up to menopause when you can still get pregnant. Most women start perimenopause in their 40s, but it can start earlier.

You can get pregnant during perimenopause even if your periods are not regular. If you want to avoid pregnancy, you need to use birth control for at least 1 year after your last period. Talk to your doctor or nurse about the methods that would be best for you.

How do I know if I'm in menopause?
The only way to know that you have gone through menopause is if you have not had your period for 1 year. If you have any of the symptoms below, talk to your doctor or nurse. You can figure things out by reviewing your health history and any symptoms together.

What are the symptoms?
- **Changes to your period** – You may start to skip periods, or they may become lighter. They may also become heavier, or last longer. While these changes can be normal, talk to your doctor or nurse about any bleeding that is abnormal for you.
- **Other changes –** You may have one, some, or none of the following symptoms:
  - hot flashes – sudden or gradual waves of body heat that last from 30 seconds to 5 minutes
  - trouble sleeping
  - night sweats
  - bladder infections
  - leaking urine or frequent urination
  - mood swings
  - changes that may affect your sex life such as vaginal dryness, pain with sex, or change in sex drive

Symptoms are temporary and may last 3 to 5 years. Some women have symptoms for 10 to 12 years.

Are there treatments for my symptoms?
Hormone therapy (MHT) can help with some symptoms of menopause, such as hot flashes, vaginal dryness, or sleep problems. It can be given in different forms – pills, patches, rings, or creams.

There are other medicines that may help. Ask your doctor or nurse about the treatment(s) that may be right for you.

Some women choose alternative treatments to relieve menopause symptoms, such as homeopathy, herbs, Chinese medicine, and acupuncture. While research has not proven their effectiveness or safety, some women may find them helpful. Talk to your doctor or nurse about any herbal or OTC products that you are thinking about trying.

(continued on next page)

For symptoms that affect your sex life, trying one or more of the following may help:

- Use a water-based lubricant.
- Have sex more often. This can increase blood flow to your vagina and keep tissues healthy.
- Give your body time to get aroused. Moisture from being aroused protects tissues.
- Talk with your partner about your feelings. They may have similar concerns.
- Practice pelvic floor exercises. This can make the muscles used in orgasm stronger, and can help with leaking urine. Ask your doctor or nurse about how to do these exercises.
- Prescription hormone medicines such as estrogen creams, tablets, or rings may improve dryness.

Sexually transmitted infections (STIs) are still a risk if you have a new sex partner or high-risk sexual activities. Use condoms and get tested, just as you would at any age.

Menopause and bone health

Bones become weaker after menopause. Osteoporosis happens when you lose too much bone and this increases your risk of broken bones. There are things you can do to prevent osteoporosis:

- Get enough calcium and vitamin D.
- Exercise. Do weight-bearing exercise (walking, jogging, dancing) and strength-training exercise for at least 30 minutes most days of the week.
- Talk to your doctor or nurse about your medical and family history, and if testing for bone loss is right for you.

Emotional changes in menopause

The hormone changes can make you feel anxious, irritable or tired. Some of the symptoms of menopause – like sleep changes – can make these feelings worse.

This may also be a time of major life changes - stress at work or in relationships, “empty nest” syndrome as adult children leave home, the need to take care of aging parents or partners.

If you find it hard to manage, talk to your doctor or nurse about treatment and resources.

What else do I need to know?

You may need to meet with your doctor or nurse more regularly. Breast exams and mammograms are recommended yearly beginning at age 40. For most women, testing for cervical cancer should continue every 3 to 5 years until the age of 65. It’s also important to regularly check your blood pressure and cholesterol, test for diabetes and colon cancer, and stay up-to-date on your vaccinations.

Ask your doctor or nurse about vaccinations and screenings that you may need to stay healthy.

Problems Sleeping

Almost half of women in their 40s and 50s have problems sleeping. Not sleeping enough can put you at higher risk for accidents at home and at work, and has been linked to some medical problems. If you are having trouble sleeping, there are things you can do to help.

How much sleep do I need?
Most adults need between 6 and 9 hours of sleep every night.

What can I do to sleep better?
There are many things that you can do to sleep better. We have listed some of them here:

- Avoid caffeine, alcohol, and smoking close to your bedtime.
- Try not to eat a big meal before bed. A small snack of a protein and carbohydrate — like peanut butter on a cracker — may help you to fall asleep.
- Exercise regularly, but don't exercise close to your bedtime.
- Don't do anything in bed but sleep and have sex.
- Keep your bedroom cool and dark.
- If you don't fall asleep within 10 to 15 minutes after you lie down, get up and leave your bedroom until you are sleepy.
- Wake up and go to sleep at the same time every day.
- Try relaxation techniques like meditation, yoga and tai chi

There are also herbal medicines and medicines you can get without a prescription.
Valerian is an herbal medicine that may help:

- Valerian extract comes as a capsule or liquid. You should take 50-100 milligrams 2-3 times a day.
- Valerian root also comes as a capsule or liquid. You should take 2,000-4,000 milligrams every day.
- It may take 5-7 days for valerian to work, and it can be used for a short time with few side effects.
- Do not take it for more than 3 months. You may get headaches, feel restless, or be unable to sleep. Using it for a long time may be connected to heart problems, too.

There are many sleeping pills available over the counter, like Unisom or Sominex. If you use these medicines, be sure you read the package carefully so you understand how to take them and the side effects and risks.

Are there prescription medicines I can take to help?
There are many prescription medicines that can help you to sleep better. Your doctor or nurse can talk to you more about these medicines and their risks and benefits.

Endometrial Biopsy

(affiliate name and telephone number)

What is an endometrial biopsy?
It is a way to take a small sample of the lining of the uterus. The lining is called the endometrium.

How is it done?
We can do it here, in the clinic. You will lie in the same position as you would for a Pap test. A speculum will be put into your vagina. The doctor or nurse gently inserts a thin instrument through the cervix into the uterus. It takes a sample of tissue. The sample is sent to a laboratory. A doctor looks at it under a microscope. The results are sent to us.

What will it feel like?
Some women feel discomfort when the clinician puts in the speculum. Most women will feel brief cramping during the biopsy. It may be mild or severe. Sometimes women feel dizzy or faint. There may be a little spotting afterward.

What is the biopsy for?
We may recommend it for three reasons:

- It can help us understand why there's abnormal bleeding from the uterus.
- It can tell us if you have abnormal or pre-cancerous cells growing in your uterus.
- It can tell us if ovulation has occurred.

What are the benefits?
It may tell us what treatment or tests you may need.

What are the risks?
It is unusual for women to have any serious problems. If they occur, they may include

- heavy bleeding
- infection
- perforation of the uterus that damages organs in the abdomen
- disruption of an early, undiagnosed pregnancy

Call the clinic right away if you have these warning signs:

- lower abdominal tenderness or pain
- severe cramping
- fever (temperature of 100.4ºF or higher)
- heavy bleeding

What are other choices?
There are two other ways to evaluate the endometrium.

- One is dilation and curettage (D&C). In a D&C, the cervix is stretched open and a metal loop is used to gently scrape tissue from the lining of the uterus.
- The other is hysteroscopy. The clinician inserts a long, thin tool through the cervix into the uterus to see inside it.

No treatment or testing is also an option. Let us know if you would like more information about these choices.

It's important that you understand the risks, benefits, side effects, and warning signs of endometrial biopsy. We are happy to answer any questions you have.

Affiliate Name and Address

EMERGENCY TELEPHONE NUMBER XXX-XXX-XXXX

Client Signature Date

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature Date

Menopausal Hormone Therapy

(affiliate name and telephone number)

What is menopause?

When a woman has had no period for a year, menopause has occurred. This usually happens around age 51, but it can be sooner or later. In the time leading up to menopause, your periods may change. They can be lighter or heavier, or they may not come every month.

Changes in your periods may be the only changes you notice. Other symptoms of menopause can include:

- Vaginal dryness
- Hot flashes
- Problems sleeping
- Mood changes — feeling anxious, feeling down or depressed, or feeling irritable
- Low libido — not feeling like you want to have sex

If these symptoms are not bothersome to you, then no treatment is needed. If they are, there are choices. The treatment that works the best is called Menopausal Hormone Therapy or MHT.

What is Menopausal Hormone Therapy (MHT)?

Menopausal Hormone Therapy (MHT) is made of two hormones — estrogen and progesterone — that are like the hormones a woman's body makes before menopause.
MHT has risks and benefits, just like all medications.

Women who have had surgery to remove their uterus or womb, called a *hysterectomy* (hiss-tuh-reck-tuh-me), only need to take one hormone — estrogen. This is called ET.

If you need birth control and also have hot flashes, combined hormonal birth control, like the Pill, Patch or Ring, may be the best choice for you, as long as you don't smoke or have certain health problems.

What are the benefits of MHT?

- It helps with hot flashes.
- It helps with vaginal dryness.
- It lowers the risk of osteoporosis (thin bones).
- It reduces the risk of urinary tract infections (UTIs).
- It reduces the risk of incontinence (unable to control urine/water).
- It reduces the risk of diabetes (sugar).

What are the side effects?

- Breast tenderness
- Nausea
- Water retention — bloating
- Headaches
- Irregular vaginal bleeding

Side effects are usually minor and don't need to be treated. They often go away on their own in a few months.

What are the risks of MHT?

- Blood clots, if it is taken by mouth — This is especially true for women with other risk factors like smoking and lack of exercise.

- Invasive breast cancer if MHT is used for more than 10-15 years
- Heart disease if MHT is started in your 60s, combined with high blood pressure, smoking, high cholesterol, and lack of exercise

What are the risks of ET?

- Uterine cancer for a woman with a uterus. Women with a uterus should take MHT.
- Blood clots if ET is taken by mouth — This is especially true for women with other risk factors like smoking and lack of exercise.
- Possible worsened heart disease if started in your 60s, combined with high blood pressure, smoking, high cholesterol, and lack of exercise
- Possible breast cancer — if used more than 5-10 years. Risk is less than for women taking MHT.
- Possible ovarian cancer — the longer it's taken, the higher the chance

What are the warning signs — Go to an emergency room right away if you have:

- Sharp pain in the lower leg
- Difficulty breathing
- Sudden back/jaw pain along with nausea, sweating, or trouble breathing
- Chest pain or discomfort

Call the clinic as soon as possible if you have:

- A new or bigger lump in the breast
- Bleeding from the vagina that is not expected

What are the other choices?

You may choose not to take MHT. Depending on your symptoms, changes to your lifestyle or other medicines may help. Talk to your doctor or nurse if you want to know more.

If you choose MHT, be sure to visit the clinic for regular checkups to make sure the treatment is working well for you. Come back sooner or call to talk with your doctor or nurse if you have problems or questions. Your health is important to us. We are happy to answer your questions.

Treatment of Bartholin's Duct Cyst Or Abscess

(affiliate name and telephone number)

You have a Bartholin's duct cyst. Before we treat you, you need to know some information about the condition and the options for treatment. You also need to know the possible benefits and risks of each type of treatment. We have listed these for you. We are happy to answer your questions.

What is a Bartholin's duct cyst?

You have two Bartholin's glands. There is one in each of your inner labia. They are on each side of the opening to the vagina. They are about the size of a pea. They make the fluid that lubricates the vagina during sex play. Each one has a tiny tube called a duct. It carries fluid from the gland to the vagina. Sometimes a duct gets blocked, the fluid backs up, and the gland swells up. This is called a cyst.

What are the symptoms?

There may be a round swelling in one of your labia. It can grow to the size of a golf ball. It may not be tender, but it can become very painful if it gets infected. Walking may become uncomfortable if that happens.

An infected cyst is also called an abscess. It's usually caused by normal bacteria that live on the skin or in the vagina. Sometimes the infection is caused by a sexually transmitted bacteria that needs to be treated. We'll test you to make sure.

Treatment

There are several treatments. Your clinician will help you decide which method is best for you based on the size of the cyst, how much pain you're having, and if it is infected.

Incision and Drainage (I&D)

This is a quick way to treat a Bartholin's cyst. We inject a small amount of numbing medicine into the area. We make a small cut into the cyst. It lets the fluid drain out. Sometimes, we need to put gauze packing into the opening. This is easy to do, but the cyst often builds up again.

Word Catheter

Word catheters are small rubber tubes. Using one can improve the success rate of I&D. The catheter is placed into the cyst after the I&D. You leave it in place for at least four weeks. This lets the fluid drain out and a new duct to form. You may notice the end of the tube that sticks out. If it bothers you, gently push it inside your vagina. You may be asked to soak in a warm tub (sitz bath) or apply warm compresses each day until your next office visit. Using a catheter is more effective than only doing I&D, but sometimes a cyst forms again after the catheter is removed. Then it has to be treated again. Sometimes the catheter falls out too soon. Then it has to be replaced.

Don't have vaginal intercourse until the catheter is removed. If you do, it can be knocked out of place. Use a panty-liner or mini-pad to keep drainage from staining your clothing.

Marsupialization

Marsupialization is another way to make a new duct to drain the cyst. It is a minor surgical procedure. It is often done in a surgical center, but it can be done in some clinics. A numbing medicine is injected into the area, or you are given a general anesthesia to make you sleep. A cut is made through the skin and the wall of the cyst. The new duct is made by stitching the edges of the cuts together. Gauze packing may be placed into the cyst. It is usually removed in a few days. Marsupialization is very effective, but sometimes a new duct closes up and a cyst forms again.

Use a panty-liner or mini-pad to keep drainage from staining your clothing. Most women have mild discomfort for a few days after marsupialization. Take ibuprofen (Advil®, Motrin®, Aleve®), acetaminophen (Tylenol®), or whatever prescription medication your clinician prescribes. You may be asked to soak in a warm tub (sitz baths) or to apply warm compresses every day, until your next office visit. You may start having vaginal intercourse when you feel comfortable again.

Alternative Treatments

Sometimes, treatment isn't necessary — the clinician will simply check the cyst regularly to make sure it's not growing. Other times, a woman will be asked to soak the area in the shower, a tub of water (sitz bath), or with a warm, moist towel to see if it will drain on its own. You may also be given antibiotics.

How can I keep from getting another Bartholin's Gland Cyst?

No treatment is 100 percent effective. A cyst or abscess may come back even after using a Word catheter or marsupialization. If it does come back, it can be treated again. It's best to return for care as soon as you think the cyst has returned.

Warning Signs — Call the health center if you have any questions or any unusual or unexpected symptoms, such as

- fever — a temperature of 100.4ºF or higher — that lasts more than four hours
- a swelling that increases or does not go down in three days
- redness or swelling that spreads beyond the immediate area of the cyst
- pain that is not relieved by acetaminophen or ibuprofen

Affiliate name and address

EMERGENCY TELEPHONE NUMBER XXX-XXX-XXXX

Client Signature Date

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature Date

SUMMARY OF THE 2010 CDC SEXUALLY TRANSMITTED DISEASES (STD) TREATMENT GUIDELINES

Planned Parenthood Federation of America

These guidelines reflect the recommendations of the 2010 CDC STD Treatment Guidelines and serve as a quick reference. Refer to the complete document from the CDC for more information or consult the STD Program. These guidelines are for HIV-negative clients only. Treatment regimens may vary for clients with HIV. Please refer to the 2010 CDC STD treatment guidelines. **(Updated September 2012)**

DISEASE	RECOMMENDED TREATMENT	ALTERNATIVES (to be used when client has medical contraindications to the recommended treatment or recommended treatment not available)
SYPHILIS (see 2010 CDC guidelines for follow-up recommendations and management of tertiary, neuro, or congenital syphilis)		
PRIMARY (1º), SECONDARY (2º) OR EARLY LATENT (<1 YEAR) Adults --- Children	• Benzathine penicillin G 2.4 million units IM in a single dose --- • Benzathine penicillin G 50,000 units/kg IM, up to the adult dose of 2.4 million units, in a single dose	• Doxycycline 100 mg orally 2 times a day for 14 days ***OR*** • Tetracycline 500 mg orally 4 times a day for 14 days ***OR*** • Ceftriaxone 1 g daily IV or IM for 10-14 days[1] ***OR*** • Azithromycin 2 g orally in a single dose[2] ---
LATE LATENT (>1 YEAR) OR LATENT OF UNKNOWN DURATION Adults --- Children	• Benzathine penicillin G 2.4 million units IM for 3 doses, 1 week apart (total 7.2 million units) --- • Benzathine penicillin G 50,000 units/kg IM up to the adult dose of 2.4 million units, administered as three doses at 1 week intervals (total 150,000 units/kg up to the adult total of 7.2 million units)	• Doxycycline 100 mg orally 2 times a day for 28 days ***OR*** • Tetracycline 500 mg orally 4 times a day for 28 days ---
PREGNANCY	Penicillin is the only recommended treatment for syphilis during pregnancy. Women who are allergic should be desensitized and then treated with penicillin. Dosages are the same as in non-pregnant patients for each stage of syphilis.	
GONOCOCCAL INFECTIONS (see 2010 CDC guidelines for management of conjunctival infection, disseminated gonorrhea, and gonococcal infections among infants)		
ADULTS OR CHILDREN >45kg Cervix, Urethra, Rectum	• Ceftriaxone 250 mg IM in a single dose ***PLUS, REGARDLESS OF CHLAMYDIA DIAGNOSIS*** • Azithromycin 1 g orally in a single dose ***OR*** • Doxycycline 100 mg 2 times a day for 7 days	If ceftriaxone is not available: •Cefixime 400 mg orally in a single dose ***PLUS, REGARDLESS OF CHLAMYDIA DIAGNOSIS*** • Azithromycin 1 g orally in a single dose ***OR*** • Doxycycline 100 mg orally 2 times a day for 7 days ***PLUS*** • Test of cure in 1 week[4] If client has severe cephalosporin allergy: • Azithromycin 2 g orally in a single dose[3] ***PLUS*** • Test of cure in 1 week[4]
--- PHARYNX	--- • Ceftriaxone 250 mg IM in a single dose ***PLUS, REGARDLESS OF CHLAMYDIA DIAGNOSIS*** • Azithromycin 1 g orally in a single dose ***OR*** • Doxycycline 100 mg orally 2 times a day for 7 days	--- • Azithromycin 2 g orally in a single dose[3]
CHILDREN (≤45KG) vagina, cervix, urethra, pharynx, rectum	• Ceftriaxone 125 mg IM once	
PREGNANCY	• Ceftriaxone 250 mg IM in a single dose ***PLUS, REGARDLESS OF CHLAMYDIA DIAGNOSIS*** • Azithromycin 1 g orally in a single dose	If ceftriaxone is not available: •Cefixime 400 mg orally in a single dose ***PLUS, REGARDLESS OF CHLAMYDIA DIAGNOSIS*** • Azithromycin 1g orally in a single dose ***OR*** • Amoxicillin 500 mg orally 3 times a day for 7 days ***PLUS*** • Test of cure in 1 week[4] If client has severe cephalosporin allergy: • Azithromycin 2 g orally in a single dose[3] ***PLUS*** • Test of cure in 1 week[4]
CHLAMYDIAL INFECTIONS		
ADULTS	• Azithromycin 1 g orally single dose ***OR*** • Doxycycline 100 mg orally 2 times a day for 7 days	• Erythromycin base 500 mg orally 4 times a day for 7 days ***OR*** • Erythromycin ethylsuccinate 800 mg orally 4 times a day for 7 days ***OR*** • Ofloxacin 300 mg orally 2 times a day for 7 days ***OR*** • Levofloxacin 500 mg orally once a day for 7 days
CHILDREN <45 KG ----------→ ≥45 KG and <8 years of age ----------→ ≥ 8 years of age ----------→	• Erythromycin base or ethylsuccinate 50 mg/kg/day orally divided into 4 doses daily for 14 days[5] • Azithromycin 1 g orally single dose • Azithromycin 1 g orally single dose ***OR*** • Doxycycline 100 mg orally 2 times a day for 7 days	
PREGNANCY	• Azithromycin 1 g orally single dose ***OR*** • Amoxicillin 500 mg orally 3 times a day for 7 days	• Erythromycin base 500 mg orally 4 times a day for 7 days ***OR*** • Erythromycin base 250 mg orally 4 times a day for 14 days ***OR*** • Erythromycin ethylsuccinate 800 mg orally 4 times a day for 7 days ***OR*** • Erythromycin ethylsuccinate 400 mg 4 times a day for 14 days
NONGONOCOCCAL URETHRITIS	• Azithromycin 1 g orally single dose ***OR*** • Doxycycline 100 mg orally 2 times a day for 7 days	• Erythromycin base 500 mg orally 4 times a day for 7 days ***OR*** • Erythromycin ethylsuccinate 800 mg orally 4 times a day for 7 days ***OR*** • Ofloxacin 300 mg orally 2 times a day for 7 days ***OR*** • Levofloxacin 500 mg orally once a day for 7 days
EPIDIDYMITIS[6]	• Ceftriaxone 250 mg IM single dose ***PLUS*** • Doxycycline 100 mg orally 2 times a day for 10 days	• Ofloxacin 300 mg orally 2 times a day for 10 days ***OR*** • Levofloxacin 500 mg orally once daily for 10 days

[1] Although limited clinical studies, along with biologic and pharmacologic evidence, suggest that ceftriaxone is effective for treating early syphilis, the optimal dose and duration of ceftriaxone have not been established. Because of increasing reports of resistance, azithromycin should be used with caution and only when penicillin or doxycycline is not feasible.

[2] Azithromycin is not acceptable therapy for treatment of syphilis in MSM or pregnant women.

[3] Azithromycin should be used in limited circumstances due to mounting concern about emerging resistance.

[4] For TOC culture is preferred. NAAT is acceptable if culture not available.

[5] Oral erythromycin has been associated with infantile hypertrophic pyloric stenosis (IHPS) in infants <6 weeks. Infants treated with erythromycin should be followed for signs and symptoms of IHPS.

[6] The recommended regimen of ceftriaxone and doxycycline is for epididymitis that is most likely caused by GC or CT. Additional therapy can include a fluoroquinolone if acute epididymitis is not found to be caused by GC or if the infection is likely caused by enteric organisms. For MSM at risk for both sexually transmitted and enteric organisms, ceftriaxone and a fluoroquinolone are recommended.

PELVIC INFLAMMATORY DISEASE (PID) (outpatient management) All recommended and alternative regimens to be used with or without metronidazole 500 mg orally 2 times a day for 14 days[7,15] These regimens are for non-pregnant clients only. Pregnant clients should be hospitalized and treated with the appropriate parenteral treatments (see CDC guidelines).	REGIMEN A • Ceftriaxone 250 mg IM single dose ***PLUS*** • Doxycycline 100 mg orally 2 times a day for 14 days REGIMEN B • Cefoxitin 2 g IM single dose with probenicid 1 g orally ***PLUS*** • Doxycycline 100 mg orally 2 times a day for 14 days REGIMEN C • Other parenteral third generation cephalosporin (e.g., ceftizoxime or cefotaxime) ***PLUS*** • Doxycycline 100 mg orally 2 times a day for 14 days	• Levofloxacin 500 mg orally once daily for 14 days[8] ***OR*** • Ofloxacin 400 mg 2 times a day for 14 days[7]
CHANCROID	• Azithromycin 1 g orally single dose ***OR*** • Ceftriaxone 250 mg IM single dose ***OR*** • Ciprofloxacin 500 mg orally 2 times a day for 3 days[9] ***OR*** • Erythromycin base 500 mg orally 3 times a day for 7 days	
HERPES SIMPLEX VIRUS (for non-pregnant adults). See 2010 CDC guidelines for the management of herpes in pregnancy and in the neonate		
First clinical episode of genital herpes	• Acyclovir 400 mg orally 3 times a day for 7-10 days[10] ***OR*** 200 mg orally 5 times a day for 7-10 days[10] ***OR*** • Famciclovir 250 mg orally 3 times a day for 7-10 days[10] ***OR*** • Valacyclovir 1 g orally 2 times a day for 7-10 days[10]	
Daily Suppressive therapy	• Acyclovir 400 mg orally 2 times a day ***OR*** • Famciclovir 250 mg orally 2 times a day ***OR*** • Valacyclovir 500 mg orally once a day[11] ***OR*** 1 g orally once a day	
Episodic Recurrent Infection	• Acyclovir 400 mg orally 3 times a day for 5 days ***OR*** 800 mg orally 2 times a day for 5 days ***OR*** 800 mg orally 3 times a day for 2 days ***OR*** • Famciclovir 125 mg orally 2 times a day for 5 days ***OR*** 500 mg once, followed by 250 mg twice daily for 2 days ***OR*** 1000 mg orally 2 times a day for 1 day • Valacyclovir 500 mg orally 2 times a day for 3 days ***OR*** 1 g orally once a day for 5 days	
ENTEROPARASITIC INFECTIONS		
PEDICULOSIS PUBIS[12]	• Permethrin 1% cream rinse applied to affected area and washed off after 10 minutes ***OR*** • Pyrethrins with piperonyl butoxide applied to affected area and washed off after 10 minutes	• Malathion 0.5% lotion applied for 8-12 hours and washed off[13] ***OR*** • Ivermectin 250 ug/kg orally, repeated in 2 weeks
SCABIES	• Permethrin 5% cream applied to all areas of the body from the neck down and washed off after 8-14 hours ***OR*** • Ivermectin 200ug/kg orally, repeated in 2 weeks	• Lindane 1% 1 oz of lotion (or 30 g of cream) applied in a thin layer to all areas of the body from the neck down and thoroughly washed off after 8 hours[14]
DISEASES CHARACTERIZED BY VAGINAL DISCHARGE		
BACTERIAL VAGINOSIS (BV)	• Metronidazole 500 mg orally 2 times a day for 7 days[15] ***OR*** • Metronidazole gel 0.75% one full applicator (5g) intravaginally once a day for 5 days ***OR*** • Clindamycin cream 2% one full applicator (5g) intravaginally at bedtime for 7 days[16]	• Tinidazole 2 g orally once daily for 2 days[17] ***OR*** • Tinidazole 1 g orally once daily for 5 days[17] ***OR*** • Clindamycin 300 mg orally 2 times a day for 7 days ***OR*** • Clindamycin ovules 100 g intravag. at bedtime for 3 days
PREGNANCY AND BV	• Metronidazole 500 mg orally 2 times a day for 7 days[15] ***OR*** • Metronidazole 250 mg orally 3 times a day for 7 days[15] ***OR*** • Clindamycin 300 mg orally 2 times a day for 7 days	
TRICHOMONIASIS	• Metronidazole 2 g orally single dose[15] ***OR*** • Tinidazole 2 g orally single dose[17]	• Metronidazole 500 mg orally 2 times a day for 7 days[15]
PREGNANCY AND TRICHOMONIASIS	• Metronidazole 2 g orally single dose[15]	

GENITAL WARTS (for non-pregnant adults). See 2010 CDC Guidelines for the management of genital warts in pregnancy

External	Urethral Meatus	Vaginal	Anal (not intra-anal)
PROVIDER-ADMINISTERED Cryotherapy with liquid nitrogen or cryoprobe. Repeat every 1-2 weeks if necessary ***OR*** Trichloroacetic acid (TCA) or bichloroacetic acid (BCA) 80% -90%[18] ***OR*** Podophyllin resin 10%-25% in a compound tincture of benzoin. Allow to air dry. Limit application to <10 cm^2 and to <0.5 ml. Wash off 1-4 hours after application. Repeat weekly if necessary ***OR*** Surgical removal PATIENT-APPLIED Podofilox 0.5% solution or gel. Apply 2 times a day for 3 days, followed by 4 days of no therapy. This cycle can be repeated as necessary for up to 4 times. Total wart area should not exceed 10 cm^2 and total volume applied daily not to exceed 0.5 ml. ***OR*** Imiquimod 5% cream.[19] Apply once daily at bedtime 3 times a week for up to 16 weeks. Wash treatment area with soap and water 6-10 hours after application. ***OR*** Sinecatechins 15% ointment. Apply three times daily, a 0.5 cm strand of ointment to each wart, using a finger, for up to 16 weeks. Do not wash off after use.[20]	Cryotherapy with liquid nitrogen ***OR*** Podophyllin 10%-25% in a compound tincture of benzoin. Treatment area must be dry before contact with podophyllin. Repeat weekly if necessary.	Cryotherapy with liquid nitrogen. Cryoprobe not recommended (risk of perforation and fistula formation) ***OR*** TCA or BCA 80%-90% applied to warts[18]	Cryotherapy with liquid nitrogen ***OR*** TCA or BCA 80%-90%[18] ***OR*** Surgical removal Many persons with anal warts may also have them in the rectal mucosa. Inspect rectal mucosa by digital examination or anoscopy. Intra-anal warts should be managed in consultation with a specialist.

[7] Metronidazole will also treat bacterial vaginosis, found in many women with PID.
[8] As a result of the emergence of quinolone-resistant gonococcal organisms, quinolone-containing regimens are no longer recommended. These alternative regimens are for use only when community prevalence and individual risk for gonorrhea are low. Diagnostic tests for gonorrhea must be performed before instituting therapy. Refer to *CDC Guidelines* for management if patient positive.
[9] Ciprofloxacin is contraindicated in pregnant and lactating women.
[10] Treatment can be extended if healing is incomplete after 10 days of therapy.
[11] Valacyclovir 500 mg once daily might be less effective than other valacyclovir or acyclovir dosing regimens in patients who have very frequent recurrences (i.e., ≥10 episodes per year).
[12] These regimens are not to be applied to the eyes.
[13] Malathion can be used when treatment failure is believed to have resulted from drug resistance.
[14] Lindane not recommended as first line therapy because of toxicity. Should not be used immediately after a bath or shower and should not be used by persons who have extensive dermatitis or women who are pregnant or lactating.
[15] Patients should be advised to avoid consuming alcohol during treatment with metronidazole. Abstinence from alcohol should continue for 24 hours after completion of metronidazole.
[16] Clindamycin cream is oil-based and may weaken latex condoms and diaphragms for 5 days after use.
[17] Patients should be advised to avoid consuming alcohol during treatment with tinidazole. Abstinence from alcohol should continue for 72 hours after completion of tinidazole.
[18] Apply small amount only to warts. If excess amount applied, powder with talc, baking soda or liquid soap. Repeat weekly if necessary.
[19] Imiquimod may weaken condoms and vaginal diaphragms.
[20] Sexual contact (genital, anal, or oral) should be avoided while ointment is on skin. May weaken condoms or diaphragms.

Acute PID (Pelvic Inflammatory Disease)

Here is some information about acute PID (pelvic inflammatory disease). Be sure you understand it and the possible benefits and problems of treatment before you begin treatment. We have also listed the warning signs you should watch out for. We are happy to answer any questions you have.

Symptoms

Many women do not have any early signs of infection. Sometimes they have longer, heavier, or more painful periods, pain in the abdomen, tiredness, fever or chills, bad-smelling vaginal discharge, or pain during sexual intercourse.

Diagnosis

A pelvic exam must be done even though it may be uncomfortable. Tests will be done for gonorrhea and chlamydia. Blood tests may also be done.

Risks

This infection is serious. Later complications that may occur include sterility (inability to become pregnant) and ectopic pregnancy (a pregnancy in the tubes). An ectopic pregnancy may require an operation. If it is not treated, it can cause death. Early complete treatment of PID lowers the chance of these serious problems.

Prevention

Know your partner(s) and limit the number of them. The more partners you and your partner have, the higher the chance you have of getting a sexually transmitted infection (STI). If you only have sex with one uninfected partner who has sex only with you, you are at low risk of STIs and PID. Condoms are the best way for sexually active people to reduce the risk of STIs. Always use a condom if you or your partner have other sex partners.

Treatment

You should

- Take your medicine exactly the way you were instructed. Finish **all** of the medicine, even if you feel better before it is gone.
- Take good care of yourself.
  - Rest — in bed. You need several days of bed rest to treat a serious infection.
  - Drink lots of fluids, and eat a healthy diet.
  - Do not douche or use tampons.
  - You may take aspirin, ibuprofen, or Tylenol for pain. You may also put a heating pad on your abdomen.
- Tell your partner(s) that you have an infection. Any recent partner will need to get checked and get medicine (even if feeling fine). If your partners are not treated, you can get the infection back again.
- Not have sex until you and your partner(s) have finished all the medicine, have been examined, and know that they are cured. It is safest if you use latex condoms **each time** you do have sex.
- Keep your appointments to be sure you are better. Your next appointment is _____.

Call the health center at X-XXX-XXX-XXXX

- if you feel worse, or if you have questions. If it is an emergency and you can't reach us, go to the emergency room of a nearby hospital.
- if you think you may be allergic to the medication
- immediately, if you have
  - a high fever with temperature 101ºF or more after the first two days
  - nausea and vomiting for more than 24 hours, especially if you are unable to take your medication
  - abdominal swelling or abdominal pain that is becoming worse
  - fainting or continuous dizziness

Directions For Sex Partners - Chlamydia

We recently treated your sex partner for chlamydia. Chlamydia is a sexually transmitted infection (STI). You can get chlamydia from having sex with a person who has it. You are probably infected, too. It is easy to treat.

How would I know if I have chlamydia?
Many people who have chlamydia do not know it. They may have no symptoms and feel fine. Others may feel pain. It can be in their lower belly, testicles (balls), vulva, or vagina. It can also happen when they urinate or have sex. Unless it's treated, you can get very sick. And chlamydia can cause sterility in women — not being able to have children.

What is the treatment for chlamydia?
Chlamydia is treated with an antibiotic. The best way to take care of chlamydia is to be seen at a clinic — either at Planned Parenthood or somewhere else. Call us at _____ if you want to make an appointment.

Your partner has brought you the medicine or a prescription that you can fill at a pharmacy. If you can't get to a doctor or nurse in the next few days, you should take the medicine. Even if you take the medicine, it is very important that you be seen and get tested for STIs. Having an STI can increase your risk of getting HIV, so you should get an HIV test too. The clinic can also provide other sexual health and birth control services.

Please read the following before you take the medicine:
The medicine is very safe. But **DO NOT TAKE IT if any of the following are true:**

- You are a man and have a fever, or pain or swelling in the testicles (balls).
- You are a woman and have pain in the lower belly, pain during sex, vomiting, or fever.
- You think you may be pregnant.
- You have a serious long-term illness, such as kidney, heart, or liver disease.
- You are currently taking another prescription medicine.
- You have a bad reaction, rash, breathing problems, or allergy to antibiotics.

Talk with us, or your doctor or nurse, as soon as possible if any of these are true for you.

Possible Side Effects of the Medicine

Some people get a mildly upset stomach or diarrhea after taking this medicine. Others may develop dizziness, fatigue, or headache. Women may get a yeast infection. These side effects won't last long.

Call 911 or go to the nearest emergency room if you develop itching or a rash or have difficulty breathing — you may be having an allergic reaction. There can be other, more serious side effects, but they are extremely rare.

The medicine you have been given, or prescribed, is [Delete medication you do not offer.]

- **Azithromycin**

  Do not take this medicine if you ever had a bad reaction, rash, breathing problems, or allergy to it or other antibiotics. If you're allergic to antibiotics, check with your doctor or contact us before taking this medicine.

  Directions for taking azithromycin [Delete any of the regimens you do not offer.]
  - If you got 2 *tablets* (500 mg) — take both at one time. Take with or without food. (Having some food in your stomach may prevent stomach ache.)
  - If you got 4 *tablets* (250 mg) — take all four at one time. Take with or without food. (Having some food in your stomach may prevent stomach ache.)

- If you got 4 *capsules* (250 mg) — take all four at one time. Take them at least one hour before, or two hours after, a meal. Do not take them with food.
- If you got the powder — mix the whole packet of it thoroughly in a glass with two ounces of water. Drink it all right away. Add another two ounces of water to the glass. Mix it well with whatever's left in the glass. Drink it all right away. Take it with or without food. (Having some food in your stomach may prevent stomach ache.)

- **Doxycycline**

  Do not take this medicine if you ever had a bad reaction, rash, breathing problems or allergy to it or other antibiotics. If you're allergic to antibiotics, check with your doctor or contact us before taking this medicine.

Directions for taking doxycycline

- Take 1 capsule, twice a day (approximately every 12 hours), for seven days.
- Take with or without food. (Having some food in your stomach may prevent stomach ache.)
- Do not take within 2 hours of taking antacids or calcium supplements

Finish all the medicine. Don't share or give your medication to anyone else.

When can I have sex?

Do not have sex until you've taken all the medicine and at least 7 days have passed. It takes 7 days for the medicine to cure chlamydia. You can still pass the infection to your sex partners if you have unprotected sex – vaginal, anal, or oral – before 7 days have passed. The safest way to make sure you don't pass the infection on to anyone is to not have sex for 7 days.

If you have other sex partners, tell them you are getting treated for chlamydia so they can get treated too. People who get chlamydia are very likely to get it again. It's important to get tested for chlamydia and other STIs 3 months from now.

Who do I call with questions?

If you have any questions or want to make an appointment, please call _____.

DIRECTIONS FOR SEX PARTNERS — GONORRHEA

We recently treated your sex partner for gonorrhea. Gonorrhea is a sexually transmitted infection (STI). You can get this infection from having sex (oral, vaginal, or anal) with a person who has it. You may be infected, too. It is easy to treat.

How would I know if I have gonorrhea?

Many people who have this infection do not know it. They may have no symptoms and feel fine. Others may have an unusual discharge from the penis, vagina, or anus. Or they may feel pain when they urinate. Unless it's treated, gonorrhea can make you sick and cause sterility — not being able to have children — in women.

What is the treatment for gonorrhea?

Gonorrhea is treated with antibiotics. The best way to take care of this infection is to be seen at a clinic — either at Planned Parenthood or somewhere else. Call us at XXX-XXX-XXXX if you want to make an appointment.

Your partner has brought you the medicines or prescriptions that you can fill at a pharmacy. If you can't get to a doctor or nurse in the next few days, you should take the medicines. If you take the medicines, you should have a gonorrhea test one week later. It is very important that you be seen and get tested for other STIs too. Having an STI can increase your risk of getting HIV, so you should get an HIV test too. The clinic can also provide other sexual health and birth control services.

PLEASE READ THE FOLLOWING BEFORE YOU TAKE THE MEDICINE.

The medicines are very safe. But **DO NOT TAKE THEM if ANY of the following are true:**

- You are a man and have a fever or pain or swelling in the testicles (balls).
- You are a woman and have pain in the lower belly, pain during sex, vomiting, or fever.
- You have one or more painful and swollen joints or a rash all over your body.
- You think you may be pregnant.
- You have a serious long-term illness, such as kidney, heart, or liver disease.
- You are currently taking another prescription medicine.
- You have a bad reaction, rash, breathing problems, or allergy to antibiotics.

Talk with us, or your doctor or nurse, as soon as possible if any of these are true for you.

Possible Side Effects of the Medicine

Some people get a mildly upset stomach or diarrhea after taking this medicine. Others may develop dizziness, fatigue, or headache. These side effects won't last long. Women may get a yeast infection.

Call 911 or go to the nearest emergency room if you develop itching, a rash or hives or have difficulty breathing. You may be having an allergic reaction. There can be other, more serious side effects, but they are extremely rare.

DIRECTIONS FOR SEX PARTNERS — GONORRHEA

The medicines you have been given, or prescribed, for gonorrhea are [Delete medications you do not offer.]		
Select Medication	**Medication**	**Directions for taking medication**
	Cefixime (also called Suprax) Do not take this medicine if you ever had a bad reaction, rash, breathing problems, or allergy to it or other antibiotics. If you're allergic to antibiotics, check with your doctor or contact us before taking this medicine.	**Directions for taking cefixime** [Alter directions to correspond to your regimen.] ▪ Take both pills (200 mg each) at the same time. ▪ Take with or without food.
	Cefpodoxime (also called Vantin) Do not take this medicine if you ever had a bad reaction, rash, breathing problems, or allergy to it or other antibiotics. If you're allergic to antibiotics, check with your doctor or contact us before taking this medicine.	**Directions for taking cefpodoxime** [Alter directions to correspond to your regimen.] ▪ Take both pills (200 mg each) at the same time. Take with food. ▪ Do not take within two hours of taking antacids or calcium.
AND		
	Azithromycin Do not take this medicine if you ever had a bad reaction, rash, breathing problems, or allergy to it or other antibiotics. If you're allergic to antibiotics, check with your doctor or contact us before taking this medicine.	**Directions for taking azithromycin** [Delete any of the regimens you do not offer.] ▪ If you got 2 *tablets* (500 mg each) — take both at one time. Take with or without food. (Having some food in your stomach may prevent stomach ache.) ▪ If you got 4 *tablets* (250 mg each) — take all four at one time. Take with or without food. (Having some food in your stomach may prevent stomach ache.) ▪ If you got 4 *capsules* (250 mg each) — take all four at one time. Take them at least one hour before, or two hours after, a meal. Do not take them with food. ▪ If you got the powder — mix the whole packet of it thoroughly in a glass with two ounces of water. Drink it all right away. Add another two ounces of water to the glass. Mix it well with whatever's left in the glass. Drink it all right away. Take it with or without food. (Having some food in your stomach may prevent stomach ache.)
	Doxycycline Do not take this medicine if you ever had a bad reaction, rash, breathing problems, or allergy to it or other antibiotics. If you're allergic to antibiotics, check with your doctor or contact us before taking this medicine.	**Directions for taking doxycycline** ▪ Take 1 capsule, twice a day (approximately every 12 hours), 7 days. ▪ Take with or without food. (Having some food in your stomach may prevent stomach ache.) ▪ Do not take within 2 hours of taking antacids or calcium.
Finish all the medicine. Don't share or give your medication to anyone else.		

DIRECTIONS FOR SEX PARTNERS — GONORRHEA

When can I have sex?

Do not have sex for the next 7 days after taking the medicine**.** It takes 7 days for the medicine to cure gonorrhea. You can still pass the infection to your sex partners if you have unprotected sex – vaginal, anal, or oral – before 7 days have passed. The safest way to make sure you don't pass the infection on to anyone is to not have sex for 7 days.

If you performed oral sex on someone who has gonorrhea, the medicine may not work as well. You may need a different medicine. Call us or another doctor or nurse.

If you have other sex partners, tell them you are getting treated for gonorrhea so they can get treated too. People who get gonorrhea are very likely to get it again. It's important to get tested for chlamydia, gonorrhea and other STIs 3 months from now.

Who do I call with questions?

If you have any questions or want to make an appointment, please call XXX-XXX-XXXX.

Directions for Sex partners - Trichomoniasis

We recently treated your sex partner for trichomoniasis (also called trichomonas or trich). Trichomoniasis is a sexually transmitted infection (STI). You can get trichomoniasis from having sex with a person who has it. You are probably infected, too. It is easy to treat.

How would I know if I have trichomoniasis?
Many people who have trichomoniasis do not know it. Most men have no symptoms and feel fine. Some may notice a discharge (drip) from their penis or have pain when they urinate. Most women notice a frothy, yellow-green vaginal discharge. They may also feel itching and burning in the genital area or notice a fishy smell.

What is the treatment for trichomoniasis?
Trichomoniasis is treated with an antibiotic called metronidazole. The best way to take care of trichomoniasis is to be seen at a clinic — either at Planned Parenthood or somewhere else. Call us at _____ if you want to make an appointment.

Your partner has brought you the medicine or a prescription that you can fill at a pharmacy. If you can't get to a doctor or nurse in the next few days, you should take the medicine. Even if you take the medicine, it is very important that you be seen and get tested for STIs. Having an STI can increase your risk of getting HIV, so you should get an HIV test too. The clinic can also provide other sexual health and birth control services.

Please read the following before you take the medicine:
The medicine is very safe. **But if you drink any alcohol while you take the medicine, you can get a very bad reaction** that may include stomach pain, nausea, vomiting, headache, and flushing. **DO NOT take the medicine if you have had any alcoholic drink in the past 12 hours and do not drink any alcohol until 24 hours after you finish the medicine.**

DO NOT TAKE IT if any of the following are true:
- You ever had an allergic reaction — rash, itching, swelling, dizziness, or trouble breathing — to metronidazole or Flagyl.
- You are a man and have a fever, or pain or swelling in the testicles (balls).
- You are a woman and have pain in the lower belly, pain during sex, vomiting, or fever.
- You think you may be pregnant or are breast feeding.
- You have liver disease or a neurological disorder.
- You are currently taking another prescription medicine.

Talk with us, or your doctor or nurse, as soon as possible if any of these are true for you.

Possible Side Effects of Metronidazole
Some people get dizziness, headache, diarrhea, nausea, vomiting, stomach ache, rash, change in taste sensation, or a dry mouth. Women may get a yeast infection. These side effects won't last long. But if they don't go away or get worse, call us or your doctor or nurse.

Your urine may be a darker color while you take the medicine. This is not harmful.

Seek urgent medical attention if you get a seizure, lose consciousness (pass out or faint), have tingling or numbness of the hands or feet, feel unsteady on your feet, notice mood or mental changes, have bad stomach pain, itching, or a fever. These more serious side effects are rare.

How do I take the medicine?
The medicine you have been given, or prescribed, is metronidazole.
[Delete the regimen you do not offer.]

- If you got 4 white *tablets* (500 mg) — take all 4 at one time. Take with a full glass of water or with food.
- If you got 8 white *tablets* (250 mg) — take all 8 at one time. Take with a full glass of water or with food.

Finish all the medicine. Don't share or give your medication to anyone else.

When can I have sex?
Do not have sex until you've taken all the medicine and are cured. It takes 7 days for the medicine to cure trichomoniasis. You can still pass the infection to your sex partners if you have unprotected sex before 7 days have passed. The safest way to make sure you don't pass the infection on to anyone is to not have sex for 7 days.

If you have other sex partners, tell them you are getting treated for trichomoniasis so they can get treated too. People who get trichomoniasis are very likely to get it again. It's important to get tested for trichomoniasis and other STIs 3 months from now.

Who do I call with questions?
If you have any questions or want to make an appointment, please call _____.

Genital Herpes

What is genital herpes?
Genital herpes is a very common sexually transmitted infection (STI). It is caused by two viruses called herpes simplex type 1 (HSV 1) and herpes simplex type 2 (HSV 2).

What are the symptoms?
Most of the time there are no symptoms. Because they have no symptoms many people don't know they have herpes.
Herpes can cause one or more blisters or sores on the vagina, thighs, penis, scrotum, butt, or anus. The sores can feel itchy and/or painful. Sometimes they cause burning with urination. You may have them only once and never again, but because the virus stays in your body forever, sores can come back again in weeks, months, or years in the same or different places. When the sores come back, it is called an "outbreak."

The first time you have sores it is usually the worst time. You may also have swollen glands, fevers, and body aches - like you have the flu. The first outbreak usually takes 2 to 4 weeks to heal. Many people have "warning signs" before they have an outbreak. Warning signs include itching, burning, or tingling on your genitals. After the first time, outbreaks usually happen less often, become less painful, and heal in 10 to 14 days.

How do you get genital herpes?
Genital herpes is spread by skin touching skin –usually by having oral, vaginal, or anal sex with someone who has the infection.

The virus lives in the fluid in a herpes sore. It also can be released from the skin of people who don't get sores. This is known as "asymptomatic shedding", and is common. This is also why it is not always possible to tell exactly when you got herpes or who passed it to you.

How can I find out if I have genital herpes?
Only a doctor or nurse can diagnose herpes by looking at it or by taking a sample from the sore and having it tested. This is called a culture. Cultures work best if taken within 1 to 2 days of when you notice symptoms. Other STIs can cause sores that look like herpes, so it's important to get yourself tested so you get the right treatment.

If you are not having symptoms, you can talk to your doctor or nurse about a blood test. Routine testing of people without symptoms or known exposure to herpes is not recommended. However, there are certain circumstances when it might be helpful.

How is genital herpes treated?
Although the virus stays in your body for life and cannot be cured, there are medicines to help with outbreaks. They can be prescribed by your doctor or nurse and you may take them

- when you have an outbreak. This reduces the symptoms and shortens the outbreak, and works best if you start the medicine as soon as you notice symptoms.

OR

- every day to prevent future outbreaks. This can also decrease the risk of passing herpes to your partner.

You might choose not to take medicine. If your symptoms or outbreaks are not bothersome or if you are not currently having sex, this may be right for you.

(continued on page 2)

Taking good care of yourself by following a good diet, getting enough rest and sleep, and keeping your stress levels down may also help prevent outbreaks.

To reduce pain during an outbreak, try

- sitting in warm water for about 20 minutes using a portable bath (a Sitz bath) or your bathtub.
- keeping the genital area clean and dry, and avoid tight clothes.
- taking acetaminophen (Tylenol) or ibuprofen (Advil, Motrin).

How do I tell my partner that I have herpes?

You may be concerned about how genital herpes will affect your health, sex life, and relationships. For some people, telling a partner that they have genital herpes may make them feel unsafe. Talk to your doctor or nurse about managing your infection, how to talk to sex partners, and keeping yourself safe. Counseling and support groups may also be helpful.

What can I do to not get herpes?

The best way to protect yourself is to not have sex. If you do have sex:

- talk to your partner about any history of STIs before you have sex with each other.
- use condoms every time you have sex.
- avoid sex if your partner has a herpes outbreak.

What can I do to not pass herpes to my sex partner?

- Tell your partner that you have herpes.
- Use a condom every time you have sex.
- When you have symptoms
  - do not have vaginal, anal, or oral sex — even with protection – as soon as you feel warning signs of an outbreak.
  - wait at least 7 days after the sores heal before you start to have sex again.
  - don't touch the sores. If you do, wash your hands with soap and water — this kills the virus.
  - If you have a sore on your mouth, don't kiss anyone or have oral sex.
- Talk to your doctor or nurse about starting medicine

Herpes and HIV

If you have herpes, it is especially important to practice safer sex. People with genital herpes have at least twice the risk of getting HIV if exposed to it than people without herpes. And people with HIV and genital herpes are more likely to pass HIV to their partners.

Could genital herpes harm my pregnancy?

If you are pregnant, tell your doctor or nurse if you have been diagnosed with genital herpes.

Sometimes genital herpes can cause miscarriage or delivering too early. Rarely it can be passed to a newborn during childbirth. This can cause brain damage and eye problems in the baby. You may be given medicine towards the end of your pregnancy to decrease the risk of passing the infection on.

If you have never been diagnosed with genital herpes, the most important thing you can do is to avoid getting it during your pregnancy because a new infection is the most dangerous to the pregnancy.

HIV Test

Who should get tested for HIV?
Getting an HIV test is the only way to know if you have HIV. Many people have HIV but don't know it. You might not feel sick or have any health problems. But you can still pass HIV to other people. Experts recommend that everyone between the ages of 15 and 65 be tested at least once, even if they have no known risks of HIV infection. ***Anyone who is sexually active should get tested regularly for HIV.*** Talk to your doctor or nurse about how often you should get tested.

When should I get tested if I think I was exposed to HIV?
It usually takes from 3 weeks to 2 months for your body to make antibodies to the virus that causes HIV. During this "window period" your test might be negative for HIV even if you are infected. If you think you were exposed to HIV, you should wait for 2 months before being tested. **If you are infected, you can give HIV to others during the window period even if your test is negative. In fact, during this time, you have the greatest chance of passing HIV infection to others.**

What kinds of HIV tests are there?
Most tests look for the antibodies that your body makes against HIV. Tests can be done on blood or fluid from your mouth. Some tests, called rapid tests, can be done in the clinic in about 20 minutes. Others need to be sent out to a lab.

What do the results mean?
A negative result means that no antibodies to HIV have been found in your body. If the test is done during the window period, you may get a false negative result. Your doctor or nurse will help decide when you should be retested.

A positive result on a rapid test means that you may have HIV antibodies. All positive results are re-checked with a second test so you can know for sure if you have HIV. If it is confirmed that your HIV test is positive, we will help you get the care you need.

Who will know my test results?
Your test results are protected by privacy laws. They can only be released with your permission. Whether anyone can know about your test results or your HIV status depends on what kind of test you take: confidential or anonymous. Some states only allow confidential testing.

- Confidential testing means that your name will be used. The results will go in your medical record and may be shared with your doctor or nurse and your health insurance company. Your results will be reported to the health department.
- With anonymous testing a code number is used instead of your name. Nothing ties your test results to you. Tell us if you want anonymous testing.

Remember that no HIV test is 100 percent accurate. The test may have been done too soon to find antibodies. There is a risk that the results may not be right or can't be read. These kinds of results can be very upsetting and frustrating. We are here to talk with you in this case.

Reducing Your Risk for STIs

Sexually transmitted infections (STIs) are passed from person to person during sex – vaginal, anal, or oral - through blood, body fluids, or skin in the genital area. They are very common. But the good news is there are ways to protect each other and ourselves from STIs. It's called safer sex, and here are some suggestions for what you can do.

Get Immunized
Vaccines are a safe and effective way to prevent Hepatitis A and B, and HPV (human papillomavirus). It's best to get your vaccines *before* you start to have sex, but if you already have had sex, it's not too late. Talk to your doctor or nurse about the vaccines that are right for you.

Consider Abstinence
The best way to avoid STIs is to not have sex of any kind. This is called abstinence.

Talk to your Partner(s)
Speak honestly and openly with your partner(s) about STIs and prevention *before you have sex*. Your partner's sexual history is as important as your own.

Limit Sex Partners
The more partners you or your partners have, the higher your risk of getting an STI. One way to reduce your risk is called mutual monogamy. This is when 2 people agree to have sex with only each other. If you and your partner have never had sex of any kind with another person, there is no risk of STIs. If you or your partner has ever had sex with anyone else, get tested before you have sex with each other.

Get Yourself Tested
The only way to know if you or your partner has an STI is to get tested. You can't tell if others are infected by how they look. Get tested and ask your sex partner(s) to get tested ***before*** having sex. Know that some infections may take several months to show up on a test, so you may need to retest.

Talk to your doctor or nurse about your sex life and the types of testing that are right for you.

Understand Safe, Safer and Unsafe Activities

- ***Safe*** activities don't spread STIs. Abstinence, fantasy, masturbation, sexy talk, online sex, phone sex and non-sexual massage are all safe.
- ***Safer*** activities have some risk of spreading STIs. These include open mouth kissing, hand-to-genital contact, body-to-body rubbing ("outercourse"), oral sex, or playing with sex toys with a partner.
- ***Unsafe*** activities have the highest risk of spreading STIs. High-risk activities include vaginal sex and anal sex. Other unsafe activities include sharing needles, exchanging sex for drugs or money, and sex with an infected partner. Having an STI also increases your risk of getting other STIs.

Use Protection
Barriers prevent contact with blood or body fluids. Condoms and dental dams can reduce the risk of STIs, if used correctly and every time.

Use dental dams during oral sex. Dams are small pieces of latex or silicone that you put on the outside of the vagina or anus. They prevent passing of sexual fluids between you and your partner during oral sex. For oral sex with a penis, it is best to use an unlubricated condom. Dental dams do not prevent pregnancy.

Take PrEP (Pre-Exposure Prophylaxis)
PrEP is medicine that is used to reduce the risk of getting HIV in people at highest risk. Your doctor or nurse can give you more information about PrEP.

Be in control.
Don't let alcohol, drugs or a partner make you forget how to protect yourself. Alcohol and drug use can make it harder to make good decisions and safer sex less likely to happen.

STI Testing

Sexually transmitted infections (STIs) are spread through sex. After you are exposed to an infection, it can take days, weeks, or months for them to show up on a test. This is known as the "incubation period". There is no perfect test, sometimes test results can be wrong. There is no test or exam that screens for all STIs. Talk to your doctor or nurse about your risks for STIs. Your doctor or nurse will recommend testing based on your symptoms, health history and risk factors.

STI	ABOUT THE INFECTION	WHO SHOULD GET TESTED AND WHEN	INCUBATION PERIOD	HOW DO I GET TESTED?
CHLAMYDIA	▪ Caused by bacteria ▪ May have genital discharge, pain during urination, or pelvic or testicular pain ▪ Usually no symptoms ▪ Can be cured	Routinely, at least every year for ▪ women <26 years old ▪ pregnant women ▪ men who have sex with men ▪ HIV+ Testing based on your risk factors.	1 to 2 weeks	urine test or swab of the genital area sent to lab
GENITAL HERPES	▪ Caused by virus ▪ Can cause sores on the genitals or other areas of skin ▪ May not have symptoms ▪ Can be treated but not cured	Anyone with symptoms should see a doctor or nurse.	2 to 12 days	Swab of sore sent to lab. Most accurate within 2 days of noticing symptoms.
GENITAL WARTS	▪ Caused by virus ▪ Painless, sometimes itchy, genital bumps ▪ Can be treated but usually goes away on its own	Anyone with concerns should see a doctor or nurse.		By exam
GONORRHEA	▪ Caused by bacteria ▪ Symptoms same as Chlamydia ▪ Can be cured	Routinely, at least every year for ▪ women <26 years old ▪ pregnant women ▪ men who have sex with men ▪ HIV+ Testing based on your risk.	2 to 7 days	Urine test or swab of genital area sent to lab
HEPATITIS B	▪ Caused by virus ▪ May have fatigue, abdominal pain, yellowing of eyes or skin ▪ May not have symptoms ▪ Can also get from contact with infected blood ▪ Vaccine available for prevention ▪ Can be treated but not cured	Testing based on risk.	6 weeks to 6 months	Blood test sent to lab
HEPATITIS C	▪ Caused by virus ▪ Symptoms same as Hepatitis B ▪ May not have symptoms ▪ Usually get from contact with infected blood ▪ Can be treated but not cured	Testing based on risk.	Up to 6 months	Blood test sent to lab
HIV	▪ A virus ▪ Early symptoms may include flu-like illness, rash, joint pain ▪ May not have symptoms ▪ Can be treated but not cured	At least once for anyone sexually active between the ages of 13 and 65. And testing based on risk.	2 to 12 weeks	Blood test or swab from inside of mouth. May be sent to lab.

STI Testing

STI	ABOUT THE INFECTION	WHO SHOULD GET TESTED AND WHEN	INCUBATION PERIOD	HOW DO I GET TESTED?
HUMAN PAPILLOMA VIRUS (HPV)	▪ A virus ▪ Over 40 types ▪ Some types are associated with cancers of the cervix, vagina, vulva, penis, anus, or mouth ▪ Usually no symptoms ▪ Vaccine available for prevention ▪ Can be treated but not cured	HPV testing is used for cervical cancer screening and management only. HPV testing is not recommended for men.	1 to 8 months	
MOLLUSCUM CONTAGIOSUM	▪ Caused by virus ▪ May have painless bumps on lower belly, genital area or thighs and can appear in other areas of the body ▪ Can be treated but usually goes away on its own	Anyone with concerns should see a doctor or nurse.	1 week to 6 months	By exam
PUBIC LICE (CRABS)	▪ Caused by tiny parasites which attach to hair ▪ Have itching, nits (eggs) can be seen on hair ▪ Can be treated	Anyone with symptoms should see a doctor or nurse. No test available.	Within 5 days	By exam
SCABIES	▪ Caused by tiny parasites on the skin ▪ May have itching (worse at night), skin rashes ▪ Can be treated	Anyone with symptoms should see a doctor or nurse. No test available.	1 day to 6 weeks	By exam
SYPHILIS	▪ Caused by bacteria ▪ May have a painless sore on genitals or mouth, rash on hands or feet ▪ May not have symptoms ▪ Can be treated	Anyone with symptoms should see a doctor or nurse. Testing is recommended for ▪ pregnant women ▪ men who have sex with men ▪ others at risk	10 days to 3 months	Blood test or swab taken from a sore sent to lab.
TRICHOMONIASIS (TRICH)	▪ Caused by tiny parasites in the genitals ▪ May have genital discharge and itching, pain during urination ▪ May not have symptoms ▪ Can be treated	Anyone with symptoms should see a doctor or nurse. If no symptoms testing is not recommended.	4 to 20 days	Swab of genital area, or checking a sample of discharge. May be sent to lab.

Urinary Tract Infection (UTI)

What Is a UTI?

There are two kinds of UTI. Cystitis is an infection of the bladder, the part of the body that stores urine after it is made. Urethritis is an infection of the urethra, the part of the body that carries urine from the bladder to outside the body. Both women and men can get UTIs. They are more common in women.

If a UTI is not treated right away, the infection may move up to the kidney and cause a more serious infection called pyelonephritis (py–lo–ne–fry-tis).

What causes a UTI?

Bacteria that live in the vagina, genital and anal areas may enter the urethra, travel to the bladder, and cause cystitis. Urethritis is commonly caused by the sexually transmitted infection, chlamydia. It may also be caused by gonorrhea or other organisms.

What are the symptoms of a UTI?

You may have any of the following:

- frequent need to pee, usually in small amounts
- urgent need to pee
- pain or burning when you pee
- pressure or cramps in the lower abdomen when you pee
- bad-smelling and/or cloudy urine
- blood in the urine
- painful sex
- feeling tired
- fever, and sometimes sweats or chills
- pain in the mid-back (to the right or left of the spine)

What is the treatment for a UTI?

Medicines are used to treat UTIs. Read the information about the medicine we give you. Take all the medicine on time until it is all gone. If you are allergic to any medicines, or if you think you may be pregnant, tell your doctor or nurse right away.

If your symptoms do not go away with the medicine we give you, you need to come back to the clinic. You may need more tests.

What can I do to keep from getting a UTI again?

- Make sure you finish all of your medicine**,** even though you feel better.
- Be sure to drink plenty of water to keep your urinary tract flushed.
- Pee as soon as you need to. Don't hold it.
- Pee before and after sex.
- For women who have frequent UTIs, drinking cranberry juice or taking cranberry pills may help.

Call the clinic at X-XXX-XXX-XXXX if you

- have a fever of 100.4ºF or higher
- feel worse at any time
- have nausea or vomiting (feel sick to your stomach) that keeps you from taking the medicine
- don't feel any better or have blood in

Post-Exposure Prophylaxis (PEP)

(affiliate name and telephone number)

What Is PEP?

PEP is taking anti-HIV medicines as soon as possible after you may have been exposed to HIV to try to reduce the chance of becoming HIV positive. This could happen because of a sexual assault, or having unprotected sex with someone who has HIV, or sharing needles with someone who has HIV.

One or more medicines are taken several times a day for at least 28 days. The medicines work by keeping HIV from spreading through your body. Even if taken correctly, there is no guarantee that taking PEP will work.

Who Can Take PEP

PEP is only used for people who have a negative HIV test.

It should only be used rarely, right after a possible exposure. Your doctor or nurse will help decide if PEP is right for you, depending on what happened, when it happened, and what you know about the HIV status of the person whose blood or body fluids you were exposed to.

Before taking PEP, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits of PEP?

- PEP may keep you from getting HIV after you have been exposed.

What are the side effects of PEP?

- The most common side effects are nausea and generally not feeling well.
- PEP may also cause headaches, fatigue, vomiting, and diarrhea. Side effects are bad enough that many health care workers who were given PEP did not finish the medicine.
- The side effects are not life threatening.

Besides Pep what other choices do I have?

- There is no other medicine to prevent HIV after a possible exposure,
- You could choose not to take PEP.
- For some people who are at very high risk of getting HIV (for instance, if you have unprotected sex regularly with someone who is HIV+), pre-exposure prophylaxis (PreP) may be an option. Ask your doctor or nurse.

What are the risks of PEP?

- If you miss doses of the medicine and become HIV positive, it may be harder to treat.

What else should I know?

- PEP should be started as soon as possible after you may have been exposed to HIV, but it must be started within 72 hours.
- You will need an HIV test before starting PEP, and then in 1 month, 3 months, and 6 months
- You will need blood tests to see if you have anemia or kidney disease. You may also need screening for other sexually transmitted infections (STIs).
- You will need to tell your doctor or nurse about any medicines you take, in case they interact with PEP.
- You will need to schedule a follow up appointment so we can check how you are doing on the medicines. You should return at any time if you have problems while taking them.
- You will need to use condoms or abstain from sex or sharing needles to prevent others from possibly being exposed to HIV until you are sure you have not become HIV positive.
- You should be aware of some of the symptoms of acute HIV infection: fever or flu-like illness, swollen lymph nodes, a rash, a sore throat, mouth sores, nausea and diarrhea, and muscle pain. If you have these symptoms, you should see your doctor or nurse.

What if I have an emergency?

Call us immediately at XXX-XXX-XXXX, go to the nearest emergency room, or call 911.

Pre-exposure Prophylaxis (PrEP)

(affiliate name and telephone number)

What Is PrEP?

PrEP is a way to help prevent HIV by taking a pill every day. It reduces your risk of getting infected. When PrEP is combined with condoms and other prevention methods it works even better. PrEP may not work if you skip doses. Even if used correctly, there is no guarantee that PrEP will work.

Who Can Take PrEP?

PrEP is only used for people who are at very high risk for HIV through sex or IV drug use. PrEP might be right for you if

- your partner is HIV-positive
- your partner is HIV-negative and either you or your partner has sex with someone whose HIV status isn't known
- you are a gay or bisexual man who has had anal sex without a condom or been told you have a sexually transmitted infection (STI) in the past 6 months
- you are a heterosexual man or woman who does not use condoms every time you have sex with people who inject drugs or have bisexual male partners
- you have injected drugs in the past 6 months and have shared needles or been in drug treatment for IV drug use in the past 6 months.

Before taking PrEP, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits of PrEP?

PrEP may keep you from getting HIV.

What are the side effects of PrEP?

- The most common side effects are upset stomach or loss of appetite. These are mild and usually go away after the first month.
- PrEP may also cause headaches.
- No serious side effects were seen when PrEP was studied.

Besides PrEP what other choices do I have?

- PrEP is the only medicine that can help prevent HIV if taken every day.
- You could choose not to take PrEP.
- Whether or not you take PrEP, using a condom every time you have sex will help prevent HIV.

What are the risks of PrEP?

For people with certain medical problems, PrEP could make them worse. Talk to your doctor or nurse about your medical history.

What else should I know?

- PrEP may not start working right away. Talk to your doctor or nurse about when it might start working for you.
- You will need an HIV test before starting PrEP and every 3 months.
- You will need other tests before you start and every 3 to 6 months while you are on PrEP.
- You will need to schedule a follow up appointment so we can check how you are doing on PrEP. You should return at any time if you have problems while taking them.
- You will receive advice about ways to help you take PrEP every day so that it has the best chance to help you avoid HIV.
- You should be aware of some of the symptoms of new HIV infection: fever or flu-like illness, swollen glands, a rash, a sore throat, mouth sores, nausea and diarrhea, and muscle pain. If you have these symptoms, you should see your doctor or nurse.

What if I have an emergency?

Call us immediately at XXX-XXX-XXXX, go to the nearest emergency room, or call 911.

Sexually Transmitted Infection (STI) Treatment Without Testing

(affiliate name and telephone number)

Your sex partner has been diagnosed with a sexually transmitted infection. You probably have the same infection. You should be treated to

- prevent complications for yourself
- avoid spreading the infection back to your partner
- avoid infecting others

You have not had a test. There is no proof that you have an infection. We offer you this treatment because there is a chance you are infected. We recommend that you be tested to know for sure if you are infected.

You may also have an STI(s) other than the one your partner was treated for. The only way to be sure is to be tested.

Finish all the medicine we have prescribed for you. Don't share or give your medication to anyone else. Do not have sex until seven days after finishing all the medicine. You can still pass the infection to your sex partners if you have unprotected sex – vaginal, anal, or oral — before seven days have passed.

If you have other sex partners, tell them you are getting treated for a STI so they can get treated too.

It's important that you understand this information. We are happy to answer your questions.

Treatment of Genital Warts

(affiliate name and telephone number)

What are genital warts?
Genital warts are skin-colored bumps that can look like small pieces of cauliflower. In women, they are most common around the opening of the vagina and in the vagina. In men, they are most common on the shaft or tip of the penis and on the scrotum. In women and men, they also can be found on the skin around the anus. Rarely, they are found inside the rectum or urethra.

What do they feel like?
Most of the time there are no symptoms. Sometimes there is bleeding, burning, discomfort during sex, or itching.

How did I get them?
Genital warts are caused by a virus called the human papilloma virus (HPV). There are more than 100 kinds of HPV. Most genital warts are caused by two kinds. These viruses go from one person to another by skin touching skin — usually during sex.

What are my choices for treatment?
You could do nothing. The body's immune system often kills the virus. If so, the warts go away with no treatment. That's why some people choose to just wait for the warts to go away on their own. But you may choose to have them treated. If you are pregnant, your doctor or nurse may decide that the warts may get in the way of delivery and that they should be removed before your labor begins.

We have listed, below, the different treatments for genital warts. Some of them may not be available at this clinic. Your doctor or nurse will help you decide which method is best for you based on where the warts are located and how large an area they cover. Even if the warts go away with treatment, they may return. This is because the treatments can remove the warts, but they don't cure the virus that causes warts.

Chemicals Put On by a Doctor or Nurse
Some chemicals can be put on warts to destroy them or stop their growth. Acids such as **bichloroacetic acid (BCA)** and **trichloroacetic acid (TCA)** and a chemical called **podophyllin** are used to remove warts. They must be put on by a doctor or nurse at the clinic. They are usually put on once a week for several weeks. If podophyllin is used, you should wash it off 4 hours after it was put on. Podophyllin should not be used by women who are, or might be, pregnant.

All of these chemicals are easy to use, don't cost much, and work well for 6 out of 10 people who use them. There may be burning for a few minutes after the chemicals are put on the warts. You may have redness, pain, itching, or swelling.

Chemicals You Can Put on Yourself
Podophylox (Condylox) is a chemical that you can put on yourself. Be sure to follow the instructions that come with it. Put it on 2 times a day for 3 days in a row. Don't put any on for the next 4 days. You can repeat this one-week cycle until the warts are gone but no more than 4 times. It should not be used by women who are, or might be, pregnant

Imiquimod (Aldara) and **sinecatechin ointment (Veregen)** are prescription creams that you can put on yourself. Be sure to follow the instructions that come with your medicine.

- Aldara should be put on 3 times a week, for example, on Monday, Wednesday and Friday, or Tuesday, Thursday and Saturday. It is usually put on at bedtime. It should be washed off 6 to 10 hours later. Use it until the warts are gone but for no longer than 16 weeks. Side effects are burning or irritation of the skin.

- Veregen should be put on 3 times a day to each wart. The medicine should not be washed off. Don't have sex while the cream is on the skin, or wash it off first and then put it back on when you're done.

  This medicine may weaken latex condoms and diaphragms. Use it until the warts are gone, but for no longer than 16 weeks. Side effects are redness, itching, burning, or irritation of the skin.

Both Aldara and Veregen are very good at getting rid of warts. They cost a lot, and some health insurance may not pay for them. But you won't have to make multiple visits to the clinic. Be sure to wash your hands after using them. Safety in pregnancy is not known. If you think you might be pregnant, be sure to let your doctor or nurse know.

Cryotherapy (freezing)
Another treatment is freezing the warts. A very cold liquid is put on by the doctor or nurse.
Several treatments may be needed. Cryotherapy works in more than 7 out of 10 people. It is safe for pregnant women. There is usually some mild burning when cold is first put on the warts. After treatment, sores or blisters may form and cause mild discomfort or itching. The area heals in about a week. Rarely, there is scarring of the skin.

Electric cauterization destroys warts. It burns them with electricity. A shot of numbing medicine usually is given first. There can be pain afterward, until healing is complete. Healing takes 2-4 weeks. There is a small chance of bleeding or infection in the area that is treated. Rarely, there is scarring of the skin. Cauterization works very well. It is safe for pregnant women.

Excision cuts the warts off with a sharp knife or a thin wire with electricity passing through it — a procedure called LEEP. Excision works for more than 7 out of 10 people. It is used mostly for warts that don't get better with other treatments. A shot of numbing medicine usually is given first. Stitches may be needed to repair the area that has been cut. Problems such as bleeding, infection, pain, or scarring only occur occasionally.

Laser is a high-energy beam of light that can destroy warts. It works very well. It costs a lot and usually must be done in a hospital. It is used for very difficult cases only.

After Treatment
- Keep the area clean and don't scratch it.
- Wash your hands after touching the warts.
- Don't have sex if it is uncomfortable.
- Cold compresses may make you feel better. You may take acetaminophen (Tylenol) or ibuprofen (Advil, Motrin, etc.).

How can I keep from giving genital warts to others?
The best way is not to have any kind of sexual contact, so the warts do not touch someone else's skin. Using a condom every time reduces the chance of giving HPV to a new partner. If you or your partner has genital warts, using condoms may make the warts go away faster. If you and your partner have been together for a while, both of you have been exposed to HPV. Once the warts have healed, it is probably not necessary to use condoms unless one or both of you have other partners.

Warning Signs — Call the clinic if you have any questions or any of the following

- a temperature of 100.4ºF or higher that lasts more than 4 hours
- heavy bleeding or bleeding for a long time
- a bad odor or yellow discharge
- pain that doesn't go away with acetaminophen

Affiliate name and address

EMERGENCY TELEPHONE NUMBER XXX-XXX-XXXX

Treatment of Molluscum

(affiliate name and telephone number)

You have been diagnosed with molluscum contagiosum. Before we treat it, you need information about it and the options for treatment. You also need to know the possible benefits and risks of each type of treatment. We are happy to answer your questions.

What is molluscum contagiosum?
Molluscum contagiosum is a kind of poxvirus. Poxviruses affect the skin. Molluscum causes small bumps. There is often a tiny depression or dimple in the middle of each bump. The bumps may be found anywhere on the skin. They are usually seen on the main body, the inner thighs, and the genitals. In women, they can appear around the opening of the vagina. In men, they can appear on the shaft of the penis and on the scrotum. In women and men, they sometimes occur on or near the anus.

What are the symptoms?
Usually, there are none. Sometimes, the bumps get itchy.

How did I get them?
It is usually by contact with an infected person. Scratching or other irritation may cause them to spread.

How are molluscum treated?
They usually go away with no treatment. It can take a few months. That's why a lot of people choose to just wait for them to go away on their own. But you may choose to have them treated.

There are different ways to treat molluscum. We may not have some of the ways at this health center. Your clinician will help you decide which method is best for you.

One way is to take out the material inside the bump. First, we may inject medicine to numb the area. Then, we open up the top of the bump. After that, we scrape or squeeze out the viral material that's in the middle of the bump. This is a very effective way to treat the infection. And it's not too painful. But it may cause mild scarring.

Some chemicals can be applied to molluscum to destroy them or stop their growth. One is called **bichloroacetic acid (BCA)**. Another is called **trichloroacetic acid (TCA**). Both are commonly used to treat genital warts. Either one may be used. They must be applied by a clinician. Several treatments, one or two weeks apart, may be needed.

These chemicals are easy to use and usually effective. There are side effects. There is likely to be mild to moderate burning for a few minutes after they are applied. Redness, pain, itching, or local swelling may last for a while, but are usually mild. There may be some mild scarring.

Imiquimod (Aldara) is a cream you can get by prescription. You apply it at home. It gets your body's immune system going so it can destroy the virus. You apply it three times a week, until the bumps are gone. You can do it on Monday, Wednesday, and Friday, for example. Or Tuesday, Thursday, and Saturday. It is usually applied at bedtime. It should be washed off six to 10 hours later. You can use Aldara for up to 16 weeks. Be sure to read the instruction sheet that comes with it.

Aldara is effective. It is expensive. Side effects are burning or irritation of the skin. Be sure to wash your hands after applying Aldara.

Cryotherapy (freezing)
Molluscum can be destroyed by freezing them. A very cold liquid, like liquid nitrogen, is used in one of two ways. It can be put directly on the bumps. Or it can be put in a metal instrument that is held against the bumps for a minute or two. Several treatments may be necessary. Freezing is usually effective. There is usually some mild burning when the cold is first applied. Afterward, sores or blisters may form. They can cause mild discomfort or itching. The area heals in about a week. Only rarely is there scarring of the skin.

What should I do after treatment?
- Keep the area clean. Use a different towel for drying other parts of your body after a shower or a bath.
- Don't scratch the treated area.
- Wash your hands after touching the areas.
- Avoid having sex if it is uncomfortable.
- Apply cold compresses to relieve discomfort, or you may take acetaminophen (Tylenol) or ibuprofen (Advil, Motrin, etc.)

Warning Signs — Call the health center if you have any questions or any unusual or unexpected symptoms, such as
- fever (a temperature of 100.4º F or higher) that lasts more than four hours
- redness or pain that doesn't go away in one or two days
- pain that can't be relieved with acetaminophen or ibuprofen

affiliate name and address

EMERGENCY TELEPHONE NUMBER XXX-XXX-XXXX

Vulvar Biopsy

(affiliate name and telephone number)

Before having a vulvar biopsy to diagnose or remove an abnormal area on your vulva, you need to know the possible benefits, risks, warning signs, alternatives, and special instructions. We have listed them here for you. We are happy to answer your questions.

What is a vulvar biopsy?
A vulvar biopsy takes one or more small samples of tissue from the vulva. The vulva is a woman's external sex organs, including the inner and outer lips, the opening to the vagina, and the clitoris. Sometimes the area is washed with a solution to highlight abnormal changes in the tissue. Then it may be viewed with a colposcope, which is like binoculars. Before the biopsy, numbing medicine is injected in the area where the sample will be taken. The sample is taken by making a small cut on the surface. Occasionally, a stitch or suture is needed.

The sample is sent to a lab. It is examined under a microscope by a doctor. The test results are sent to Planned Parenthood. We will contact you to let you know them.

Reasons for vulvar biopsy
It is done to find out why an area on the vulva looks abnormal. The cause could be non-cancerous, precancerous, or cancerous. Sometimes, the biopsy is also used to treat the abnormality. In such a case, the whole abnormal area is removed. This is called excision. It usually removes a bigger area than a regular biopsy does.

What will the biopsy feel like?
Most women feel burning or stinging when the numbing medicine is given. There may be slight spotting (bleeding) from the area after the sample is taken — especially if more than one biopsy is taken.

Benefits
Biopsy is a more certain way than visual inspection to find out the cause of many conditions. More certain results can make for a better treatment plan. It also is an effective way to remove an abnormal area.

Risks
To have a serious problem from a vulvar biopsy is unusual. There may be bleeding or infection. In very rare cases, test results will be wrong. No exam or test is 100 percent accurate. So there can be no guarantee that a diagnosis is always correct.

Warning Signs — Call the health center if you have
- fever or chills
- more tenderness, redness, or swelling after the first 24 hours
- foul-smelling drainage from the area

Alternatives
No other procedure can give you or your clinician the same information. Alternatives to excision may include putting medicine on the area, cryotherapy (freezing) and electrocautery (burning).

After a vulvar biopsy
- Keep the area as clean and as dry as possible.
- Avoid irritating the area for the first two or three days. If the area will be irritated during intercourse, abstain for two or three days to let it heal.
- Take other medicines as usual — including the pill.
- You may shower or bathe as soon as you want. Pat the area dry gently with a towel.
- You may use a tampon, unless you are told otherwise.

Further Treatment
Treatment depends on test results. Sometimes no additional treatment is necessary. If treatment is needed, we can usually provide it at Planned Parenthood. If you need more specialized care than we can provide, we will refer you to another physician for further management.

Client Signature Date

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature Date

Testing Your Semen

We need to test your semen to tell whether or not you are able to cause a pregnancy. This test is called semen analysis. It tells us three things:

- how many sperm are in your semen
- how many of them move
- how many of them look normal

Here's how to collect your semen:

- Don't have sex — including masturbation — for 2 or 3 days before making a sample. Going without sex for more or less time may make the test come out wrong.
- Put your full name, date of birth, and the time and date you make the sample on the side of the cup we give you. Don't touch the inside of the cup.
- Wash your hands and penis before you begin to masturbate.
- Do not use oil or lubricant.
- Ejaculate [ee-jak-yoo-late] or "come" into the cup we give you. Try to get it all in the cup. Do not use a jar or bottle from home.
- If any semen spills, let us know. Don't try to put spilled semen into the cup.
- Do not come into a condom. This will make the test come out wrong.
- Bring the sample to the clinic or laboratory within 2 hours. Keep it close to your body to keep it at body temperature. (Don't put it in a bag or purse).

Please fill this out and bring it with your sample:

Name_____ Partner's name_____

Date of birth_____ Phone number for results _____

Date sample was made _____ Time sample was made_____

Have you had a fever over 100ºF for longer than 24 hours in the last 3 months? □ Yes □ No

Number of days of going without sex and masturbation before making sample_____

Did all of the semen get in the cup? □ Yes □ No

List any prescription or over-the-counter drugs that you have taken during the last 3 months_____
_____

List any street drugs that you have taken during the last 3 months
_____

Healthy Relationships

Romantic or sexual relationships are one way to connect and share with other people. They can make you very happy, but they can also be difficult. It's important to remember that relationships can be unhealthy, or even unsafe. Knowing about what makes healthy relationships can help you decide if yours is good for you.

As part of a healthy relationship, you have the right to

- be treated with kindness
- be with your friends or family when you want to be
- wear what you want to wear
- feel safe and respected
- go only as far as you want to go with touching, kissing, or doing anything sexual.
- get pregnant when you want to be
- speak up if you feel controlled, such as getting too many texts, phone calls, or posts about you on Facebook or other sites

Healthy and happy relationships make you feel better about yourself and your place in the world. Unhealthy relationships can make you feel unhappy and unsafe. If you are in an unhealthy relationship, you are not alone and you do deserve better.

People choose to end relationships for many reasons.

- Your relationship may make you uncomfortable or unhappy.
- You may not feel ready to be in a relationship.
- You may have to end a good relationship because circumstances make the relationship too difficult — for example, if one person has to move far away from the other.
- You are not safe. If you are planning to end your relationship because you are being abused, remember that it is best to have a safety plan. You can get more information and support from The National Domestic Violence Hotline: www.thehotline.org or 1-800-799-7233.

Benign Prostatic Hyperplasia (BPH)

What is BPH?

BPH is a problem that can affect your prostate gland, which is just below the bladder. As you age, your prostate slowly gets bigger. When it does, it may press on your urethra (the tube that takes urine from your bladder to outside your body).

What are the symptoms of BPH?

Most symptoms start slowly. They include

- more urinating at night or during the day
- longer for the urine flow to begin
- dribbling from the penis before and after urinating or at other times

More than one of these symptoms may mean that you have BPH. But they can also be caused by other things. They may be signs of more serious diseases, such as a bladder infection or bladder cancer.

How do I find out if I have BPH?

- Your doctor or nurse will talk with you about your symptoms.
- The next step is a digital rectal exam (DRE). A doctor or nurse uses a gloved finger and some lubricant to check the lower part of the rectum that is near the prostate gland. It lets your doctor or nurse feel the size of your prostate gland.
- Your urine may need to be tested for signs of infection.
- You may also need to have a blood test.
- Your doctor or nurse may refer you to a specialist for more testing, if needed.

How is BPH treated?

- **Watchful waiting –** This means you don't have treatment right away and wait to see if your symptoms change. You can try treatment later if your symptoms start to bother you more.
- **Medicines -** Some men are helped with medicine. Some medicines relax the bladder muscles to make it easier to urinate. Others block the hormone that makes the prostate get bigger.
  - The side effects of treatment are rare and mild. Some men have
    - less sexual desire
    - trouble getting hard and staying hard
    - trouble urinating when they feel the need to go
  - It is important to talk to your doctor or nurse about any problems you get after starting medicine. Side effects will go away when the medicine is stopped. But the prostate may also get bigger again so you may need a different treatment.
- **Surgery –** If medicines do not work, you may be referred to a specialist to discuss the option to have surgery. There are different kinds of surgery to treat BPH.

What can I do on my own to feel better?

You may be able to improve your symptoms by

- Drinking less fluids, especially just before bed
- Limit alcohol and caffeine. These drinks make you urinate more often.
- Avoid cold and allergy medicine that have antihistamines or decongestants.
- Try "double voiding" – after you urinate, wait a moment, relax, and try to urinate again.

Erectile Dysfunction (ED)

What is ED?
ED can mean that a man can't get hard enough to have sex. Or it can mean that he can't stay hard enough to finish having sex. Most men who have ED are 65 or older. But it can happen at any age.

Is ED just a part of old age?
No. It doesn't have to be a part of getting older. It's true that older men need more direct touch — like stroking — to get hard. They may also need more time between erections. But older men should still be able to get hard and enjoy sex. And some younger men have problems with ED, too.

What causes ED?
The causes include

- hardening of the arteries (atherosclerosis), which also causes heart disease and stroke
- chronic liver or kidney disease
- diabetes — high blood sugar
- hypertension — high blood pressure
- hypogonadism — low testosterone, a male hormone
- many kinds of medications
- relationship issues
- stress
- use of alcohol, tobacco, or other drugs

How can I find out the cause of my ED?
Your doctor or nurse will ask you some questions and do a physical exam. They will check to see if you have any medical problems or are taking any medicines that might be causing it. You may need blood and urine tests. Other tests may also be needed.

How is ED treated?
It's usually treated with medicine. Not all men can use these medicines. If there is no health risk for you we may offer you a pill — like Viagra, Levitra and Cialis — to help you get and stay hard.

What other choices do I have?
You have other options if the medicines aren't right for you. You could try using a vacuum pump device. There are also treatments that are injected into the penis or inserted into the urethra. Some men are helped by talking to a mental health specialist. Or you could have surgery. Your doctor or nurse may refer you to a urologist to talk about your choices.

Premature Ejaculation (PE)

What is premature ejaculation?
It is when a man comes before he wants to. It also usually happens before a man's partner has an orgasm. It is the most common sexual problem for men under 40. And nearly 1 out of 3 men in the U.S. has it.

There's nothing to worry about if premature ejaculation happens once in a while. But, it is considered a sexual dysfunction if it happens in more than half the times a man tries to have sex. Getting treatment may be helpful in these cases.

What causes premature ejaculation?
We know that it is not caused by disease or infection. And we know that it is not caused by anything to do with the nervous system. It is generally considered to have a psychological or emotional cause.

How is premature ejaculation treated?
There are many different ways. Not all of them work for all men:

- Counseling or psychotherapy
- Sex therapy with a certified therapist
- Stress reduction with a certified therapist
- Prescription medications that can lengthen the time before orgasm
- Limiting the use of alcohol and other drugs
- Using relaxation and breathing exercises
- Timed masturbation exercises that are done with dry hands and include slowing and stopping help some men learn to stay hard without ejaculation.
- Getting used to masturbating with a partner
- Trying "pause and squeeze" during sex. With this method, a man stops having sex and presses behind the tip of the penis when he feels like he is going to ejaculate. After the feeling goes away, he continues to have sex.

Skin Biopsy

(affiliate name and telephone number)

What is a skin biopsy?

A very small piece of skin – the biopsy - is sent to the lab to find out if you have a skin disease or to remove the problem.

How is it done?

It is done in the clinic. The doctor or nurse will clean your skin. The area is numbed with a shot of medicine. A very small cut is made and a piece of skin is taken. Sometimes a stitch is needed.

The biopsy will be sent to the lab for testing by a doctor. The lab will send the results back to the clinic. We will let you know what the results show.

What are the benefits of a skin biopsy?

- A biopsy can find out if there is cancer or what problem you have and what kind of treatment you need.
- It can remove the problem area.
- It can make the area look better.

What are the risks of a skin biopsy?

It is unusual to have a serious problem from a skin biopsy. You may have

- pain at the time of the biopsy
- rarely, bleeding, or infection, that needs treatment
- scarring
- allergy to the numbing medicine

A biopsy is like other tests. It can sometimes give a wrong result.

What are my other choices?

There is no other test that can give you the same information. You can choose to **not** have the biopsy. Without a biopsy, you won't know for sure what is wrong. You can choose to have your doctor or nurse check the area regularly.

After the biopsy

- Keep the area clean and dry. You may shower.
- Change the Band-Aid or dressing, if you have one, after you clean the area.
- If you have stitches, return to the clinic when you were told to have them removed.

Warning Signs — Call the clinic if you have

- severe swelling, pain, bleeding, redness, or warmth where the biopsy was taken
- fever of 100.4° or higher
- foul-smelling drainage from the area

Further Treatment

Treatment depends on test results. Sometimes, no further treatment is needed. If it is, your doctor or nurse will make a plan with you.

Affiliate Name and Address

EMERGENCY TELEPHONE NUMBER XXX-XXX-XXXX

Client Signature Date

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature Date

Tests For Prostate Cancer

(affiliate name and telephone number)

What is the prostate gland?

The prostate gland is under the bladder in men. It makes part of the semen.

What is prostate cancer?

- An overgrowth of the prostate gland.
- It is a common cancer — 1 in 6 men will develop it in their lifetimes, most after 50 years old. Most men with prostate cancer do not die from it.
- It is more common in African-American men than in white men.

What is the PSA test?

- It is a blood test.
- PSA is short for prostate-specific antigen. It is made by the prostate gland.
- It is sometimes used to find cancer of the prostate gland before there are symptoms. Men who have prostate cancer may have more PSA in their blood than other men.
- Other less serious problems can cause the PSA to go up too. They are
  - when the prostate gland gets bigger (common as you get older)
  - when there is inflammation (swelling)
  - when there is infection

What is the Digital Rectal Exam (DRE)?

- An exam of the rectum. A doctor or nurse uses a gloved finger and some lubricant to check the lower part of the rectum that is near the prostate gland.
- It is used to feel for a lump in the prostate or anything else unusual about the prostate.

Who should get the PSA test and/or the DRE?

- Men who have symptoms of a prostate problem should be tested. Symptoms include
  - problems urinating
  - blood in the urine or semen
  - suddenly and then continuing to have a problem getting hard
- Men who should consider getting the PSA test are
  - men who have a close relative who had prostate cancer — when they are 45 or older
  - African American men - when they are 45 or older
  - All other men - when they are 50 or older
- A doctor or nurse can help you make this decision.

What are the possible benefits of testing?

It may help find cancer earlier.

What are the possible harms of testing?

The test result could be wrong (false positive or false negative) and that could lead to anxiety and more tests.

What will happen if the PSA test is not normal?

It depends on your personal medical history and exam, as well as the level of your PSA. Your doctor or nurse may

- treat you with medicine if they think you have an infection and then repeat the PSA test
- refer you to a specialist to have further tests

Whether or not you decide to get a PSA test or DRE is up to you. We are happy to answer your questions.

Where can I get more information?

- The National Cancer Institute: http://www.cancer.gov/cancertopics/pdq/screening/prostate/Patient
- American Cancer Society: http://www.cancer.org/Cancer/ProstateCancer/MoreInformation/ProstateCancerEarlyDetection/index

Ectopic Pregnancy

What is an ectopic pregnancy?
An ectopic pregnancy is a pregnancy outside of the uterus (usually in the fallopian tube). The tube can rupture (break) when it is stretched too much by the growing pregnancy. This can cause bleeding, which in some cases can lead to death,

Why does it happen?
We do not know the cause, but it is more common in women who have scarring of the fallopian tubes from infection or surgery. Women who have had an ectopic pregnancy in the past are at higher risk for another ectopic.

What are the signs and symptoms of an ectopic pregnancy?
A woman with an ectopic pregnancy might have the symptoms of normal pregnancy (missed period, nausea, and breast tenderness). More commonly, she will have vaginal bleeding and lower abdominal pain; especially on one side. If there is internal bleeding, the abdominal pain will get worse and sometimes will cause shoulder pain, dizziness or fainting.

What should I do if I think I have an ectopic pregnancy?
If you have severe pain or bleeding, go to the emergency room. Otherwise, call the clinic or the 24-hour emergency number XXX-XXX-XXXX.

Treatment
Sometimes medications can be given to try to end the pregnancy. Other times, surgery will be needed.

Miscarriage

What is a miscarriage?
A miscarriage is the loss of a pregnancy before 20 weeks. It is common. Ten to 20 percent of all pregnancies end in miscarriage.

What are the different kinds of miscarriage?

- **Threatened Miscarriage —** You bleed, with or without mild cramps, but your cervix (the opening to the uterus, or womb) is closed. In half of the cases, the pregnancy ends; in the other half the pregnancy continues.
- **Inevitable Miscarriage —** Your bleeding increases, and the cervix begins to open. In this case, miscarriage is certain.
- **Incomplete Miscarriage —** Some pregnancy tissue passes out of the uterus. But some stays inside. Sometimes treatment is needed to remove the remaining tissue.
- **Complete Miscarriage —** All the pregnancy tissue is passed. Treatment is usually not needed.
- **"Missed" Miscarriage (also known as Missed Abortion) —** You have no cramps or bleeding. But ultrasound shows an embryo without a heartbeat or an empty pregnancy sac without an embryo. Usually the tissue passes, but treatment is sometimes necessary or preferred.

How would I know if I was having a miscarriage?
Usually you will have cramps and bleeding. Your pregnancy test will be positive. Sometimes there is no bleeding and if you did feel pregnant, you don't anymore. Sometimes you find out during an ultrasound.

What usually happens during a miscarriage?
You will most likely have bleeding and cramping.

Bleeding may be heavy. You may pass large blood clots the size of a lemon. If bleeding continues, the pregnancy will often pass on its own. The bleeding usually decreases after the pregnancy tissue has passed.

Cramps are a normal part of miscarriage. Some women feel stronger cramps than other women. Cramping will ease after the pregnancy tissue has passed.

A miscarriage can cause many emotions. You may feel sadness, guilt, or have other emotional reactions. Sometimes the feelings are so strong that you may have trouble doing your normal activities. Call us if this happens. We can help or refer you to someone who can.

Will I see the embryo or fetus during the miscarriage?
You may or may not. Before 8 weeks, the embryo is small and will look white or tan in color. You may not notice it with the bleeding and clots. If the pregnancy is 8 weeks or more, you may see the fetus. At 8 weeks, it is about 1/4 to 1/2 an inch long.

What causes miscarriage?
We don't know what causes most miscarriages. Miscarriage is almost never caused by something you did. Having sex, minor injuries such as falling, and most medications do not affect a normal pregnancy, and they do not cause miscarriage.

Things we do know that can cause miscarriage include
- When the fertilized egg has an abnormal number of chromosomes (genes).
- Certain illnesses, such as severe diabetes (sugar), are more likely to cause a miscarriage.
- A very serious infection or a major injury may cause miscarriage.
- Late miscarriages – after 3 months – may be caused by abnormalities in the uterus, such as those caused by fibroid tumors.

Women who have had more than 2 miscarriages in a row are also at higher risk of miscarriage.

How do you treat a miscarriage?
There are 3 ways. You can
- **Do nothing and wait and see** if the pregnancy passes on its own. How long it takes varies. It can take up to a week or more, depending on your situation.
- **Use medication(s)** to help make the pregnancy pass. Medications such as misoprostol and/or mifepristone can be used to treat miscarriage. They make the uterus contract and pass the pregnancy tissue. Medications often work faster than doing nothing or waiting and seeing.
- **Have a suction procedure.** It empties the uterus with gentle suction and is done by a doctor. It is the quickest way to complete the miscarriage, and works the best.

What is the best treatment?
It depends on what you want and your specific situation. Each option has different benefits and risks. In general, if you wait and see or use medications, you have a greater risk of needing a suction procedure or emergency care than if you had a suction procedure to begin with. We will talk with you about all the options and give you more information to help you choose.

Your health is important to us. If you have any questions or concerns, please call us at XXX-XXX-XXXX. We are happy to help you.

Molar Pregnancy

Your doctor or nurse has referred you for further testing and/or treatment because you may have a molar pregnancy.

What is a molar pregnancy?
In a molar pregnancy, the placenta does not grow normally. There are two other medical terms for it. One is "gestational trophoblastic disease." The other is "hydatidiform mole."

There are two types of molar pregnancy. In one, an abnormal placenta grows and an embryo never forms. This is called a "complete mole." In the other, an abnormal placenta grows with an embryo, but the embryo is not normal and cannot survive. This is called a "partial mole." About one out of 1,000 pregnancies in the U.S. is a molar pregnancy.

What causes a molar pregnancy?
It is caused by problems during fertilization (when the egg and sperm meet).

How is a molar pregnancy diagnosed?
These tests can tell you that you may have a molar pregnancy:

- Ultrasound
- Blood pregnancy test

Only looking at the pregnancy tissue with a microscope can tell for sure.

How is a molar pregnancy treated?
Most of the time, a doctor or nurse empties the uterus, and no further treatment is needed. About 10% of the time, molar tissue may remain and continue to grow. This is called persistent gestational trophoblastic disease (GTD), and is a kind of cancer. This is why it is important you come back for a follow-up to make sure that no further treatment is needed.

What kind of follow-up will I need?
Your doctor or nurse will ask you not to get pregnant for at least one year. During that time, you will have blood tests to make sure that no molar tissue is still growing.

Can I have a normal pregnancy after a molar pregnancy?
Yes, you can. The chance of having another molar pregnancy is one or two out of a hundred. There is no reason that you could not have a perfectly normal pregnancy and delivery after your year of follow-up is over.

Positive Pregnancy Test – No Pregnancy Seen On Ultrasound

You have had a positive urine pregnancy test and we have done an ultrasound to find out how many weeks pregnant you are.

What did the ultrasound show?
When we did your ultrasound, the doctor or nurse was unable to see the pregnancy inside your uterus.

Why couldn't the doctor or nurse see the pregnancy?
- You could have a very early pregnancy that is too early to see with our ultrasound. This is the most common reason (75-80% of the time).
- You could be pregnant but may be having a miscarriage. This happens in about 10-20% of pregnancies.
- You could have an ectopic pregnancy, where the pregnancy is outside of the uterus (usually in the fallopian tube). The tube can rupture (break) when it is stretched too much by the growing pregnancy. This can cause bleeding which in some cases can lead to death. This happens in 1-2% of pregnancies.
- Last, the pregnancy test could be wrong and you are not pregnant. This is rare, and happens less than 1% of the time.

Do I need more tests or treatments?
Because an ectopic pregnancy can be life threatening, we recommend further testing at this time. We recommend:
- Having two blood tests 48-72 hours apart to help us see if you have a normally growing pregnancy, are having a miscarriage, or have an ectopic pregnancy.
- Returning to the clinic for a repeat ultrasound in _____ days.
- Having a more detailed ultrasound done outside of Planned Parenthood to get more information about your pregnancy.
- Seeing a doctor outside of Planned Parenthood for more tests and/or treatment.

What are the signs and symptoms of an ectopic pregnancy?
A woman with an ectopic pregnancy might have the symptoms of a normal pregnancy (missed period, nausea, and breast tenderness). More commonly, she will have vaginal bleeding and lower abdominal pain, especially on one side. If there is internal bleeding, the abdominal pain will get worse and sometimes will cause shoulder pain, dizziness or fainting.

What should I do if I think I have an ectopic pregnancy?
If you have severe pain or bleeding, go to the emergency room. Otherwise, call the clinic or the 24-hour emergency number XXX-XXX-XXXX.

Taking Care of Yourself - Miscarriage

Here are general instructions about what to expect and how to take care of yourself if you've chosen have a suction procedure, take medicine, or to wait and see to treat your miscarriage. If you're taking medicine for your miscarriage, follow the directions given to you with the pills. We've also included instructions for handling an emergency if one occurs.

What should I do to prepare?

- buy maxi pads and pain medicine (e.g., ibuprofen/Advil or acetaminophen/Tylenol) to use during and afterwards
- fill any prescriptions you were given
- plan for your family or friends to help you

What should I expect at home?

If you had a suction procedure:
Plan on relaxing for the rest of the day. Don't drive if you had any sedation. Some vaginal bleeding is normal. It may be different from your period. It is normal to have no bleeding, spotting that lasts up to 6 weeks, heavy bleeding for a few days, or bleeding that stops and starts again. You may have cramps. Use a heating pad or hot water bottle, take pain medication (like Tylenol or Motrin), and rest.

If you are taking medicine:
Follow the directions you were given in the clinic. It explains what you will feel, what will happen, and what you can do to feel better.

If you decided to wait and see:
Follow the directions you were given in clinic. It explains what you will feel, what will happen and what you can do to feel better.

Whether or not you have symptoms, it is important to return to the clinic in a week. If you decide you want a suction procedure or to take medicine, let us know.

How do I take care of myself after a miscarriage?

- **Daily Activities —** You may go back to your usual activities as soon as you feel up to it. Strenuous activity may increase bleeding. Do **NOT** do hard work or heavy exercise for several days. This includes swimming, lifting heavy things, bicycling, or jogging. If you bleed heavier than a period, rest and decrease your activities.
- **Tampons or Pads —** Using pads makes it easier to tell how much you're bleeding. When the bleeding is lighter, you can use tampons if you wish.
- **Sex —** We recommend that you wait one week after miscarriage before you have sex again.
- **Trying to Get Pregnant Again —** We can talk with you about how long to wait before you try to get pregnant again. If you have had two or more miscarriages in a row, we can talk with you about the possibility of testing for problems that may cause miscarriage
- **Avoiding Pregnancy** — You can get pregnant again within 2 weeks of having a miscarriage. If you don't want to get pregnant again right away, you should start your birth control as you were told by the clinic staff. We can help you if you haven't chosen a method yet.

EMERGENCIES

Call our 24-hour emergency number at XXX-XXX-XXX if ANY of these things happen. Do not wait for your follow-up visit.

- You have a fever of 100.4°F or higher for more than 24 hours.
- You soak more than 2 maxi pads an hour for more than 2 hours.
- You pass "big" (larger than the size of a lemon) blood clots for more than 2 hours.
- You bleed heavily for more than 12 hours in a row.
- You can't eat or drink for more than 4 to 6 hours.
- Pills, rest, a hot water bottle, or heating pads don't help with abdominal pain or cramps.
- You are weak, feel sick-to-your stomach, have abdominal pain or discomfort, throw up, or have diarrhea for more than 24 hours. All of these could be signs of serious infection.

If you need to call, tell us

1. How many maxi pads you have used in the past hour (60 minutes).
2. The phone number and name of an "open" drugstore that you can get to.
3. Your temperature (fever) in the past hour (60 minutes).

If you have not spoken to a doctor or nurse 20 minutes after you call, or if you feel you are too sick to wait, go to the nearest emergency room or call 911.

Make an appointment to see us as soon as possible, or call the clinic if you

- have a bad smelling vaginal discharge
- still feel pregnant

Keep your follow-up appointment if one was scheduled for you.

Your health is important to us. If you have any questions or concerns, please call us at XXX-XXX-XXXX. We are happy to help you.

Treatment of Miscarriage: Medication (Misoprostol)

(affiliate name and telephone number)

What medicine is used to treat miscarriage?
The medicine is called misoprostol. It works by opening the cervix and making the uterus contract to pass the pregnancy.

Before deciding to use misoprostol, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits?
- It is safe and effective.
- Using medication may help complete the miscarriage faster than doing nothing.
- It can help you avoid a suction procedure.

What are the side effects?

Side effects usually do not last long. They usually need little or no treatment.
- **Cramping is expected —** It is the worst in the first few hours after you take the misoprostol. Milder cramps may last a day or 2 after that.
- **Bleeding is expected —** It will be the worst soon after taking the misoprostol. You may bleed or spot for 4 to 6 weeks after the abortion.
- **Fever —** Having a temperature of 99-100°F is okay. It should only last a short time.
- **Other —** It is common to have diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness. They usually lighten up 3 days later. They usually stop within 2 weeks.

Can I breastfeed?
Misoprostol can pass into your breast milk in small amounts after you take it. These amounts shouldn't cause any problems for you or your baby. Tell your doctor or nurse if you're breastfeeding so you can work out the best plan together.

What are the risks?
There are risks with all medical procedures, including all of the options for managing miscarriage. Your risk may be higher if you have had a c-section or uterine or abdominal surgery.

The risks of using misoprostol are
- The bleeding may last a long time or become heavy.
- Heavy bleeding may make you anemic (low iron).
- If the uterus does not fully empty, you will need a suction procedure.
- Any tissue remaining in your uterus may become infected.

These risks, compared to those of a suction procedure, increase the chance of needing hospitalization, emergency suction, and transfusion. Risk of death is very rare.

Besides taking misoprostol, what other options do I have?

- You can wait and see if the pregnancy will pass on it's own.
- You can have a suction procedure.
- You can use the abortion pill.

Which option is best for you depends on your individual situation. If you decide you want to try a different option, let us know. We can talk about any of these options with you, and help you with whatever you decide to do.

What else do I need to know?

We will give you instructions on how to take care of yourself. We will give you a time to return to Planned Parenthood for a follow-up visit.

No promise can be made about the outcome of your treatment. In the unlikely event that you need emergency medical care that cannot be provided at Planned Parenthood, you will be responsible for paying for it. This is the case even if Planned Parenthood sends you to another doctor or hospital because of a problem.

Your health is important to us. If you have any questions or concerns, please call us at XXX-XXX-XXXX. We are happy to help you.

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

Treatment of Miscarriage: Suction Procedure

(affiliate name, and telephone number)

What is a suction procedure?
Suction is used to take the pregnancy out of your uterus (womb). Other surgical tools may be used. How the procedure is done depends on how long you've been pregnant and how much tissue is in your uterus.

Before having a suction procedure, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits?
- It is safe and effective.

What are the side effects?
Side effects don't usually last long and don't need to be treated. Call us if the problem doesn't go away or you are worried. Common side effects are
- light or medium bleeding. If your bleeding is very heavy — soaking more than 2 maxi pads for 2 hours in a row, contact us.
- cramping
- feeling tired (usually from anesthesia and/or pain medications)

Besides a suction procedure, what other options do I have?
- You can "wait and see" if the pregnancy will pass on its own.
- You can use medication.

Which option is best for you depends on your individual situation. If you decide you want to "wait and see" or use medication instead, let us know. We can talk about any of these options with you, and help you with whatever you decide to do.

What are the risks of the suction procedure?
The procedure is very safe. But, there are risks with any medical procedure. Your risk may be higher if you
- are not healthy
- have had a c-section or certain other surgeries

Risk also goes up the longer you are pregnant and if sedation is used.

Risks linked with the procedure are:
- **Incomplete abortion —** This means some of the pregnancy tissue may be left inside the uterus (womb). This may lead to heavy bleeding, infection, or both. If this happens, a procedure may need to be done again. Other tests or treatments may be needed.
- **Blood clots in the uterus —** Clots may cause cramping and belly pain. A procedure may need to be done again.
- **Infection of the uterus —** Most infections can be found and treated with medicines. But, there is a small chance that a suction procedure may need to be done again. You may have to go to the hospital, or even have surgery to treat the infection.

(continued on page 2)

- **Heavy bleeding (hemorrhage) —** This may require treatment with medicine, a repeat procedure, blood transfusion, and/or surgery — including possible hysterectomy (removal of the uterus).
- **Injury to the cervix (opening to the uterus) —**This may be treated with medicine or rarely with stitches
- **Injury to the uterus or other organs —** A surgical tool may go through the wall of the uterus, which could damage organs inside the body like the intestines, bladder, or blood vessels. Treatment may mean just watching and waiting for a while or surgery on your belly. There is a small chance that hysterectomy (removal of the uterus) may be needed. Scars may develop inside the uterus, which may need to be treated.
- **Allergic and/or drug reaction —** Some women may be allergic to the local anesthetic (numbing medicine) or to other medicines used. It is important that you tell us about all medicines you are allergic to. Also, tell us about any medicines you are taking. We need to be sure they are safe to mix with medicines we give you.
- **Death** — Death from the procedure is very rare. The risk of death goes up the longer you are pregnant.
  - When a procedure is done when a woman is less than 20 weeks pregnant (about 4 ½ months), the risk of death from a full-term pregnancy or childbirth are higher than the risk of the procedure. After 20 weeks of pregnancy, the risks are about the same.

What will be done to get me ready for the suction procedure?

Education and Consent — A staff person will

- talk with you about your medical history
- tell you about the procedure
- answer any questions you have
- get your written consent (permission) for you to have the procedure.

Laboratory Tests — You will have:

- a pregnancy test (if an ultrasound doesn't show a pregnancy in the uterus)
- a blood test to check your Rh factor - a protein on the outside of red blood cells
- a blood test to see if you have anemia (low iron)
- other tests your doctor or nurse thinks you need

Ultrasound — You may need an ultrasound. It can help tell how long you've been pregnant. A probe (like a wand) will be placed on your abdomen (belly) or into your vagina to get a picture of the pregnancy.

Physical Exam — You will have your blood pressure taken and have a pelvic exam. You may get other exams if the doctor or nurse thinks you need them.

Review — A doctor or nurse will talk to you about your medical history, exams, and any tests you had to decide if the procedure can be done at Planned Parenthood.

Pain Medicine — A staff person will tell you about pain medicines that can be used. You will be given written instructions to read and sign if you are going to get medicine to make you relaxed or drowsy during the procedure.

Opening (Dilating) Your Cervix — Your cervix may need to be opened (dilated) before your procedure. If so, you will be given separate information about the medicine and/or steps that will be taken to open your cervix.

What will happen to me during the procedure?
You will be given pain medicine. You may get medicine to numb your cervix. You and your doctor or nurse will talk about what other medicines you may need to help with pain and discomfort during your abortion.

After your pain medicine begins to work, your doctor or nurse will decide if your cervix is ready (open enough). If your cervix needs to be dilated (opened) more, your doctor or nurse will stretch it with dilators.

When your cervix is stretched open enough, the contents of your uterus (womb) are taken out with suction. Suction is used by putting a small plastic tube into your uterus and connecting it to a hand-held or electric suction machine. Surgical tools may be put into the uterus through the opening in the cervix. The way it is done will depend on how long you were pregnant.

You may feel cramping during and after the procedure as your uterus gets smaller. Your doctor or nurse may also use a curette (a thin surgical tool) to remove the pregnancy. What has been removed will be looked at to help make sure the procedure is finished

What will happen to me after the procedure?
You will be taken to a recovery area for rest. We will also watch to see if you are OK. You will be given instructions on what to expect and how to care for yourself. We will talk about birth control plans or planning your next pregnancy, unless this was already done.

When you feel comfortable, in about 30 minutes or so, you may leave. You may need someone to drive you home. This depends on if you had medicine to make you relaxed or drowsy during the abortion.

What else do I need to know?
You will be given instructions on caring for yourself after your procedure and information on when to come back to us if you are having a problem.

No promise can be made about the outcome of your procedure. In the unlikely event that you need emergency medical care that cannot be provided at Planned Parenthood, you will be responsible for paying for it. This is the case even if Planned Parenthood sends you to a hospital because of a problem.

Your health is important to us. If you have any questions or concerns, please call us at XXX-XXX-XXXX. We are happy to help you.

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

Treatment of Miscarriage: The Abortion Pill

(affiliate name and telephone number)

What is the abortion pill and how do I take it?

"Abortion pill" is a popular name for a medicine called mifepristone. It is the first pill you will take to start the process.

After you take the abortion pill, you need to take a second medicine called misoprostol. It opens the cervix and makes the uterus contract. This empties the uterus and completes the process.

There are a few different ways to take these medicines. There is the way approved by the FDA. Other ways to take the medicines have been studied. You might take a different amount of medicine. When you take the medicine might be different. These other ways are also safe and are usually more effective than the FDA way. We will give you instructions on how to take your pills. It is important to follow these instructions.

Before you take the abortion pill, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

What are the benefits?

- It is safe and effective.

What are the side effects?

Side effects usually do not last long. They usually need little or no treatment.

- **Cramping is expected —** It will be the worst after you take the misoprostol. Milder cramps may last a day or 2 after that.
- **Bleeding is expected —** It will be heaviest soon after taking the misoprostol. You may bleed or spot for 4 to 6 weeks after the abortion.
- **Fever —** Having a temperature of 99-100°F is okay. It should only last a short time.
- **Other —** It is common to have diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness. They usually lighten up 3 days later. They usually stop within 2 weeks.

Can I breastfeed?

Both misprostol and mifepristone can pass into your breast milk in small amounts after you take it. These amounts shouldn't cause any problems for you or your baby. Tell your doctor or nurse if you're breastfeeding so you can work out the best plan together.

Besides the abortion pill, what other options do I have?

- You can "wait and see" if the pregnancy will pass on its own.
- You can have a suction procedure.
- You may be able to take other medicines for treatment of your miscarriage.

Which option is best for you depends on your individual situation. If you decide you want to try a different option, let us know. We can talk about any of these options with you, and help you with whatever you decide to do.

What are the risks?
Using the abortion pill is very safe. But, there are risks with any medical procedure. Your risk may be higher if you are not healthy.

Risks linked with the abortion pill are

- **The pregnancy doesn't end —** Sometimes the medicines do not end the pregnancy. You may be able to "wait and see". Or you will need to take additional medicines or have a suction procedure in a clinic or a hospital.
- **Incomplete abortion —** This means some of the pregnancy tissue may be left inside the uterus (womb). This may lead to heavy bleeding, infection, or both. If this happens, you may need a suction procedure in a clinic or a hospital. Other tests or treatments may be needed.
- **Blood clots in the uterus —** Clots may cause cramping and belly pain. You may need a procedure if that happens.
- **Bleeding too much or too long —** This may require treatment with medicine, a suction procedure, or a blood transfusion.
- **Infection of the uterus —** Most infections can be found and treated with medicines. But, there is a small chance that you may need a suction procedure. You may have to go to the hospital, or even have surgery to treat the infection.
- **Allergic reaction —** Some women are allergic to the medicines that are used.
- **Death —** Death from the abortion pill is very rare. The risk of death from a full-term pregnancy and childbirth is much greater.

What else do I need to know?
We will give you instructions on how to take care of yourself. We will give you a time to return to Planned Parenthood for a follow-up visit.

No promise can be made about the outcome of your treatment. In the unlikely event that you need emergency medical care that cannot be provided at Planned Parenthood, you will be responsible for paying for it. This is the case even if Planned Parenthood sends you to another doctor or hospital because of a problem.

Your health is important to us. If you have any questions or concerns, please call us at XXX-XXX-XXXX. We are happy to help you.

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

Treatment of Miscarriage: Doing Nothing or "Wait And See"

(affiliate name and telephone number)

What is choosing to do nothing or "wait and see"?
Choosing to do nothing or "wait and see" means you will wait to see if the pregnancy passes on its own. This is also called "expectant management."

Before deciding to wait and see, you need to know the most common benefits, risks, and other choices you have. We are happy to answer any questions you have.

What are the benefits?
Waiting to see if the pregnancy passes on its own may help you avoid having a procedure or using medication. Some women consider this more natural.

What other options do I have?
- You can have a suction procedure.
- You can use medication.

The best option for you depends on what you want and your own situation. If, at any time, you want a suction procedure or want to use medication instead, call us. We are here to help you.

What are the risks?
There are risks with all medical procedures, including all of the options for treating miscarriage.

The risks of if you choose to wait and see are
- It may take a week or more for the pregnancy to pass on its own.
- The bleeding may last a long time or become heavy.
- Heavy bleeding may make you anemic (low iron).
- If the uterus does not fully empty you may need a suction procedure.
- Any tissue remaining in your uterus may become infected.

These risks, compared to those of a suction procedure, increase the chance you will need to go to the hospital, have an emergency suction procedure, or have a blood transfusion. The risk of death is very low.

What will happen if I wait and see?
You can expect several things to happen during a miscarriage.

- **Bleeding —** You will begin to bleed. You may bleed heavily and pass large blood clots. They may be the size of a lemon. Bleeding can last for several hours. If you are over eight weeks into your pregnancy, you may see pregnancy tissue. The fetus is small and about ¼ to ½ inch in size. It is light tan in color. It may not be noticed with the bleeding and clots. The bleeding usually begins to ease after the pregnancy tissue has passed.
- **Cramps —** You will start to have cramps. Some women feel stronger cramps than other women. Cramping will get better after the pregnancy tissue has passed. It can last for several hours. Pain medicines such as acetaminophen (Tylenol) and ibuprofen (Motrin) can help. **DO NOT** take aspirin, because it may increase bleeding. Other things can help you to be comfortable:
  - Have back rubs.
  - Put a hot water bottle or heating pad on your abdomen.
  - Sit on the toilet.
  - Stand in the shower.

What else do I need to know?
You will be given instructions on caring for yourself while you wait and see and information on when to come back for follow-up.

No promise can be made about the outcome when you choose to wait and see. In the unlikely event that you need emergency medical care that cannot be provided at Planned Parenthood, you will be responsible for paying for it. This is the case even if Planned Parenthood sends you to a hospital because of a problem.

Your health is important to us. If you have any questions or concerns, please call us at XXX-XXX-XXXX. We are happy to help you.

Client Signature _____ Date _____

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature _____ Date _____

(Note: Highlighted data points are from Barnhart Nov 2004. Intermediate points are smoothed by hand)

If initial hCG is…	Repeat hCG on indicated day should be less than…					
	Day 2	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
250	198	164	141	124	111	101
300	234	195	162	144	126	114
350	273	224	186	165	144	126
400	308	252	208	180	156	136
450	347	279	230	198	171	153
500	379	303	251	213	185	162
550	418	336	275	237	204	171
600	450	360	294	252	216	180
650	488	390	319	267	228	195
700	518	413	336	280	238	203
750	555	443	360	300	255	218
800	592	464	376	312	264	224
850	621	493	400	332	281	238
900	657	513	414	342	288	243
950	722	532	437	361	304	257
1000	723	559	447	368	308	262
1100	792	605	495	407	341	286
1200	852	660	528	432	360	300
1300	923	702	559	455	377	312
1400	980	742	602	476	392	322
1500	1056	800	628	506	415	346
1600	1120	848	672	544	448	368
1700	1190	901	697	561	459	374
1800	1242	936	738	594	486	396
1900	1311	988	760	608	494	399

If initial hCG is…	Repeat hCG on indicated day should be less than…					
	Day 2	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
2000	1381	1031	798	634	513	422
2100	1449	1092	840	672	546	441
2200	1518	1122	858	682	550	451
2300	1564	1173	897	713	575	460
2400	1632	1200	912	720	576	480
2500	1701	1256	961	755	605	492
2600	1768	1300	988	780	624	520
2700	1836	1323	1026	810	635	540
2800	1876	1372	1036	812	644	546
2900	1943	1421	1073	841	667	551
3000	2016	1476	1119	872	692	558
3250	2178	1593	1203	910	715	618
3500	2310	1680	1260	980	770	630
3750	2475	1800	1350	1013	788	675
4000	2638	1903	1423	1093	856	680
4250	2805	1998	1530	1148	893	723
4500	2925	2115	1575	1170	900	743
4750	3088	2185	1663	1235	950	760
5000	3249	2319	1715	1302	1009	793

Induced Abortion

Following induced abortion by a suction procedure or mifepristone/misoprostol, hCG levels are expected to decline by 50 percent in 48-72 hours. Retained trophoblastic tissue or an ectopic pregnancy **must** be considered in women whose hCG does not decline by at least 50 percent in 24-48 hours following evacuation.

Symptomatic Women with a Viable Intrauterine Pregnancy

In women who experienced first-trimester bleeding or pain suggestive of a miscarriage or an ectopic pregnancy, but who were ultimately found to have a viable intrauterine pregnancy, hCG levels rise a minimum of 53 percent in 2 days and a minimum of 88 percent in three days. See following table. A rise in hCG of less than 53 percent in 48 hours or 88 percent in 72 hours suggests an abnormal pregnancy and should prompt intervention to distinguish an ectopic pregnancy from a failed intrauterine pregnancy. In the Standards for evaluation for ectopic pregnancy and the algorithm above, these minimum cut points are rounded to a 50% rise in 2 days and a 100% rise in 3 days to simplify calculations.

hCG Rise in Viable Symptomatic Pregnancies

	% Increase in hCG from Baseline		
Percentile	**1 day later**	**2 days later**	**3 days later**
1	24	53	88
5	31	71	123
10	35	81	144
50	50	124	235
99	81	228	494

(Barnhart, et al. 2004)

Complete Spontaneous Abortion

In symptomatic women with a nondiagnostic ultrasound ultimately found to have a complete spontaneous abortion, hCG levels decline a minimum of 21-35 percent in 2 days and 60-84 percent in 1 week, depending on the initial hCG level, as shown in the following table:

Expected Decline in hCG Levels in Women with Complete Spontaneous Abortion

Initial	**Percent Decline — 95th percentile**					
hCG (mIU/ml)	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
250	21	34	44	50	56	60
500	24	39	50	57	63	68
1,000	28	44	55	63	69	74
1,500	30	47	58	66	72	77
2,000	31	48	60	68	74	79
2,500	32	50	62	70	76	80
3,000	33	51	63	71	77	81
4,000	34	52	64	73	79	83
5,000	35	54	66	74	80	84

(Barnhart, et al. 2004)

A rate of decline less than the 95th percentile, e.g., 21-35 percent at 48 hours, 34-54 percent at 72 hours or 60-84 percent at one week, depending on initial level, suggests an intrauterine pregnancy with retained trophoblastic tissue or an ectopic pregnancy. To determine the maximum level for a repeat hCG that is consistent with a spontaneous abortion, use the table in Appendix A or calculate it as follows: Multiply the initial hCG by the expected minimum percent decline (as a decimal) from the table above for the day the hCG is repeated and subtract that value from the initial hCG. If the repeat hCG is higher than the calculated result, the decline is inappropriate.

Example

Initial hCG = 1000
Repeat hCG done on day 3
Initial hCG x expected % fall on day 3
1000 x 0.44 = 440
Initial hCG – 440
1000 – 440 = 560
hCG on day 3 should be less than 560

Ectopic Pregnancy

hCG curves in ectopic pregnancy can be unpredictable, but usually rise more slowly than in a viable intrauterine pregnancy or fall more slowly than in a complete spontaneous abortion. Seventy-one percent of women with an ectopic pregnancy will have hCG levels that rise less than the minimum rise for a viable pregnancy or that fall more slowly than the minimums for spontaneous abortion as described above (Seeber and Barnhart 2006). If hCG levels rise or fall at rates beyond these minimum thresholds and the client is asymptomatic for ectopic pregnancy, she can continue to be followed.

Twenty-one percent of women with an ectopic pregnancy will have a rise in hCG greater than the minimum for a viable pregnancy, and 8 percent will have a fall greater than the minimum for spontaneous abortion (Seeber and Barnhart 2006). In the absence of a gestational sac on ultrasound, there is no way to completely distinguish an ectopic from an intrauterine pregnancy based solely on hCG curves. Therefore, clients who meet the criteria for expectant management are likely to include some with ectopic pregnancies. Clinicians **must** be alert to the signs and symptoms of ectopic pregnancy and refer promptly if they occur. If hCG levels do not rise or fall as expected, the client **must** be referred for ectopic management or a suction procedure **must** be performed. As long as hCG levels rise by less than 50 percent in 48 hours or 100 percent in 72 hours, one can intervene with a suction procedure or methotrexate management of ectopic pregnancy without fear of disrupting a normal pregnancy. Affiliates may opt to choose a different threshold based on comfort level, the ability of clinicians to obtain prompt consultation, etc. If a higher percentage rise is used, more clients with viable intrauterine pregnancies will be referred for ectopic management. If a lower level rise is used, care for more clients with ectopic pregnancies will be delayed.

Symptoms of Early Pregnancy

Your body goes through many changes when you become pregnant. While most of these changes lead to symptoms that are normal and expected, others may warn of a problem.

Some pregnant women have just a few or even none of these symptoms. This is also normal.

What are normal symptoms of early pregnancy?

- Feeling pressure or mild cramps in your lower belly that are similar to your period
- Light spotting from your vagina without cramps or belly pain
- Frequent urination (peeing more often)
- Feeling tired and sleeping more than usual
- Soreness and / or swelling of your breasts
- Changes in mood
- Mild nausea and vomiting
- Whitish or milky discharge from your vagina
- Heartburn or an upset stomach
- Bloating
- Constipation (trouble moving your bowels)
- More headaches than usual
- Mild dizziness or feeling lightheaded

When should I call my doctor or nurse?

Call your doctor or nurse **immediately** if you have any of the following symptoms. If you cannot speak to them right away, go to the emergency room.

- Pain in your lower belly (usually only on one side) and/or shoulder pain
- Severe belly pain that does not go away
- Heavy bleeding from your vagina (heavier than your period)

Call your doctor or nurse if you have the any of the following symptoms:

- Severe nausea
- Vomiting more than 2 or 3 times in one day
- Any bleeding from your vagina
- Dizziness that does not go away
- Fainting (passing out)
- Pain when you urinate
- Severe headache
- Discharge from your vagina with unusual color or smell
- Fever higher than 100.4°F

If your client lives in close proximity to one of these agencies, they can call the agency directly to request further adoption information or counseling.

California

Adoption Connection
1710 Scott Street
San Francisco, CA 94115
800.972.9225
Text 415.355.4636
info@adoptionconnection.org
www.adoptionconnection.org

Adoption Choices
1469 Humboldt Road, Ste 200
Chico, CA 95928
530.891.1911
Spanish: 800.714.8151
adoptionchoices@cawhs.org
www.womenshealthspecialists.org/our-services/adoption/aboutus

Sacramento
1442 Ethan Way, Suite 10
Sacramento, CA 95825
916.451.0621
Spanish: 800.714.8151

Redding
1901 Victor Avenue
Redding, CA 96002
530.221.0193
Spanish: 800.714.8151

Santa Rosa
3317 Chanate Rd Suite 2C
Santa Rosa, CA 95404
707.537.1171
Spanish: 800.714.8151

Independent Adoption Center
5777 W. Century Blvd., Suite 1450
Los Angeles, CA 90045
1.800.877.6736
www.adoptionhelp.org

San Francisco Bay Area
391 Taylor Blvd., Suite 100
Pleasant Hill, CA 94523
925.827.2229

Colorado

Adoption Options
13900 E. Harvard Avenue, Suite 200
Aurora, CO 80014
303.695.1601
info@adoption-options.com
www.adoption-options.com/

Connecticut

Adoptions From The Heart
703 Hebron Ave 1st Fl
Glastonbury CT 06033
860.657.2626
michaelinab@afth.org
www.afth.org

Delaware

Adoptions From The Heart
18-A Trolley Square
Wilmington, DE 19806
302.658.8883
michaelinab@afth.org
www.afth.org

District of Columbia

Adoptions Together
900 Varnum, NE
Washington, DC 20017
202.526.4802

Georgia

Independent Adoption Center
2060 East Exchange PL, Suite 140
Tucker, GA 30084
404.321.6900

Illinois

The Cradle
2049 Ridge Avenue
Evanston, IL 60201
Text: 312.800.1559
1.800.272.3534
cradle@cradle.org
www.cradle.org

Indiana

Independent Adoption Center
5162 E Stop 11 Road, Suite 1
Indianapolis, IN 46237
317.887.2015

Iowa

Avalon Center
22 N. Georgia, Suite 102
Mason City, IA 50401
641.422.010
leah@avaloncenter.us
www.avaloncenter.us

Maryland

Adoptions Together
10230 New Hampshire Avenue
Ste. 200
Silver Spring MD, 20923
301.439.2900
info@adoptionstogether.org
www.adoptionstogether.org

Baltimore
5750 Executive Drive, Suite 107
Baltimore, MD 21228
410.869.0620

Michigan

Hands Across The Water, Adoption & Social Services
781 Avis Drive, Suite 200
Ann Arbor Michigan 48108
734.477.0135
info@hatw.org
www.hatw.org

New Jersey

Spence-Chapin Services to Families
57 Union Place
Suite 212
Summit, NJ 07901
800.321.5683
helpline@spence-chapin.org
www.spence-chapin.org

Adoptions From The Heart
451 Woodland Ave
Cherry Hill, NJ 08002
856.665.5655
michaelinab@afth.org
http://www.afth.org

New York

Spence-Chapin Services to Families
410 East 92nd Street
New York, NY 10128
212.369.0300
helpline@spence-chapin.org
www.spence-chapin.org

Long Island
1363 Veterans Memorial Hwy
Suite 40
Hauppauge, New York 11788
631.979.5863
amy.silverman@spence-chapin.org

Friends in Adoption
653 Plank Road, Suite 208
Clifton Park, NY 12065
800.844.3630
dawn@friendsinadoption.org
www.friendsinadoption.org

North Carolina

Independent Adoption Center
11030 Raven Ridge Rd, Suite 109
Raleigh, NC 27614
Phone: 919.676.6288
www.adoptionhelp.org

Ohio

Adoption Circle
One Americana, Suite 304
400 South Fifth, Columbus, OH 43215
614.237.7222
info@adoptioncircle.org
www.adoptioncircle.org

Choice Network
1258 Grandview Ave, Suite B
Columbus, OH 43212
866.989-1466
molly@choicenetworkohio.com
www.choicenetworkohio.com

Oregon

Open Adoption & Family Services
Portland
5200 SW Macadam #250
Portland, OR 97239
503.226.4870
information@openadopt.org (www.openadopt.org)

Eugene
315 West 10th Ave.
Eugene, OR 97401
Phone: 541.343.4825

Medford
Phone: 541.608.6134

Bend
Phone: 541.388.2535

Salem
Phone: 503.540.5832

Pennsylvania

Adoptions From The Heart
30-31 Hampstead Circle
Wynnewood, PA 19096
610.642.7200
michaelinab@afth.org
www.afth.org

2212 Union Boulevard
Allentown, PA 18109
610.432.2384

1525 Oregon Pike, Suite 402
Lancaster, PA 17601
717.399.7766

1225 South Main Street, Suite 207
Greenburg, PA 15601
724.853.6533

Rhode Island

Friends in Adoption
26 Simmons St
Newport, RI 02840
800.98.ADOPT
dawn@friendsinadoption.org
http://www.friendsinadoption.org

Texas

Independent Adoption Center
11601 Shadow Creek Pkwy
Suite 111-221
Pearland, TX 77584
404.321.6900

Vermont

Friends in Adoption
44 South Street, PO Box 1228
Middletown Springs, VT 05757
800.982.3678
dawn@friendsinadoption.org
www.friendsinadoption.org

Virginia

Adoptions From The Heart
1407 Stephanie Way, Suite H
Chesapeake, VA 23320
757.361.0008
michaelinab@afth.org
www.afth.org

Adoptions Together
457A Carlisle Drive
Herndon, Virginia 20170
703.689.0404

Washington

Open Adoption & Family Services
Seattle
200 West Mercer St. #E-508
Seattle, WA 98119
206.782.0442
www.openadopt.org

Genetic Counseling and Diagnostic Testing

(affiliate name and telephone number)

Women often wonder about the health of their pregnancies. Some worry about the possibility of birth defects. Some may be especially concerned if they

- have a family history of genetic disorders
- had an abnormal screening blood test or ultrasound (nuchal translucency)
- are older (Certain defects, such as Down syndrome, are more common as women age.)
- have insulin-dependent diabetes
- have taken medications that put the fetus at risk

Your doctor or nurse recommends that you be tested so we can learn more about the health of your pregnancy.

We may offer different tests at different points in your pregnancy. This handout will explain the ones we might recommend.

The tests may include genetic counseling. That is an appointment with a specialist to discuss your personal and family medical history. A genetic counselor may offer more tests that can detect certain problems with the pregnancy. These problems include open neural tube defects, abdominal wall defects, and chromosome abnormalities such as Down syndrome and trisomy 18.

Genetic counselors only make recommendations. You will decide which tests you want to have. You can also decide not to have any. The test results will only apply to this pregnancy.

What tests will be offered?

That depends on the results of your screening test and how far you are in your pregnancy. We may offer genetic counseling, a more detailed ultrasound, chorionic villus sampling (CVS), or amniocentesis.

Who should have genetic counseling?

- women who have a medical or family history of inherited conditions
- women whose partners have a medical or family history of inherited conditions
- women taking certain medicines
- women who have insulin-dependent diabetes
- women whose blood tests and/or age indicate an increased risk of birth defects

What is chorionic villus sampling (CVS)?

It is a test done early in pregnancy. It is usually done in the first nine to 12 weeks. A doctor will use an ultrasound to find the placenta. She will pass a thin tube through the cervix or a thin needle through the abdomen. The doctor will take a tiny piece of tissue from the placenta. It will be examined for chromosomal defects.

Test results are usually ready in a few weeks. They are 98 percent accurate for Down syndrome and other chromosomal defects. They cannot, however, spot neural tube defects like spina bifida. To tell if there are defects like that, we recommend a blood test called a multiple marker, or expanded AFP test. It is done between 15 and 20 weeks of pregnancy.

There is a small risk of miscarriage after CVS. About one to three out of 100 women who have CVS will have a miscarriage.

What is amniocentesis?
Amniocentesis is usually done between 15 and 20 weeks of pregnancy. The doctor uses an ultrasound to locate the fetus and the placenta. She will insert a thin needle through your abdomen. She'll take about three tablespoons of fluid (called amniotic fluid) from your uterus.

Cells from the fetus that float in the fluid can be examined for chromosomal defects, such as Down syndrome. The fluid can also be tested for neural tube defects, such as spina bifida.

The test results are usually ready within a few weeks. They are more than 99 percent accurate in spotting chromosome defects, such as Down syndrome. They also detect nearly all open neural tube defects.

There is a small risk of miscarriage after amniocentesis. Fewer than one out of 100 women who have it will have a miscarriage.

How do I know which test is best for me?
Your genetic counselor will make recommendations. She should be able to offer you detailed information and answer any questions you have about the two tests.

What if the tests show that the fetus has a birth defect?
The doctor and/or genetic counselor will give you information to help you make an informed decision:
- They will talk with you the type of defect that has been found.
- They will talk with you any available treatments.
- They will talk with you about your options for continuing or ending the pregnancy.

Can these tests pick up every type of birth defect?
No. Birth defects may still develop even if the test results are normal.

Clinician's Copy (File in Client's Chart)

Client's Name _____

ID Number _____

Consent/Refusal
Genetic Counseling and Diagnostic Testing

1. I have read this information about genetic counseling and diagnostic testing, or _____ has read it to me.

2. I have learned that genetic testing is intended to detect many different possible conditions. They include open neural tube defects, abdominal wall defects, Down syndrome, or trisomy 18:
   - I know that the tests cannot always spot all of these defects.
   - I know that there are other defects that this test cannot spot.
   - I know that I will need to make a decision about follow-up testing.
   - I know that if the fetus has a defect, the decision to continue or end my pregnancy will be all mine.
   - I know that having a genetic test is voluntary.
   - I know I can refuse any test at any time.

3. I am satisfied with the answers I've been given to my questions.

YES	I would like to be referred for genetic counseling and diagnostic testing. Signed_____Date_____
NO	I don't want genetic counseling and diagnostic testing. Signed_____ Date _____

Client's Copy

Client's Name _____

ID Number _____

Consent/Refusal
Genetic Counseling and Diagnostic Testing

1. I have read this information about genetic counseling and diagnostic testing, or _____ has read it to me.

2. I have learned that genetic testing is intended to detect many different possible conditions. They include open neural tube defects, abdominal wall defects, Down syndrome, or trisomy 18:
   - I know that the tests cannot always spot all of these defects.
   - I know that there are other defects that this test cannot spot.
   - I know that I will need to make a decision about follow-up testing.
   - I know that if the fetus has a defect, the decision to continue or end my pregnancy will be all mine.
   - I know that having a genetic test is voluntary.
   - I know I can refuse any test at any time.

3. I am satisfied with the answers I've been given to my questions.

YES	I would like to be referred for genetic counseling and diagnostic testing Signed_____Date_____
NO	I don't want genetic counseling and diagnostic testing. Signed_____ Date _____

Prenatal Care

(affiliate name and telephone number)

You can help to have a healthy pregnancy by doing the following:

- Come in for all your scheduled checkups.
- Eat well.
- Get enough rest.
- Don't smoke.
- Don't drink alcohol.
- Don't take any drugs that are not ordered by your doctor or nurse.

Please feel free to ask as many questions as you like now and at each of your visits. It can be helpful to make a list of questions you want to ask at each visit.

YOUR FIRST VISIT

Medical History and Physical Exam — You will be asked about your health and any symptoms or problems you may be having now. You will also be asked about your heath in the past and your family's health.

A doctor or nurse will give you a complete physical exam, including a breast and pelvic exam.

Lab Tests — Some tests will be needed during your first visit. Some may need to be repeated later on to help us keep track of your health and the health of your pregnancy. Tests will include

- blood tests for
  - anemia — low iron
  - rubella — German measles
  - syphilis
  - hepatitis B
  - blood group, Rh type, and blood antibodies
  - HIV
- urine tests for
  - infection
  - sugar — diabetes
  - protein
  - street drugs
- Pap tests — to find abnormal cells in the cervix
- tests for sexually transmitted infections - chlamydia and gonorrhea
- other tests for conditions that can be passed on

And we may recommend an ultrasound to confirm the dating of the pregnancy.

YOUR LATER VISITS

You will have visits

- every 4 to 6 weeks for the first 32 weeks
- every 2 to 3 weeks from the 32nd to the 37th week
- weekly from the 37th week until delivery

Checkups may be scheduled more often if necessary.

Your pregnancy will be checked at each visit. The doctor or nurse will

- check your blood pressure, weight, urine (for sugar and protein) and look for swelling
- measure the growth of your belly
- feel your belly to check the position of the fetus
- listen to the heartbeat of the fetus
- update your history
- give you a chance to ask questions

The following tests will also be recommended:

- Blood test(s) and/or ultrasound for birth defects, such as Down syndrome and spinal cord abnormalities
- at 18–20 weeks — an ultrasound to look more closely at the fetus
- at 26–28 weeks — blood tests for diabetes and anemia
- after 28 weeks — swab of the vagina, perineum, and rectum to check for Group B strep infections

You may have other lab tests depending on your medical history.

PROBLEMS DURING PREGNANCY

We will refer you to another health care provider for more specialized care if we believe that high-risk problems have developed for you or your pregnancy. Potential problems include

- abnormal blood tests
- high blood pressure
- heart/lung problems
- bladder/kidney infection
- more than one fetus — twins, triplets, etc.
- diabetes (sugar in blood)
- anemia (low iron) that is not helped by medicine
- sickle cell anemia
- exposure to infection
- threatened miscarriage
- a pregnancy outside the uterus (ectopic)
- bleeding from the vagina
- leaking of fluid from the vagina
- early labor
- possibility of needing a cesarean section
- not gaining enough weight
- not enough fetal growth or fetal movement
- expected due date passes without delivery
- possible birth defect

(Continued on Page 3)

Warning Signs — Call the clinic, X-XXX-XXX-XXXX, right away if you have

- bad headaches, or ones that don't go away
- swelling of the face, hands, feet, or ankles
- vomiting for 24 hours
- vaginal bleeding
- dimness or blurring of vision
- double vision and/or dizziness
- spots before your eyes
- sudden gush or steady trickle of watery fluid from the vagina
- burning or pain with urination
- fever or chills
- suspected labor
- belly pain that doesn't go away or keeps coming back
- rashes or sores
- fainting
- decreasing or no fetal movement after 24 weeks

Call us if you have any of these symptoms, any other emergency, or if you have other questions.

YOUR DELIVERY

There are about 40 weeks in a full-term pregnancy, starting from the first day of your last menstrual period. You will receive more information about delivery and follow-up care throughout your prenatal visits. Your delivery will occur at _____ _____, located at _____.

Your delivery provider will be _____.

You will be given the opportunity to meet your delivery provider before your due date. We will send a copy of your medical record to the hospital about one month before your due date. When you go to the hospital, it is important to remind staff there that your prenatal care was with Planned Parenthood.

You will be told after your delivery when you should return to Planned Parenthood for follow-up care and family planning services.

No guarantee can be made about the outcome of your pregnancy. It is important that you understand the possible problems and warning signs. You will be responsible for paying for all delivery and hospital charges and fees for emergency medical care that cannot be provided by Planned Parenthood — even if Planned Parenthood refers you to another doctor or hospital because of a medical problem.

_____ _____

Client Signature Date

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

_____ _____

Witness signature Date

Screening for Birth Defects

(affiliate name and phone number)

Women are often concerned about the health of their pregnancies. Some worry about the possibility of birth defects. We are offering you screening tests for birth defects. We offer these tests to all women even if there is little chance of a problem. Women who have positive screening tests will then be referred for further evaluation.

There are different screening tests. You can choose them at different points in your pregnancy. This handout will explain the different tests.

We will talk with you about your personal and family medical history. We will recommend tests that can help you have the information you want about your pregnancy. These tests can spot problems such as open neural tube defects, abdominal wall defects, and chromosome abnormalities such as Down syndrome and trisomy 18.

Your doctor or nurse will only make recommendations. You will decide which tests you want to have. You can also decide not to have any. The test results will only apply to this pregnancy.

Questions and Answers about Screening Tests for Birth Defects

Who should consider having screening tests?
All pregnant women should consider having them done. It is the best way to find out if your pregnancy has a high or low risk of certain birth defects. Some women may need genetic counseling. This is an appointment with a specialist to discuss their personal and family medical histories. It is especially important if they or their partners have certain conditions in their medical or family histories that can be passed on to their children. Further tests may also be recommended. Make sure you have talked with your doctor or nurse about your medical and family histories.

What tests will be offered?
That depends on your medical history and how far you are in your pregnancy. We might offer you blood tests and/or a special ultrasound.

How is the blood test done in the first trimester (between 11 and 13 weeks)?
For a first-trimester blood test, we will take a small amount of blood from your arm. The blood will be tested for two proteins made by the placenta and the fetus.

How is the blood test done in the second trimester (between 15 and 20 weeks)?
We will take a small amount of blood from your arm. The blood will be tested for four different proteins made by the placenta and the fetus. This special test can only be done between 15 and 20 weeks of pregnancy. Taking the test before 15 weeks is too early for reliable results. After 22 weeks is too late for most laboratories. The best time is between 16 to 17 weeks.

How is ultrasound used to screen for birth defects?
You may be referred to a specialist when you are between 11 and 14 weeks pregnant. An ultrasound will be used to measure the thickness of the skin at the base of the fetal neck. This test is called a nuchal translucency. It can only be done in conjunction with your first-trimester blood test.

Questions and Answers about the Results of your Prenatal Screening Tests

What does a "screen negative" result mean?
Screen negatives are the most common results. They mean that the risk for *certain* birth defects is so low that further testing isn't needed. Risk is calculated by taking into account a woman's age, the results of her blood tests, certain medical conditions, and the nuchal translucency ultrasound, if it was done.

A screen negative means that there is very little risk. But there is still a small chance that the fetus may have a problem.

What does a "screen positive" result mean?

A "screen positive" test result will mean that you need follow-up tests. Your doctor or nurse will discuss this with you if you have this result. Most women with these results will have normal follow-up tests and healthy babies, too. But they do mean that the risk may be higher than usual for *certain* birth defects. These include neural tube defects, abdominal wall defects, Down syndrome, or trisomy 18.

Most screen positives are *not* caused by birth defects. Other reasons include

- A due date that is earlier or later than thought.
- There is more than one fetus (twins, triplets).
- The proteins in the blood are not at expected levels, but there is no known pregnancy problem.

Clinician's Copy (File in Client's Chart)

Client's name _____

ID number _____

Consent/Refusal
Screening for Birth Defects

1. I have read this information about screening for birth defects, or _____ has read it to me.

2. I have learned that screening for birth defects is intended to spot certain problems with the pregnancy. They include open neural tube defects, abdominal wall defects, Down syndrome, or trisomy 18.
   - I know that the screening tests cannot always spot all of these defects.
   - I know that there are other defects that these tests cannot spot.
   - I know that I will need to decide about follow-up testing if the result is screen positive.
   - I know that, if the fetus has a defect, the decision to continue or end the pregnancy will be all mines.
   - I know that having a test for birth defects is voluntary.
   - I know I can refuse any test at any time.

3. I am satisfied with the answers I've been given to my questions.

YES	I want testing for birth defects Signed_____Date_____
NO	I don't want testing for birth defects Signed_____ Date _____

Client's Copy

Client's name _____

ID number _____

Consent/Refusal
Screening for Birth Defects

1. I have read this information about screening for birth defects, or _____ has read it to me.

2. I have learned that screening for birth defects is intended to spot certain problems with the pregnancy. They include open neural tube defects, abdominal wall defects, Down syndrome, or trisomy 18.
   - I know that the screening tests cannot always spot all of these defects.
   - I know that there are other defects that these tests cannot spot.
   - I know that I will need to decide about follow-up testing if the result is screen positive.
   - I know that, if the fetus has a defect, the decision to continue or end the pregnancy will be all mines.
   - I know that having a test for birth defects is voluntary.
   - I know I can refuse any test at any time.

3. I am satisfied with the answers I've been given to my questions.

YES	I want testing for birth defects Signed_____Date_____
NO	I don't want testing for birth defects Signed_____ Date _____

What You Can Do to Help Lower Your High Blood Pressure

There are several things you can do that can help lower your blood pressure. They might also help to keep you off or come off blood pressure medicines.

Eat a healthy diet

- Eat lots of vegetables, fruits, and whole grains like brown and wild rice, whole wheat bread and pasta, and oatmeal
- Eat fish, poultry, legumes, nuts, and low-fat dairy products.
- Limit sweets, sugary drinks and red meats.
- Cut down on salt. (Called sodium on food labels) Lowering the amount of salt you get by 1,000 mg a day will be helpful.
  - First, make a goal to get no more than 2,400 mg a day of salt.
  - Then cut back even more to 1,500 mg a day or less - this may lower your blood pressure even more.

Nutrition Facts

Serving Size 5 crackers
Servings Per Container 6

Amount Per Serving

Calories 180 Calories from Fat 70

	% Daily Value*
Total Fat 8g	**12%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 390mg	**16%**
Total Carbohydrate 21g	**7%**
Dietary Fiber 4g	**16%**
Sugars 0g	
Protein 5g	

Vitamin A 0% • Vitamin C 0%
Calcium 8% • Iron 15%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Saturated Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Exercise regularly

- Make sure your exercise makes your heart rate go up and you sweat.
- Do it every day for 30 minutes, or you can try 10 minutes 3 times a day.

Lose weight – losing just 10 pounds can help lower blood pressure.

- Talk to your doctor or nurse about a goal weight for you and the best way to reach it.

Limit alcohol - Drinking alcohol can raise your blood pressure and can make your blood pressure medicine not work as well.

- Women should have no more than 1 drink a day.
- Men should have less than 2 drinks a day.

Stop smoking and avoid secondhand smoke

- If you smoke, talk to your doctor or nurse about getting help to quit.

Tips For Losing Weight

Date _____

Today your weight is _____ Your BMI is _____

Overweight is a BMI of 25-29.9. Obese is a BMI of 30 or more.

A Healthy Weight Is Important for Your Health.

Being overweight or obese means you have an increased chance of getting many health problems:

- arthritis
- breathing problems
- diabetes (sugar)
- gallbladder problems
- heart disease
- high blood pressure
- sleep apnea (breathing problems while sleeping)
- some cancers
- stroke

Losing Weight — Getting Started

Start slowly. At first, just try to keep from gaining any more weight. Then set a weight loss goal. Exercise to *burn* calories and improve your diet by eating *fewer* calories. Both can help you to lose. Expect your weight loss to be slow and steady.

Tips for Getting Exercise

- Get at least 30 minutes of physical activity a day at least five days a week.
- Ten minutes of exercise three times a day works as well as 30 minutes all at once.
- Try these five methods — Park farther away in the parking lot. Take the stairs instead of the elevator. Get off the bus, subway, or train a stop early or late. Walk around your house or apartment. March in place.
- Try exercising to a tape or DVD at home. Tapes can be checked out of the library or bought at many stores.
- Some women like to work out with others. You can sign up for classes at your local Y, gym, or recreation center.

Tips for Healthier Eating

- Eat three meals a day, with two small snacks in between.
- Make healthy food choices:
  - Whole grains — Eat whole-grain breads, cereals, crackers, pasta, and rice. Replace white grains with brown grains.
  - Fruit — Eat a variety of fruits: canned, dried, fresh, or frozen. Stay away from fruit juice and fruit drinks.
  - Vegetables — Eat those with more color, such as green vegetables (broccoli, kale and spinach) and orange vegetables (carrots, squash, and sweet potatoes).
  - Protein — Choose lean meats and poultry, or other sources of protein such as tofu, dairy, and legumes (beans). Baking, grilling, and roasting are better than frying.
  - Dairy — Choose low-fat or nonfat cheese, milk, and yogurt. Try lactose-free milk products.
  - Omega-3 fatty acids — Eat enriched eggs, flaxseed, salmon, sardines, and walnuts.
- Stay away from high fructose corn syrup, processed foods, and refined sugars that are found in prepared foods — especially baked goods.
- Cut out fruit drinks, soda, and lots of cream and sugar in your coffee or tea.

Tips For Losing Weight

- Snack on small amounts of healthier foods such as almonds, low-fat yogurt drinks, peanut butter with apples, and protein bars.
- Read labels. If you don't understand the label, don't buy the product.
- Sign up with a national weight loss program such as Weight Watchers®.

Helpful Information

- http://www.choosemyplate.gov/ — ChooseMyPlate offers eating plans and tools to help you plan, make smart food choices, and find your balance between food and physical activity.
- http://www.fruitsandveggiesmatter.gov/

Feminizing (Male to Female) Therapy

(affiliate name and telephone number)

What is Feminizing Hormone Therapy?

Feminizing hormone therapy is medicine to make your body look less like a man and more like a woman. There are two medicines that you might be given.

- **Estrogens** are the main sex hormone in women. Estrogen may be given as a pill that you put under your tongue, as a shot, or as a patch you put on your skin.
- **Androgens** are the main sex hormone in men. A medicine called spironolactone can block the androgens made by your body. It comes as a pill.

Your doctor or nurse may recommend one or both of these medicines.

Every medicine has benefits, side effects, and risks that are important to understand before you take them. Some medicines need to be taken all the time to keep up their effects.

What are the benefits?

Feminizing hormone therapy will make your body look more like a woman.

- You will probably develop breasts.
- Your body hair, beard and moustache will become less noticeable and will grow more slowly. But it won't stop completely, even if you take the medicines for years.
- You will probably have less fat on your belly and more on your butt, hips, and thighs.
- Your skin may become softer.

What are the side effects?

Your body will make less of the male hormone (androgen) testosterone. This can affect your sex life in different ways:

- Your testicles may shrink to half their size. You will still need regular checkups for them.
- Sometimes you may not feel like having sex.
- You may not be able to get hard enough for vaginal or anal sex.
- You won't have as much cum when you come.
- You may be less able to cause a pregnancy.

You may lose muscle and strength in your body.

You might have a milky liquid come from your nipples. If this happens it is important you tell your doctor or nurse so they can check it for you.

What are the risks?

Estrogen can

- harm the liver
- increase the amount of fat and/or cholesterol in the blood
- increase the risk of heart disease
- increase the risk of blood clots in the legs, lungs, or brain (stroke)
- increase blood pressure
- increase the risk of diabetes (sugar)
- increase the risk of gallbladder problems
- cause migraine headaches
- cause pituitary tumors (tumor of small gland in the brain which makes prolactin)

Spironolactone can cause high amounts of potassium (an important mineral in the body) in the blood, which can cause changes in your heartbeat that may be life-threatening. This is rare.

There may be long-term risks that we don't know about.

The risks of estrogen may be higher for people who
- smoke
- are overweight
- are older than 40
- have a history of blood clots
- have a history of high blood pressure
- have a family history of breast cancer

How long does it take the medicine to work?
It can take a month or longer for the medicine to start to work. Some of the changes can take 2-3 years. No one can tell how fast — or how much — change will happen.

How long do I need to take the medicine?
Some of the medicine may need to be taken forever to keep the changes in your body.
The following changes are usually **not** permanent — they will probably go away if you stop taking the medicines:
- changes to your body hair
- changes to your body fat
- changes to your skin

If you lose the hair at the front or top of your head (male pattern baldness), it may slow down, but will probably not stop completely. Hair that you lose will probably not grow back.

If you grow breasts, they will stay, even if you stop taking estrogen.

Can I get someone pregnant?
No one can tell you for sure if you'll be able to cause a pregnancy after taking feminizing hormone therapy.

If you are having vaginal sex with a woman at risk of pregnancy you still need to use some kind of birth control.

If you think you may want to cause a pregnancy in the future, you should talk to your doctor or nurse about storing your sperm.

What are my other choices?
You could do nothing. Other ways to make your body look more like a woman are having surgery and using cosmetic products. Even if you choose surgery, you will need to take feminizing hormone therapy to make or keep some of the changes in your body. If you are interested in other options, talk with your doctor or nurse.

You can choose to stop taking feminizing hormone therapy at any time, if you do that, do it with the help of your doctor or nurse.

I have read and understand the above information regarding feminizing hormone therapy.

I have had the chance to talk about my treatment with a doctor or nurse and all of my questions have been answered.

_____ I want to take estrogen.

_____ I want to take spironolactone.

_____ I do not wish to begin taking feminizing medicine at this time.

Client Signature Date

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature Date

Your health is important to us. If you have any questions or concerns, please call us at XXX-XXX-XXXX. We are happy to help you.

Masculinizing (Female to Male) Therapy

(affiliate name and telephone number)

What is testosterone?
Testosterone is the main sex hormone in men. Taking it will make you look less like a woman and more like a man. It can be given as a shot or put on the skin as a gel, a cream, or a patch.

Every medicine has benefits, side effects, and risks that are important to understand before you take them. Some medicines need to be taken all the time to keep up their effects.

What are the benefits?
Testosterone will make your body look and sound more like a man.

- Your clitoris will get bigger.
- Your voice will become deeper.
- You will grow a moustache and beard.
- Hair on your body will be thicker and darker.
- Your muscles will get bigger and stronger.
- You will stop having a period.
- You will notice less fat on your butt, hips and thighs and more on your belly.

It will also increase your sex drive.

What are the side effects?

- acne
- thicker and more oily skin
- The hair on your head may get thinner or fall out (male pattern baldness).
- mood changes

Your vagina will become smaller and it will be more painful to have vaginal sex.

What are the risks?
Taking testosterone may

- cause problems with your blood count
- increase the amount of fat and/or cholesterol in the blood
- increase the chance of getting diabetes (sugar)
- harm the liver

There may be long-term risks that we don't know about.

The risks of testosterone may be higher for people who

- smoke
- are overweight
- have a family history of heart disease

How long does it take to work?
It can take a month or longer for the medicine to start to work. Some of the changes can take 2-5 years. No one can tell how fast — or how much — change will happen.

How long do I need to take testosterone?
You will need to take the medicine forever to keep the changes in your body. The following changes are usually **not** permanent – they will probably go away if you stop taking the medicine:

- increased sex drive
- changes to your body fat
- changes to your strength

Some of the changes will probably **not** go away even if you stop taking testosterone. These include:

- bigger clitoris
- lower voice
- moustache and beard
- male pattern baldness
- thicker, darker body hair

Can I get pregnant?
No one can tell you for sure if taking testosterone will affect your ability to get pregnant. You could get pregnant or you may never be able to get pregnant in the future, even if you stop the testosterone.

If you have vaginal sex you need to use birth control to prevent pregnancy, just in case. If you do get pregnant, you must stop the testosterone.

What are my other choices?
You could do nothing. Another way to make your body look more like a man is to have surgery. Even if you choose surgery, you will need to take testosterone to make or keep some of the changes in your body. If you are interested in other options, talk to your doctor or nurse.

You can choose to stop taking testosterone at any time, if you do that, do it with the help of your doctor or nurse.

I have read and understand the above information about testosterone therapy.

I have had the chance to talk about my treatment with a doctor or nurse and all of my questions have been answered.

_____ I want to take testosterone.

_____ I do not want to take testosterone right now.

Client Signature Date

I witness that the client received this information, said she read and understood it, and had an opportunity to ask questions.

Witness signature Date

Your health is important to us. If you have any questions or concerns, please call us at XXX-XXX-XXXX. We are happy to help you.

- Create a safe and welcoming environment by
  - ensuring a discrete check- in and check-out area.
  - avoiding traditionally gender-suggestive color schemes (e.g. pink or blue).
  - having reading materials and visuals that are inclusive of the trans community in the waiting room.

- Recognize and respect the client's preferred name, pronoun and gender by
  - ensuring that intake forms and electronic health records provide choices for gender and sex other than just male and female (transgender, other).
  - having a space for 'preferred name' and 'preferred pronoun' on all forms.
  - always referring to transgender persons by their preferred name and the pronoun that corresponds with their gender identity.
  - asking politely for clarification if you are unsure about a person's gender identity, or how they wish to be addressed.

- Ensure that all staff in your office or organization receives transgender cultural competency training and that there is a system for addressing inappropriate conduct.

- Be sure you have at least one gender-neutral (unisex) restroom.

- Create a local trans-friendly resource and referral list.

(Transgender Law Center Health Care Access Project, 2005)
(Planned Parenthood of the Southern Finger Lakes Sexuality Education and Training Center, 2006)

WEIGHT (LBS)

HEIGHT (ft/in)	120	130	140	150	160	170	180	190	200	210	220	230	240	250	260	270	280	290	300	310	320	330
4′5″	30	33	35	38	40	43	45	48	50	53	55	58	60	63	65	68	70	73	75	78	80	83
4′6″	29	31	34	36	39	41	43	46	48	51	53	56	58	60	63	65	68	70	72	75	77	80
4′7″	28	30	33	35	37	40	42	44	47	49	51	54	56	58	61	63	65	68	70	72	75	77
4′8″	27	29	31	34	36	38	40	43	45	47	49	52	54	56	58	61	63	65	67	70	72	74
4′9″	26	28	30	33	35	37	39	41	43	46	48	50	52	54	56	59	61	63	65	67	69	72
4′10″	25	27	29	31	34	36	38	40	42	44	46	48	50	52	54	57	59	61	63	65	67	69
4′11″	24	26	28	30	32	34	36	38	40	43	45	47	49	51	53	55	57	59	61	63	65	67
5′0″	23	25	27	29	31	33	35	37	39	41	43	45	47	49	51	53	55	57	59	61	63	65
5′1″	23	25	27	28	30	32	34	36	38	40	42	44	45	47	49	51	53	55	57	59	61	62
5′2″	22	24	26	27	29	31	33	35	37	38	40	42	44	46	48	49	51	53	55	57	59	60
5′3″	21	23	25	27	28	30	32	34	36	37	39	41	43	44	46	48	50	51	53	55	57	59
5′4″	21	22	24	26	28	29	31	33	34	36	38	40	41	43	45	46	48	50	52	53	55	57
5′5″	20	22	23	25	27	28	30	32	33	35	37	38	40	42	43	45	47	48	50	52	53	55
5′6″	19	21	23	24	26	27	29	31	32	34	36	37	39	40	42	44	45	47	49	50	52	53
5′7″	19	20	22	24	25	27	28	30	31	33	35	36	38	39	41	42	44	46	47	49	50	52
5′8″	18	20	21	23	24	26	27	29	30	32	34	35	37	38	40	41	43	44	46	47	49	50
5′9″	18	19	21	22	24	25	27	28	30	31	33	34	36	37	38	40	41	43	44	46	47	49
5′10″	17	19	20	22	23	24	26	27	29	30	32	33	35	36	37	39	40	42	43	45	46	47
5′11″	17	18	20	21	22	24	25	27	28	29	31	32	34	35	36	38	39	41	42	43	45	46
6′0″	16	18	19	20	22	23	24	26	27	29	30	31	33	34	35	37	38	39	41	42	43	45
6′1″	16	17	19	20	21	22	24	25	26	28	29	30	32	33	34	36	37	38	40	41	42	44
6′2″	15	17	18	19	21	22	23	24	26	27	28	30	31	32	33	35	36	37	39	40	41	42
6′3″	15	16	18	19	20	21	23	24	25	26	28	29	30	31	33	34	35	36	38	39	40	41
6′4″	15	16	17	18	20	21	22	23	24	26	27	28	29	30	32	33	34	35	37	38	39	40
6′5″	14	15	17	18	19	20	21	23	24	25	26	27	29	30	31	32	33	34	36	37	38	39
6′6″	14	15	16	17	19	20	21	22	23	24	25	27	28	29	30	31	32	34	35	36	37	38
6′7″	14	15	16	17	18	19	20	21	23	24	25	26	27	28	29	30	32	33	34	35	36	37
6′8″	13	14	15	17	18	19	20	21	22	23	24	25	26	28	29	30	31	32	33	34	35	36
6′9″	13	14	15	16	17	18	19	20	21	23	24	25	26	27	28	29	30	31	32	33	34	35
6′10″	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	34	35

Underweight:
BMI = less than 18.5

Normal weight:
BMI = 18.5 to 24.9

Overweight:
BMI = 25 to 29.9

Obesity:
BMI = 30 to 39.9

Extreme Obesity:
BMI = 40 and above

GREEN CHOICES
Planned Parenthood

Cleaning Products

Every day we eat, drink, breathe, and touch chemicals that exist around us. The chemicals can affect our health. Planned Parenthood GREEN CHOICES will give you the information you need to make choices for better health and a greener environment — for yourself, your family, and your community.

What should I know about cleaning products used at home or work?

- **Some are full of harmful chemicals and have strong smells.** Some may
  - burn your eyes, nose, or throat
  - give you trouble breathing
  - make you cough
- **Some may have chemicals that could increase your risk of cancer and other health problems.** Products that are most likely to be harmful include
  - drain cleaner
  - oven cleaner
  - toilet bowl cleaner

How can cleaning products affect my health?

- **It depends on**
  - how harmful they are
  - how long you have been near them
  - when in your life you have contact with them
- **Some can disrupt your hormones:**
  - Some may change the start of puberty in young teens.
  - Some may keep your body from making enough thyroid hormone.

- **If you're a *woman*, disrupted hormones may**
  - make it harder for you to get pregnant
  - change the pattern of your monthly period
  - increase your risk of having a miscarriage
  - make it harder for you to carry a baby to term
  - increase your risk of breast cancer
  - cause birth defects in baby boys (penis and scrotum)
- **If you're a *man*, disrupted hormones may**
  - lower your sperm count and make it harder to get a woman pregnant
  - increase your risk of cancer of the testicles

Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

GREEN CHOICES
Planned Parenthood

Cleaning Products

What are some safer ways to clean?

- **Make your own cleaning products.** You can use the following recipes:

- **Oven Cleaner**
  Mix 5 tablespoons baking soda + 3 drops dish soap + 4 tablespoons white vinegar. Apply paste to walls of oven. Scrub, wipe clean, and rinse.
- **Drain Cleaner**
  Pour ½ cup baking soda down the drain. Then pour ½ cup white vinegar down the drain. After the foam settles, rinse drain with boiling water.
- **Toilet Bowl Cleaner**
  Sprinkle bowl with baking soda. Spray with white vinegar. Scrub with toilet brush.
- **Shower Mold and Mildew Remover**
  Mix ½ cup 3 percent hydrogen peroxide + 1 cup water. Spray on area.
- **All-Purpose Cleaner**
  Fill a spray bottle with 1 part vinegar and 1 part warm water. Shake, spray, and wipe with cloth. You can also add a few drops of essential oil to reduce the smell of vinegar.

- **Read product labels.**
  - Stay away from products with labels that say, "caution," "warning," or "danger."
  - Never mix cleaning products.
- **Keep cleaning products away from children and pets.** Call the National Poison Center (1-800-222-1222) if anyone has an accident with one.

Where can I get more information about cleaning products?

- **National Geographic – The Green Guide on Cleaning:** www.thegreenguide.com/home-garden/cleaning
- **Women's Voices for the Earth:** www.womensvoices.org
- **Washington Toxics Coalition:** http://bit.ly/watoxicscleaning

Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

GREEN CHOICES
Planned Parenthood

Fish

Every day we eat, drink, breathe, and touch chemicals that exist around us. The chemicals can affect our health. Planned Parenthood GREEN CHOICES will give you the information you need to make choices for better health and a greener environment — for yourself, your family, and your community.

What do I need to know about fish?

- Fish is high in protein, and eating fish regularly is good for your health.
- Fish can have a lot of harmful chemicals in them.

When is eating fish bad for your health?

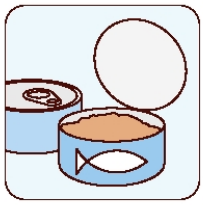
- Eating fish with a lot of harmful chemicals in them can be bad for your health.
- The chemicals can harm everyone. They are more likely to harm
  - young children
  - pregnant women
  - people who are sick
- Here are some of the dangerous chemicals that are often found in certain fish:
  - **Mercury** and **polychlorinated biphenyls (PCBs)** — they can harm
    - the health of a pregnant woman
    - the health of a developing fetus
    - the brains of babies and young children, slowing down mental development
  - **PCBs** can raise your risk of cancer.
  - **Pesticides** may raise your risk of
    - cancers of the blood, brain, and lymph system
    - Parkinson's disease

How can I tell if a fish has lot of harmful chemicals in it?

- You will not be able to tell by looking at it or tasting it.
- Fish markets, grocery stores, and restaurants will still sell it.
- You can view a list of the mercury levels in fish on the Natural Resource Defense Council's website here: **www.nrdc.org/health/effects/mercury/guide.asp**

Be safe:

- **Don't eat**: king mackerel, shark, swordfish, or tilefish.
- **Eat smaller fish**: anchovies, herring, sardines, smelts.
- **Eat smaller portions**, especially fish that may have a lot of chemicals, such as bluefish, dark tuna, and orange roughy.
- **Broil, bake, or grill your fish**. Let the fat, some PCBs, and pesticides drip away. (Deep-frying and pan-frying are not the best ways to cook fish.)
- **Trim the fat** from fish to remove some PCBs and pesticides.
- Find out how much fish is safe for you using a **"Smart Fish Calculator"**: **www.iatp.org/foodandhealth/fishcalculator/**



Be careful with tuna:

- Enjoy canned tuna sometimes, but not every day.
- Tuna steaks have more mercury than canned tuna, so don't eat them as often.
- For a guide on how much tuna is good for you based on your weight, see **"Eating Tuna Safely"**:

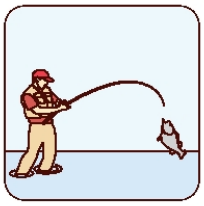
  www.nrdc.org/health/effects/mercury/tuna.asp

Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

GREEN CHOICES
Planned Parenthood

Fish

What do I need to know if I catch the fish myself?

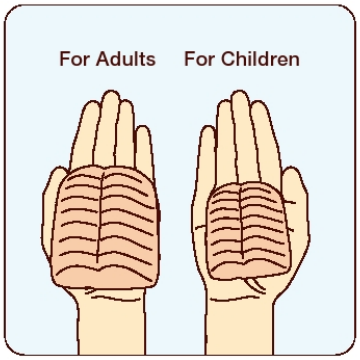


- Many people like to go fishing and share their catch. But even fish you catch yourself may not be safe to eat.

- Always check the local fish advisory. It will tell you what kinds of fish are safe to catch and eat wherever you go fishing. The U.S. Environmental Protection Agency posts local fish advisories. You can check them out at **www.epa.gov/waterscience/fish**

What is a serving?

The recommended serving of fish is about the size and thickness of the palm of your hand. Give children smaller servings.



Where can I get more information?

- The U.S. Food and Drug Administration's "What You Need to Know about Mercury in Fish and Shellfish": **www.epa.gov/waterscience/fish/advice/#what**
- The Environmental Defense Fund seafood website: **www.edf.org/seafood**
- Pocket guide to the best seafood choices in your area: **www.montereybayaquarium.org/cr/seafoodwatch.aspx**
- The Institute for Agriculture and Trade Policy's "Smart Fish": **www.iatp.org/foodandhealth/**

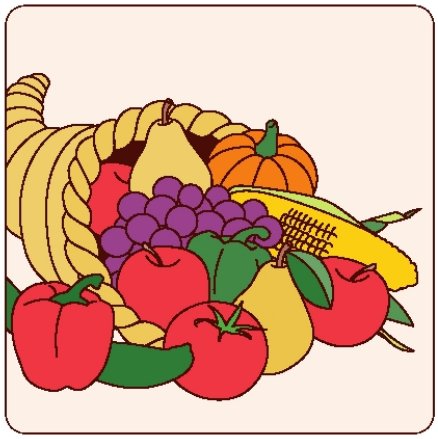
Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

GREEN CHOICES
Planned Parenthood

Fruits & Vegetables

Every day we eat, drink, breathe, and touch chemicals that exist around us. The chemicals can affect our health. Planned Parenthood GREEN CHOICES will give you the information you need to make choices for better health and a greener environment — for yourself, your family, and your community.

What do I need to know about fruits and vegetables?



- Eating fruits and vegetables is **good for your health:**
  - They contain many vitamins and nutrients.
  - They can lower your risk of getting cancer, diabetes, heart disease, and high blood pressure.
- Today, most fruits and vegetables have *pesticides* on them.

What should I know about pesticides?

- Most farmers use pesticides to grow fruits and vegetables.
- Pesticides are used to kill pests, including bugs, rodents, and weeds.
- They are made with thousands of chemicals that can be harmful to your health.
- Pesticides can **disrupt hormones** or **cause cancer** and other health problems.
- They can increase a child's risk of having **birth defects** and **learning disabilities**.

What should I know about pesticides? (continued)

- How much harm may be done depends on
  - how harmful the pesticide is
  - how you come in contact with it — through your skin, breathing it in, or eating it
  - how long you are in contact with it
  - your age — fetuses and very young children are at the highest risk of harm
  - your genes (family history)
  - other pesticides and chemicals with which you've had contact
- The government keeps watch over how pesticides are used, but we all still come in contact with many in fruits and vegetables.

How can I avoid pesticides in my food?

- **Buy ORGANIC produce when you can.**
  - Some farmers grow food without using pesticides or other dangerous chemicals. This is called **organic farming**.
  - Organic fruits and vegetables that meet government standards will have the USDA Organic label shown here:
  - The government guarantees that foods with this label are farmed without
    - pesticides
    - chemical fertilizers
    - sewage sludge
    - bioengineered seed or plants
  - Most of the time, **if a fruit or vegetable is not labeled as organic, it is *not* organic**.

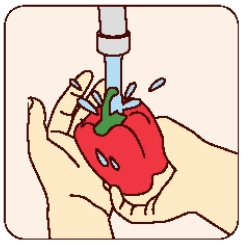
(USDA stands for United States Department of Agriculture.)

Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

GREEN CHOICES
Planned Parenthood

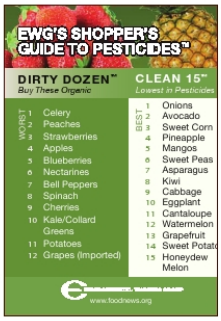
Fruits & Vegetables

How can I avoid pesticides in my food? (continued)



- **Wash**, **scrub**, and **peel** produce before cooking or eating it.

- Check out your local **farmers' market.** Farmers' markets may charge less than grocery stores for organic produce. Go to **www.localharvest.org** to find one near you.
- Since buying all organic produce can be expensive, consider doing so just for the fruits and vegetables that are most toxic. Get the Environmental Working Group's **free shopper's guide** at **www.foodnews.org** to help you.

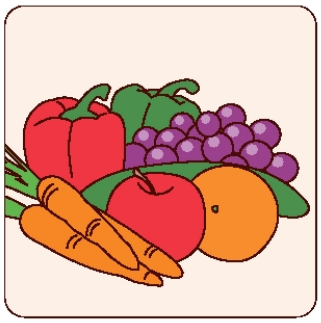


It gives an up-to-date list of the current **"Dirty Dozen"** — foods with so many pesticides that you should always buy organic if you can — and the **"Clean 15"** — foods with so little pesticides that you may not need to buy organic.

- Think about growing your own organic herbs and vegetables. You could start with a small patch or window box.
  - Use pesticides as little as you can, or get rid of pests in natural ways. Go to **www.pestinformation.com** to find natural ways to control pests.

Where can I get more information?

- U.S. Department of Agriculture: **www.usda.gov**
- U.S. Environmental Protection Agency: **www.epa.gov**
- The Advantages of Organic Food — You Are What You Eat: **www.organicfoodinfo.net**
- Environmental Working Group: **www.ewg.org**
- Local Harvest — find organic food at farmers' markets, co-ops, farms, and restaurants near you: **www.localharvest.org**



Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

Getting Enough Calcium and Vitamin D

Why do I need calcium and vitamin D?

Calcium and vitamin D are important because they can

- Help keep bones strong
- Prevent bones from breaking easily, especially bones in the spine
- Help keep teeth healthy and strong

How much calcium and vitamin D do I need?

How much you need changes throughout your life:

- As a teen, you need at least 1300 milligrams of calcium and 600 IU of vitamin D a day.
- As an adult, from age 19-50, you need about 1000 milligrams of calcium and 400 to 800 IU of vitamin D a day.
- After 50, you need at least 1200 milligrams of calcium and between 800 to 1000 IU of vitamin D a day.

How can I get enough calcium?

The best way to get enough calcium is in the food you eat. Dairy is a great source of calcium — try to eat 3 servings of dairy every day. Some vegetables have calcium in them as well. The following foods are good sources of calcium:

- Yogurt (including frozen yogurt), cheese, milk
- Tofu
- Canned salmon
- Spinach
- Kale
- Broccoli

Also, many foods have calcium added to them. Read the labels when you shop for things like bread, cereal, and orange juice.

How can I get enough vitamin D?

Some women can get enough Vitamin D just by being in sunlight (15 minutes, 2 to 3 times a week). You can also get vitamin D from some foods such as

- fatty fish (salmon, tuna or mackerel)
- beef liver
- cheese
- egg yolks
- milk, orange juice, or yogurt with vitamin D added
- cod liver oil

Are there ways to get enough calcium and vitamin D besides from food?

- calcium and vitamin D can be gotten as part of vitamin pills or in separate pills or together in one pill.
- Calcium comes in many forms like pills that you swallow whole, pills that dissolve, chewable pills, and soft chews. Some calcium supplements can be taken with food, others should be taken on an empty stomach. Certain types need to be taken multiple times a day.
- Antacids like Rolaids and Tums also have calcium.

Talk to your doctor or nurse about whether you need supplements and if so, which type is best for you.

GREEN CHOICES
Planned Parenthood

Lead

Every day we eat, drink, breathe, and touch chemicals that exist around us. The chemicals can affect our health. Planned Parenthood GREEN CHOICES will give you the information you need to make choices for better health and a greener environment — for yourself, your family, and your community.

What do I need to know about lead?

- Lead is a very harmful poison if it gets into your body. Even a tiny amount can be dangerous.
- Damage from lead poisoning
  - can last forever
  - can go on without any signs and not show up for many years
- Just a little lead poisoning can
  - Make it more likely for you to have a heart attack or stroke.
  - Make it harder for you to think, learn, and remember.
  - Make it harder for you to get rid of body wastes when you pee.
  - Make miscarriage more likely.

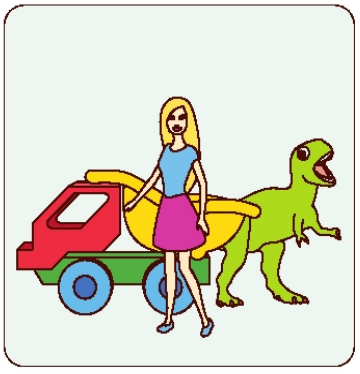
- Very young children are at the greatest risk.
  - **Very small amounts** of lead in their bodies can make it hard for them to learn, pay attention, and do well in school.
- **Small amounts** can cut down the number of blood cells in their bodies.
- **Bigger amounts** can damage their kidneys, nervous system, and other major organs.
- **Even bigger amounts** can lead to seizures or even death.

Where am I likely to come in contact with lead?

- **At home** — Lead can be in paint, dust, soil, air, and water. Homes built before 1978 may have lead paint inside and out. The dirt around your home and the dust inside it may also have lead in them.

It could come from paint, busy roads, or factories. Or you might bring it home from work on your clothes and shoes. It can get in your car and on your furniture, floors, and carpets. Lead can get in the air, soil, or water from gas exhaust or fumes from other factories, like those that make batteries. There also may be lead in your water if your home has lead pipes or other types of plumbing fixtures that contain lead.

- **At work and play** — You may get lead poisoning from casting weights for fishing, casting shot for shooting, construction, demolition, painting, pottery making, radiator repair, soldering, scrap metal recycling, working with stained glass, and target shooting.
- **In the products you buy at the store** — Many may have lead in them, including hair dye, home remedies made outside the U.S., lipstick, metal jewelry, painted furniture, and painted or plastic toys.

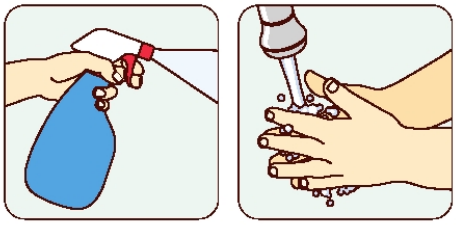


Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

GREEN CHOICES
Planned Parenthood

Lead

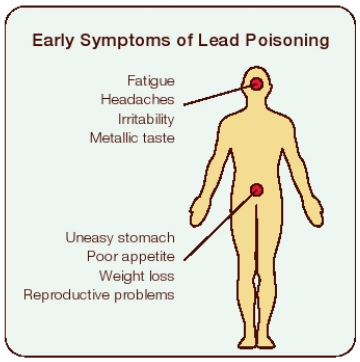
What can I do to protect myself?

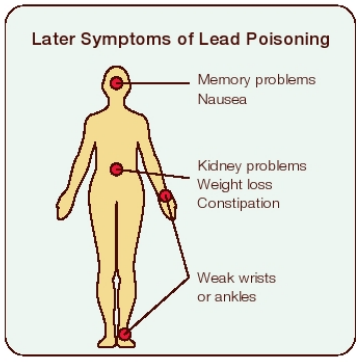


- Wash toys and all surfaces in your home with a non-toxic, all-purpose cleaner each week.
- Wash children's hands often and always before they eat.
- Feed your children low-fat meals high in iron, calcium, and vitamin C, which combat lead poisoning.
- Make sure there's no lead in paint **before** you sand, scrape, power-wash, peel, or sandblast it. Contact your local lead poisoning prevention program before painting or remodeling a home.
- Change out of contaminated work clothes and shoes before you go into your home or are around others.
- Don't use dishes for making, storing, or serving food or drinks if they are handmade, older, or imported — unless you are sure they do not contain lead.
- Don't use imported home remedies or cosmetics that might contain lead.

Where can I get more information?

- Before painting or remodeling a home, contact a local lead poisoning prevention program. They can tell you the safest ways to work with lead paint. Click on your local area on this map: **www.cdc.gov/nceh/lead/programs.htm**.
- To avoid toys that may have lead, go to: **www.healthytoys.org**.
- To avoid personal care products that may contain lead, go to: **www.cosmeticsdatabase.com**.
- For questions about lead you can call **The National Lead Information Center** at **1-800-424-5323**.





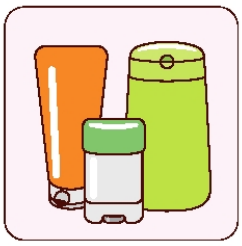
Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

GREEN CHOICES
Planned Parenthood

Personal Care Products

Every day we eat, drink, breathe, and touch chemicals that exist around us. The chemicals can affect our health. Planned Parenthood GREEN CHOICES will give you the information you need to make choices for better health and a greener environment — for yourself, your family, and your community.

What do I need to know about personal care and beauty products?



- **Think about those you use — deodorant, hairspray, lotion, lubricants, make-up, nail polish, sunscreen, shampoo, soap, and toothpaste.**

Many contain chemicals that may harm your health. These chemicals get into your body in different ways:

- You might breathe them into your lungs.
- They may soak through your skin.
- You may swallow them if they get into your mouth.

- **No government agency approves the safety of *all* the ingredients in these products.**

Does it matter if I use them only once in a while?

There may not be enough harmful chemicals in them to hurt you if you use them only once. But they can build up in your body over time — enough to really harm you.

- They can increase your risk of **cancer**.
- They may also **disrupt your hormones** and make it harder for you to get pregnant.
- They may cause other health problems.

How can I use personal care products more safely?

We can't tell you what brands to use. Here is the best advice we can give you:

- **Always read the product label.**

- **Avoid products that have**
  - fragrance — phthalates — used in all perfume and some deodorants, hair sprays, moisturizers, nail polishes, and shampoos
  - mercury — thimerosal — used in eye drops, mascara, and ointments
  - placenta — used in hair relaxers, lotions, and toners
- **Use fewer products.**
- **Use them less often.**
- **Use safer products.**

What Can I Do?

- Many products are made with safer ingredients. Go to **www.cosmeticsdatabase.com** to find safety ratings on products and ingredients.
- Learn about the Campaign for Safe Cosmetics, find companies who have pledged not to use toxic chemicals in their products, and take action at **www.safecosmetics.org**

Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

GREEN CHOICES
Planned Parenthood

Pesticides

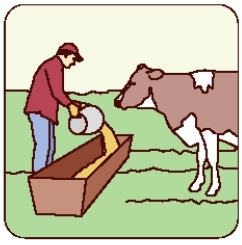
Every day we eat, drink, breathe, and touch chemicals that exist around us. The chemicals can affect our health. Planned Parenthood GREEN CHOICES will give you the information you need to make choices for better health and a greener environment — for yourself, your family, and your community.

What are pesticides?

- Pesticides are used to kill pests, including bugs, rodents, and weeds. They are made with thousands of different chemicals. They are used in many forms, including sprays, baits, crystals, gasses, liquids, pellets, and powders.
- Many pesticides are toxic and can be harmful to people.
- The government keeps watch over how pesticides are used. But we all still come in contact with many that can cause health risks.

How would I have contact with pesticides?

- **Most of us have contact with at least some pesticides.** They are everywhere. They can be in all kinds of buildings — homes, schools, markets — and in all kinds of outdoor settings — parks, pastures, woodlands, golf courses. They can be
  - on the fruits, vegetables, grains, and meat you eat
  - in the air you breathe
  - in the water you drink and bathe in
  - in the dust on your skin

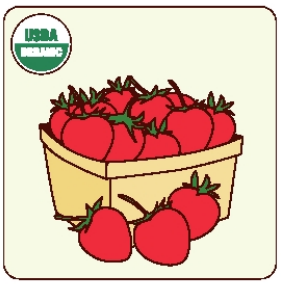


- **Workers at highest risk of having contact with pesticides are**
  - exterminators
  - farmers and other agricultural workers
  - gardeners
  - landscapers
  - livestock breeders

What are the risks of contact with pesticides?

- Pesticides can disrupt hormones or cause cancer and other health problems.
- They can increase a child's risk of having birth defects and learning disabilities.
- Your level of risk depends on
  - how harmful the pesticide is
  - how you come in contact with it — through your skin, breathing it in, or eating it
  - how long you are in contact with it
  - your age — fetuses and very young children are at the highest risk of harm
  - your genes (family history)
  - other pesticides and chemicals with which you've had contact

How can I avoid contact with pesticides?



- **Buy organic food when you can.**
  - Some farmers grow food without using pesticides or other dangerous chemicals. This is called **organic** farming.
  - Farmers' markets may charge less than grocery stores for organic foods. Find a farmers' market near you at **www.localharvest.org**
- **Wash**, **scrub**, and **peel** produce before you cook or eat it.

Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

GREEN CHOICES
Planned Parenthood

Pesticides

How can I avoid contact with pesticides? (continued)

- **Don't spray pesticides indoors**, in the garden, or on pets. Keep pests out of your home by sealing cracks and holes around doors, windows, and baseboards. Keep food in sealed containers.
- If you work with pesticides, **change out of your work clothes and shoes** before you go into your home. And be sure to **wash your hands** frequently and **shower** before you are near others.
- **Use baits and traps** instead of pesticide sprays, powders, or strips. Go to: **www.beyondpesticides.org**
- Brush children's hair with a metal lice comb to stop the spread of lice instead of using chemicals. **www.epa.gov/pesticides/ipm/schoolipm/chap-11.pdf**

Where can I get more information about pesticide exposure?

- U.S. Department of Labor Occupational Safety and Health Administration: **www.osha.gov**
- U.S. Environmental Protection Agency — Office of Pesticides: **www.epa.gov/pesticides**
- Beyond Pesticides: **www.beyondpesticides.org**
- National Pesticide Information Center: **http://npic.orst.edu** or 1-800-858-7378
- **In an emergency, call the National Poison Control Hotline at 1-800-222-1222**

Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

GREEN CHOICES
Planned Parenthood

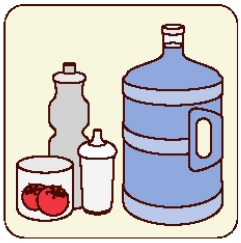
Plastic

Every day we eat, drink, breathe, and touch chemicals that exist around us. The chemicals can affect our health. Planned Parenthood GREEN CHOICES will give you the information you need to make choices for better health and a greener environment — for yourself, your family, and your community.

What do I need to know about plastics?

- Not all plastics are the same. They are made with different chemicals. Some are harmful to your health.
- Different kinds of plastic are labeled with different numbers. The numbers are usually in a triangle on the bottom of the product. You can use the numbers as a guide for the effect the chemicals in the plastic may have on your health. Some are better. Some are fair. Some are worse. See the chart below.

What do I need to know about bisphenol A?



- **Bisphenol A (BPA)** is used to make some of the worst plastics for your health. It is often used to make containers that are hard and clear. It is found in most plastics labeled "7."
- Some sports water bottles, baby bottles, canned foods, five-gallon water-cooler bottles, and "sippy cups" have **BPA**.
- **BPA** can seep out of plastic containers and into your body very easily. Most of us already have some **BPA** in our bodies. **BPA** can disrupt your hormones.
- Companies now make containers without **BPA**. Look for **"BPA-Free"** on the label.

What do I need to know about polyvinyl chloride?

- **Polyvinyl chloride (PVC)** is very harmful to your health. It is used to make all kinds of plastics. Some of the common ones are known as **vinyl**. Vinyl also has other very harmful chemicals in it, such as **phthalates**. Some people call vinyl "the poison plastic" because it is so dangerous.
- **PVC** can disrupt your hormones. Phthalates may cause birth defects in baby boys, sperm damage, and asthma. Try not to buy **PVC** plastics. They are labeled "3."
- Buy toys, sex toys, and other plastic products with **"PVC-Free"** on the label.
- Find out more about PVC at **www.pvcfree.org**.

What can I do to use plastic less often?

- Keep what you drink and eat in glass, ceramic, or metal food containers, or use plastics labeled with the numbers 1, 2, 4, or 5.
- Try not to microwave your food or drinks in plastic containers or with plastic wrap. Instead, use glass or ceramic, and cover with a paper towel.
- Try not to buy food or other items in containers made of polystyrene foam (such as Styrofoam). They are labeled "6."
- Some plastics aren't labeled. If they aren't, consider not using them.

Where can I get more information about the containers I use?

Get facts about safer plastics:

- **Environment & Human Health, Inc. Report on Plastics: www.ehhi.org/reports/plastics/**
- **Institute for Agriculture and Trade Policy Smart Plastics Guide: http://bit.ly/healthobservatory**

Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

Getting Healthy Before Pregnancy

If you are thinking about getting pregnant — sometime soon or in the future — it's never too early to start getting ready. Having a healthy baby begins before you get pregnant. There are things you can do to increase the chances of having a healthy pregnancy and baby. This is called preconception care.

Take 400 micrograms (mcg) of folic acid every day.
Folic acid is a B vitamin that cells in your body need for growing and developing. Taking 400 mcg of folic acid every day for at least 1 month *before* and *during* pregnancy can help lower the risk for problems with the baby's brain and spine – called neural tube defects (NTDs).

Some women, like those who have had a pregnancy affected by NTDs or with sickle cell disease, may need more folic acid. Talk to your doctor or nurse about the dose that is right for you.

Follow a healthy diet.
Add more healthy foods to your diet and then cut down on unhealthy foods. A more balanced diet has the following:

- **Carbohydrates (carbs).** They should make up about half of what you eat. Try to get most of your carbs from whole grains, like whole grain bread and brown rice. Avoid sugary foods and drinks like candy and soda.
- **Protein.** It is important to help a pregnancy grow and is found in meat, dairy products, tofu, and beans. If you are vegetarian or vegan, you can still have a healthy pregnancy. Talk to your doctor or nurse about how to get enough protein.
- **Fats.** They can help your body absorb vitamins. It's a good idea to get fat from fish and vegetable sources.
- **Fiber.** Eat at least 3 to 5 servings each day. It comes from fruits, vegetables, and whole grains.

Get to a healthy weight.
Women who are underweight or overweight are more likely than women at a healthy weight to have pregnancy problems. Talk to your doctor or nurse about what a healthy weight is for you and how to get there before you get pregnant.

Stop smoking, drinking alcohol, and using drugs.
Smoking, even secondhand smoke, can make it harder to get pregnant and increases the risk of miscarriage. It can also increase the risk of giving birth too early, having a baby born with health problems, and SIDS (sudden infant death syndrome).

Drinking alcohol while you are pregnant can increase the risk of miscarriage, giving birth too early, and stillbirth. It can also lead to fetal alcohol syndrome (FAS) in the baby. FAS may cause abnormal changes to the baby's body, mental retardation, learning problems, and other problems.

Using drugs while you are pregnant can increase the risk of miscarriage, the baby being too small, and the baby being born addicted to the drug.

Quitting before you get pregnant can reduce these risks. Talk to your doctor or nurse about treatment and resources.

Avoid harmful substances.
Harmful substances may be found at work or at home, such as chemicals, metals, fertilizer, bug spray, and cat or rodent feces. They can hurt the reproductive systems of men and women and make it harder to get pregnant. Some can harm your baby.

Be safe.
If someone is abusive towards you or your family, get help now. Abuse can get worse during pregnancy, and put you and your baby at risk.

Do a mental health check.
Everyone feels anxious, sad, or stressed sometimes. However, if these feelings do not go away and they interfere with your daily life, ask for help. Talk to your doctor or nurse about treatment and resources.

Make an appointment for a preconception checkup with your doctor or nurse.
At this visit, your doctor or nurse will want to discuss your

- **Health problems -** If you currently have any health problems, such as sexually transmitted infections (STIs – including HIV), diabetes, thyroid problems, seizures, high blood pressure, or depression, be sure they are under control and being treated.

- **Past pregnancies -** If you've been pregnant before and had problems, such as miscarriage, stillbirth, a baby born too early, or a baby born with a medical problem, your doctor or nurse may be able to help you avoid the same problem in your next pregnancy.

- **Medicines -** Tell your doctor or nurse about any medicines you take. Some prescription and over-the-counter medicines, dietary or herbal supplements are not safe in pregnancy. You should not stop taking any prescription medicine until you have talked to your doctor or nurse.

- **Vaccinations** - Check that your vaccinations are up to date. Some vaccines are not safe during or right before pregnancy, so it is important to get caught up on vaccinations before you get pregnant. Wait at least 1 month after getting a vaccination before trying to get pregnant.

- **Family history** - You and your partner should learn about each of your family's health histories before your appointment. This can help your doctor or nurse look out for health problems that may run in your family. Based on your family history or your partner's, your doctor or nurse might recommend meeting with a genetic counselor (someone who has special training to explain family history and the chance that a condition will occur or recur).

- **Lifestyle and Behaviors -** Let your doctor or nurse know if you smoke, drink alcohol, take drugs, aren't safe at home or work, or are exposed to harmful substances, such as chemicals, at home or work.

- **Staying Healthy** - This may be the right time to have an exam or to do lab tests, such as a Pap, tests for STIs, and blood work based on your age and risk factors.

Get a checkup with the dentist.
If you have gum disease, getting treatment before pregnancy may prevent health problems in you and your baby.

Stick with it!
Once you are pregnant, be sure to keep up all of your new healthy habits, and see your doctor or nurse early and regularly throughout pregnancy.

Preventing Cardiovascular Disease

(affiliate name and telephone number)

What is cardiovascular disease?

Cardiovascular disease, or CVD, is problems with your heart or blood vessels. It can lead to serious problems like heart attack, stroke and death. CVD is the leading cause of death in women in the U.S.

What can I do to prevent CVD?

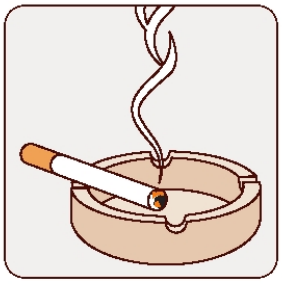
- Stay at a healthy weight.
- Eat plenty of fruit and vegetables.
- Eat whole grains and foods high in fiber — like brown and wild rice, whole-wheat bread, and pasta and oatmeal.
- Eat fish at least twice a week.
- Limit saturated and trans fats and cholesterol:
  - Choose lean meats, skinless chicken, and vegetables.
  - Choose low fat or nonfat dairy products.
  - Avoid foods that have partially hydrogenated fats (read the labels on baked goods and baking mixes, crackers, peanut butter, whipped topping, margarine, shortening, and frozen foods).
- Avoid sugary food and drinks and caffeine.
- Choose and cook foods with little or no salt.
- Limit alcohol – no more than 1 drink in women or 2 drinks in men per day.
- Exercise — try to get at least 30 minutes every day.
- Don't smoke — if you need to quit, ask us. We can help.

GREEN CHOICES
Planned Parenthood

Tobacco Smoke

Every day we eat, drink, breathe, and touch chemicals that exist around us. The chemicals can affect our health. Planned Parenthood GREEN CHOICES will give you the information you need to make choices for better health and a greener environment — for yourself, your family, and your community.

What are firsthand and secondhand smoke?



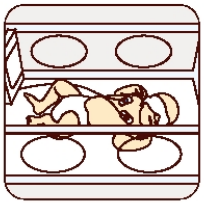
Firsthand smoke is the smoke inhaled by a smoker. **Secondhand smoke** is the smoke we inhale when others smoke. It is also called *environmental tobacco smoke*.

There are two kinds of secondhand smoke:

- One is the smoke given off by the burning end of a cigarette, pipe, or cigar. This is called *side-stream smoke*.
- The other is smoke exhaled by the smoker. This is called *mainstream smoke*.

How can smoke affect my health?

- **When we breathe it in, we breathe in harmful chemicals.**
  They are like the ones in diesel exhaust.
- **Smoke can cause**
  - heart disease
  - cancer
  - breathing problems (like asthma and emphysema)



- **If a pregnant woman breathes in smoke, the baby she has could**
  - be very small at birth (low birthweight)
  - have breathing and lung problems (like asthma)
  - have middle ear infections
  - get harmful chemicals from her breast milk
  - die from sudden infant death syndrome (SIDS)

What can I do to avoid these health problems?

You can prevent many health problems if you avoid smoke.

- If you smoke tobacco, quit or reduce how much you are smoking.
- Ask other people not to smoke in your home or car.
- Choose smoke-free restaurants, schools, day-care, and businesses.
- Support the passage of smoke-free laws where you live.
- Help people who are trying to quit smoking.
- For more information, go to **http://no-smoke.org**

How can I quit smoking?

It's not easy to quit smoking. Most people need help. You can ask your health care provider, friends, or family what you need to do to quit smoking. While you are trying to quit, it's a good idea to:

- Exercise.
- Hang out with non-smokers.
- Keep a list of reasons you want to quit and look at it often.
- Breathe deeply and try to stay relaxed.
- Save the money you would have spent on cigarettes to buy something you really want.
- For more ideas to help you quit, go to **www.smokefree.gov**

Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

GREEN CHOICES
Planned Parenthood

Environmental Health Assessment Form

Every day we eat, drink, breathe, and touch chemicals that exist around us. This assessment will help you identify some of your exposures to common chemicals. Planned Parenthood GREEN CHOICES and our staff will then give you the information you need to make choices for better health and a greener environment — for yourself, your family, and your community.

To be completed by staff: Staff name _____ Chart number _____

Name _____ Today's date _____

1. Tell us about the food you eat.

I eat fish and/or seafood.	☐ Regularly	☐ Sometimes	☐ Never
I eat meat and/or poultry (chicken, turkey, etc.)	☐ Regularly	☐ Sometimes	☐ Never
I eat fruits and/or vegetables.	☐ Regularly	☐ Sometimes	☐ Never
I eat organic fruits and vegetables.	☐ Regularly	☐ Sometimes	☐ Never

2. Tell us about the things you or your family use when cooking, eating, or storing food.

I (or my family) microwave food in plastic containers or use plastic wrap.	☐ Regularly	☐ Sometimes	☐ Never
I (or my family) eat food that comes from a can (soups, beans, baby formula, etc).	☐ Regularly	☐ Sometimes	☐ Never
I (or my family) drink from plastic bottles or cups.	☐ Regularly	☐ Sometimes	☐ Never
I (or my family) store food in plastic.	☐ Regularly	☐ Sometimes	☐ Never
My take-out comes in plastic.	☐ Regularly	☐ Sometimes	☐ Never

3. Tell us about the personal care products you use.

I use personal care products with fragrance (smell), like lotion or soap.	☐ Regularly	☐ Sometimes	☐ Never
I chemically straighten, relax, highlight, perm, or dye my hair (on head or body).	☐ Regularly	☐ Sometimes	☐ Never
I use cosmetics such as perfume/cologne, lipstick, nail polish, or mascara.	☐ Regularly	☐ Sometimes	☐ Never

4. Tell us about where you live. (This can be your house, dorm, apartment, or other living quarters).

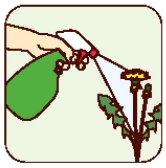
My home was built before 1978.	☐ Yes	☐ No	☐ I don't know
My home was tested for lead.	☐ Yes	☐ No	☐ I don't know
There is shower mold or mildew in my home.	☐ Yes	☐ No	☐ I don't know
There are working smoke detectors in my home.	☐ Yes	☐ No	☐ I don't know
There are working carbon monoxide detectors in my home.	☐ Yes	☐ No	☐ I don't know

Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

GREEN CHOICES
Planned Parenthood

Environmental Health Assessment Form

5. Tell us about the types of chemicals around you.



Pesticides are used at my home and/or work (pesticides are chemicals used to kill bugs, rodents, and/or weeds).	☐ Regularly	☐ Sometimes	☐ Never
Flea collars, dips, or other chemicals are used on my pets. (leave blank if you do not have pets)	☐ Regularly	☐ Sometimes	☐ Never
I live and/or work near a farm, park, or golf course.	☐ Yes	☐ No	

6. Tell us about the cleaning products you or your family use at home or at work.

I (or my family) use and/or work with strong-smelling cleaning products.	☐ Regularly	☐ Sometimes	☐ Never
I (or my family) use different cleaning products at the same time (such as bleach and ammonia).	☐ Regularly	☐ Sometimes	☐ Never
I (or my family) use air fresheners, plug-ins, scented candles, or incense.	☐ Regularly	☐ Sometimes	☐ Never

7. Tell us about your exposure to tobacco smoke (cigarettes, cigars, or pipes).

I smoke.	☐ Regularly	☐ Sometimes	☐ Never
I smoke inside my home or car.	☐ Regularly	☐ Sometimes	☐ Never
Other people smoke around me.	☐ Regularly	☐ Sometimes	☐ Never
My children are exposed to smoke from others. (Leave blank if you do not have children.)	☐ Regularly	☐ Sometimes	☐ Never

The following section will help your health care provider to better guide you.

Tell us about your or your partner's pregnancy plans and any children you already have.

I (or my partner) am currently pregnant.	☐ Yes	☐ No	☐ I don't know
I (or my partner) am thinking about getting pregnant in the next 12 months.	☐ Yes	☐ No	☐ I don't know
I have one or more children living with me.	☐ Yes	☐ No	
I have children under the age of six living with me.	☐ Yes	☐ No	

If you have questions related to environmental health, please write them down for your health care provider to answer:

Green Choices information is also online: **www.plannedparenthood.org/greenchoices**

Reason for Change	Location	Current Language	Corrected Language or Revision/Addition per NMC
NMC 2014	Part 1, Chapter 3 Clinical Services, Table 3.2.a.		
	Primary Care (p 8)	As part of limited primary care, medication management is limited to previously diagnosed hypertension and hypothyroidism	As part of limited primary care, medication management is limited to medication refills for any condition covered in expanded primary care. In addition, the following criteria **must** be met: ▪ Client's condition is stable ▪ Client has not been off medication for greater than one month ▪ Client knows their medication name and dosage (or this information can be reliably obtained through records or pharmacy) ▪ Medication is not a controlled substance ▪ Medication is not insulin The client may receive 3 months of refills to bridge them to primary care with the option of an extension of 1 month.
	Sedation (p 11)	At least 1 staff person with training in advanced resuscitative techniques (e.g. ACLS) **must** be on site (in the building) until all clients are medically discharged	As long as there is a client in the recovery area that was moderately sedated or deeper, there **must** be at least one licensed staff who is present in the recovery area with current ACLS certification and whose sole responsibility is to monitor the clients in the recovery area
	Sedation (p 11)	A physician **must** be immediately available at all times during client treatment and recovery and until all clients are medically discharged	**A clinician who is privileged to provide sedation must** be immediately available at all times during client treatment and recovery and until all clients are medically discharged
NMC 2014	Part 1 Chapter 5 Medical Records,	N/A	Documentation of sedation: Affiliates should pursue a goal of utilizing an interoperable EHR system (one that automatically captures outputs of physiologic monitors) for

Reason for Change	Location	Current Language	Corrected Language or Revision/Addition per NMC
	Documentation, and Reporting Requirements		clients who receive moderate sedation or deeper. Until that time, a paper or EHR manual real-time entry is acceptable. If paper documentation is used, it **must** be scanned into the EHR.
Erratum	Part 1 Chapter 7 Pharmaceuticals 7.1.10	Whenever clients are given a parenteral injection at the affiliate, they **must** be observed on site for at least 20 minutes before being allowed to leave	Whenever clients are given parenteral injection at the affiliate, they should be observed on site for at least 20 minutes before being allowed to leave.
	Part 1 Chapter 7 Pharmaceuticals 7.1.11	l. **Must** label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings. (Note: Medication containers include syringes, medicine cups, and basins.)[R1]	l. **Must** label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings that are not immediately administered. (Note: Medication containers include syringes, medicine cups, and basins. An immediately administered medication is one that an authorized staff member prepares and obtains, takes directly to a client, and administers to that client without any break in the process.)[R1]
Erratum	Part 2 Chapter 1 Abortion 1.3.b. Table: Delayed Complications and Problems	Bleeding in medication abortion See Table 1.1.c.	Bleeding in medication abortion See Table 1.3.a.
NMC 2014	Part 2 Chapter 1 Abortion	N/A	Clients undergoing second trimester abortion for IUFD should be evaluated for increased risk of hemorrhage/DIC if it has been 4 weeks or greater since fetal demise.
NMC 2014	Part 2 Chapter 1 Abortion	N/A	Conditions that put women at risk of hemorrhage categorized by Contraindication/Special Condition: Contraindications: • Suspected abnormal placental implantation ≥ 14

Reason for Change	Location	Current Language	Corrected Language or Revision/Addition per NMC
			weeks • Molar pregnancy ≥ 14 weeks size Special conditions requiring management by affiliate protocols or consultation with the clinician performing the procedure: • Anemia with HCT < 30% / Hgb <10 gm/dl • Hemorrhagic disorder • Molar pregnancy < 14 weeks size • Use of anticoagulants • Morbid obesity • Placentia previa in an unscarred uterus • Scarred uterus • History of obstetrical hemorrhage • Fibroids Additional notations for consideration in an FYI Box: • Client refusal to accept blood products • Risk factors may be additive and influenced by gestational age
NMC 2014	Part 2 Chapter 1 Abortion	N/A	Circumstances in which a surgical abortion may be stopped and restarted another day or **must** be completed either at the health center or by transfer to a hospital: • A procedure may be stopped and the client sent home to return on another day and/or to see another provider for any circumstance not specified below • A procedure **must** be completed, either at the health center or by transfer to a hospital for further care under the following circumstances: ○ Unstable patient ○ Known retained fetal parts greater than or equal to 13 weeks ○ Suspected complicated uterine perforation

Reason for Change	Location	Current Language	Corrected Language or Revision/Addition per NMC
			(e.g. in second trimester, lateral perforation, evidence of visceral injury) ○ Client's inability to return for care (e.g. distance from facility, unsafe environment) ○ Client's preference/choice
Erratum	Part 2 Chapter 4 Cervical Cancer Screening 4.8.c. Algorithm: Histology CIN 2,3 or HSIL* (p. 31)	Any CIN 3 or unsatisfactory Pap	Any CIN 3 or unsatisfactory colposcopy Note: An updated version of Chapter 4 will be released once interim management guidelines from the American Society for Colposcopy and Cervical Pathology (ASCCP) and Society of Gynecological Oncologists (SGO) become available. It will include the option to perform primary screening with HPV-based testing as well as guidelines for managing abnormal results. Errata will be corrected. See page 9 for list of revisions.
Erratum	Part 2, Chapter 6 Contraception – Reversible		
	6.1.b. Table: Special Conditions Drug Interaction (p 15)	Lamotrigine (Lamictal) monotherapy	Lamotrigine (Lamictal) monotherapy (CHC only)

<table>
<tr><th>Reason for Change</th><th>Location</th><th>Current Language</th><th>Corrected Language or Revision/Addition per NMC</th></tr>
<tr><td></td><td>6.2.c. Table: Timing of Initiation - CHC (p 18)</td><td>
<table>
<tr><td>Current correct use of hormonal contraception (HC)</td><td>Continuous use of pill, patch, ring, on day of implant removal, when DMPA injection due
_____
Cyclic use of pills, patch, ring

If switching from DMPA and it had been initiated > 7 days after onset of menses, must perform urine pregnancy test before prescribing CHC.</td><td>None

_____
Back up for 7 days</td></tr>
</table>
</td><td>
<table>
<tr><td>Current correct use of hormonal contraception (HC)</td><td>Anytime in cycle (pills, patch, ring) or on day of implant removal or when DMPA injection due
_____
<s>Cyclic use of pills, patch, ring</s> DELETE

If switching from DMPA and it had been initiated > 7 days after onset of menses, must perform urine pregnancy test before prescribing CHC.</td><td>None

_____
<s>Back up for 7 days</s> DELETE</td></tr>
</table>
</td></tr>
<tr><td></td><td>6.2.c. Table: Timing of Initiation - CHC (p 18)</td><td>
<table>
<tr><td>IUC</td><td>> 5 days since onset of menses and has had IC this cycle. Three options
• Start CHC, remove IUC ≥ 7 days later
• Abstain or use barrier ≥ 7 days, remove IUC, start CHC
• Remove IUC, provide EC, start CHC</td><td>
None

None

Backup for 7 days</td></tr>
</table>
</td><td>
<table>
<tr><td>IUC</td><td>> 5 days since onset of menses and has had IC this cycle. Two options
• Start CHC, remove IUC ≥ 7 days later
• <s>Abstain or use barrier ≥ 7 days, remove IUC, start CHC</s> DELETE
• Remove IUC, provide EC, start CHC</td><td>
None

<s>None</s> DELETE
Backup for 7 days after LNG EC or 14 days after UPA EC.</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Reason for Change</th><th>Location</th><th>Current Language</th><th>Corrected Language or Revision/Addition per NMC</th></tr>
<tr><td></td><td>6.2.c. Table: Timing of Initiation - CHC (p 19)</td><td><table><tr><td>Post-surgical procedure for elective or spontaneous abortion and post early pregnancy failure – no procedure</td><td>• ≤ 7 days post procedure or passing pregnancy (when day known)
• > 7 days or unknown, see “no effective contraception” above</td><td>None, if initiated that day. Other-wise, backup for 7 days</td></tr></table></td><td><table><tr><td>Post-surgical procedure for elective or spontaneous abortion and post early pregnancy failure – no procedure</td><td>• ≤ 7 days post procedure or passing pregnancy (when day known)
_____
• > 7 days or unknown</td><td>None, if initiated that day. Other-wise, backup for 7 days
_____
See “no effective contra-ception” above</td></tr></table></td></tr>
<tr><td></td><td>6.3.b. Table: Timing of Initiation – Implants (p 27)</td><td>IUC</td><td>SAME CORRECTION as CHC, above</td></tr>
<tr><td></td><td></td><td>Post-surgical procedure for elective or spontaneous abortion and post early</td><td>SAME CORRECTION as CHC, above</td></tr>
<tr><td></td><td>6.4.a. Table: Written Requirements for Written Materials as Indicated (p 37)</td><td>Written instructions for use – must give at first Rx<table><tr><td>Document</td><td>Document #</td><td>Must sign</td><td>Must Give</td><td>Must offer</td></tr><tr><td>Written Instructions for use</td><td></td><td></td><td>At first Rx</td><td></td></tr></table></td><td>~~Written instructions for use – **must** give at first Rx~~ DELETE</td></tr>
<tr><td></td><td>6.4.b. Table: Timing of Initiation - DMPA (p 38)</td><td>IUC</td><td>SAME CORRECTION as CHC, above</td></tr>
<tr><td></td><td></td><td>Post-surgical procedure for elective or spontaneous abortion and post early pregnancy failure – no procedure</td><td>SAME CORRECTION as CHC, above</td></tr>
</table>

Reason for Change	Location	Current Language	Corrected Language or Revision/Addition per NMC
	6.5.b. Table: Timing of Initiation – **IUC** (p 48)	Post-surgical procedure for elective or spontaneous abortion and post early pregnancy failure – no procedure	SAME CORRECTION as CHC, above
	6.7.b. Table: Timing of Initiation – **POPS** (p 63)	Current correct use of hormonal contraception (HC) | Anytime in cycle (pills, patch, ring) or on day of implant removal or when DMPA injection due If switching from DMPA and it had been initiated > 7 days after onset of menses, **must** perform urine pregnancy test before prescribing CHC. |	Current correct use of hormonal contraception (HC) | Anytime in cycle (pills, patch, ring) or on day of implant removal or when DMPA injection due If switching from DMPA and it had been initiated > 7 days after onset of menses, **must** perform urine pregnancy test before prescribing POPs. | None
		IUC	SAME CORRECTION as CHC, above, but backup is 2 days (for POPs)
	6.7.b. Table: Timing of Initiation – **POPS** (p 64)	Post-surgical procedure for elective or spontaneous abortion and post early pregnancy failure – no procedure	SAME CORRECTION as CHC, above, but backup is 2 days (for POPs)
NMC 2014	Part 2 Chapter 6 Contraception – Reversible		Recommended changes to MS&Gs to help clinicians distinguish migraine vs non-migraine headache and to identify aura: ▪ Simplify the FYI box in the MS&Gs on diagnosing migraine and distinguishing between aura and no aura. ▪ The validated ID Migraine Screener should be adopted for diagnosing migraine vs non-migraine headache. It includes screening for 3 associated symptoms – photophobia, impairment of function, and nausea. A positive screen for two out of three

Reason for Change	Location	Current Language	Corrected Language or Revision/Addition per NMC
			elements confirms the diagnosis of migraine headache. ▪ With respect to aura, the following screening criteria should be used - aura is the presence of any visual changes that: ○ Start prior to the onset of headache ○ Last up to hour (usually 20-30 minutes) ○ Resolve before headache onset
NMC 2014	Part 2 Chapter 8 GYN Conditions 8.5 Menopause (p 43)		Add the LNG-releasing IUC (52 mg) as a first line option for endometrial protection for clients using systemic MHT.
Erratum	Part 2 Chapter 13 Pregnancy Evaluation and Management of Complications 13.4.b. Table: New Diagnostic Criteria for EPF (p 9)	Absence of embryo without heartbeat ≥ 11 days after an ultrasound that showed a gestational sac with a yolk sac	Absence of embryo with heartbeat ≥ 11 days after an ultrasound that showed a gestational sac with a yolk sac
Erratum	Part 2 Chapter 17 Recovery Area Care 17.2.a. Table: Aldrete Scoring System (p 3)	▪ Is 20 mm Hg > preanesthetic level ▪ Is 20 to 50 mm Hg > preanesthetic level ▪ Is 50 mm Hg > preanesthetic level	▪ Is within 20 mm Hg of preanesthetic level ▪ Is within 20 to 50 mm Hg of preanesthetic level ▪ Is within 50 mm Hg of preanesthetic level

PPFA MS&Gs: Revision Sheet

January 2015

REVISION SHEET

SECTION	REVISION	RATIONALE
02_04 Cervical Cancer Screening and Management of Abnormal		
Screening	▪ Option to perform HPV test as primary screen added.	Huh 2015
Management of Abnormal	▪ 4.3.h. Algorithm: Primary HPV Screening Test (no Pap) - NEW	Huh 2015
	▪ 4.5.b. Algorithm: Pap Atypical Glandular Cells (AGC) – Endocervical or Not Otherwise Specified (NOS) – NEW number/title ▪ Deleted separate algorithm for management of AGC-Endocervical and added to AGC-NOS. All algorithms in 4.5 that follow 4.5.b have been renumbered.	Correction of error
	▪ Important Information – NEW – LEEP **must** be performed under colposcopic guidance or following application of Lugol's solution.	Correction of error (inadvertently left out of 2014 edition)
	▪ Deleted FYI – Management of CIN 1 in Women 25 and Older When HPV Testing is Not Available	No longer relevant
	▪ 4.8.c. Algorithm: Histology CIN 2,3 or HSIL – Box was changed from "Any CIN 3 or unsatisfactory Pap" to "Any CIN 3 or unsatisfactory colposcopy"	Correction of typo
	▪ 4.9.a. Algorithm: Post-Treatment Squamous Cell Disease – LEEP Histology CIN 1 and CIN2,3 – revised to make consistent with ASCCP management guidelines	Correction of error Consistency
	▪ 4.8.f. Table: Contraindications and Special Conditions for Cryotherapy and LEEP – revised bullets to make clear that cryotherapy is contraindicated if ECS shows squamous disease ≥ CIN 1 (inadvertently deleted when chapter was edited)	Correction of error