
# Clinical Protocols and Procedures 2024

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**SECTION 1**
**Providing Quality Family Planning Services**

## INTRODUCTION

The Title X Family Planning Program is administered by the Office of Population Affairs (OPA), Office of the Assistant Secretary for Health (OASH), within the U.S. Department of Health and Human Services (HHS). The family planning services grants program is authorized by Title X of the Public Health Service (PHS) Act (42 U.S.C. 300 *et seq.*). Implementing regulations are at 42 CFR part 59, subpart A. The requirements that apply to the direct recipients of Title X funds also apply to sub-recipients (42 CFR 59.1; HHS Grants Policy Statement, 2007). The information outlined in this document applies to the award of family planning services grants under section 1001 of the PHS Act (42 U.S.C. 300(a)), "to assist in the establishment and operation of voluntary family planning projects." These projects "consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children" (42 CFR 59.1(a)).

Family Planning assists individuals in determining the number and spacing of their children through the provision of affordable, voluntary family planning services including the provision of a broad range of contraceptive methods, education, and related preventive health services. By assisting the establishment and operation of voluntary family planning projects throughout Mississippi, the program positively impacts the health and well-being of women, children, and families. Services provided through family planning clinics allow women and men to make well-informed reproductive health choices. Converge funded family planning clinics are designed to address the unmet family planning needs of low-income women and men and provide access to populations with special needs. No one is denied services because of inability to pay.

Quality Title X Family Planning (QFP) includes these attributes: confidentiality, safety, effectiveness, client-centered approach, timeliness, efficiency, accessibility, equity, and cost effectiveness. Quality Family Planning Services include the following clinical elements:

- Contraceptive services
- Pregnancy testing and counseling
- Achieving desired pregnancy (fertility awareness)
- Basic infertility service
- Preconception health services
- Sexually transmitted infection (STI) services
- Adolescent-friendly health services

Title X providers **must** offer all family planning services (listed above), related preventive health services and referral for specialist care, as needed. Other preventive health services that are beyond the scope of Title X may be offered either on-site or by referral. Information about preventive services that are beyond the scope of Title X is available at http://www.uspreventiveservicestaskforce.org.

All family planning projects **must** offer family planning services and related preventive health services to female and male clients, including adolescents. All projects **must** provide for medical services related to family planning and the effective use of contraceptive devices and practices including provider's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies, as well as referral to other medical facilities when medically necessary, consistent with § 59.14(a), and provide for the effective usage of contraceptive devices and practices. This includes, but is not limited to, emergencies that require referral. Efforts may be made to aid the client in finding potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of this care.

## SERVICE PLANS AND PROTOCOLS

The service plan is the component of a sub-recipient's annual healthcare plan, which is developed by staff and the medical director and identifies the services to be provided to clients under Title X.

A. All sub-recipient agencies should offer a broad range of effective family planning methods (including contraceptive, natural family planning or other fertility awareness-based methods) and services (including infertility services, information about or referral for adoption, and services for adolescents) [§ 59.5]. Such projects are not required to provide every acceptable and effective family planning method or service. A participating entity may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services. All sub- recipient agencies **must** have written clinical protocols approved by Converge and signed by the agency's medical director, which outline procedures for the provision of each service offered. Sub-recipient agencies **must** have written protocols available at each clinical site. The clinic staff **must** use approved protocols for the provision of all family planning services.

B. Clinical protocols **must** be written in accordance with the QFP document, State of Mississippi laws and nationally recognized standards for medical care. Clinical Protocols **must** be current (i.e., updated within the past 12 months) and signed annually by the medical director. The Title X Clinical Services & Protocols **must** be available at each clinical site.

## PROCEDURAL OUTLINE

The services provided to family planning clients, and the sequence in which they are provided, will depend upon the type of visit and the nature of the service requested. All the QFP services identified in the introduction **must** be offered to all clients and documented in the medical record.

A. Service delivery to all clients **must** include the following:
   1. Assuring clients are treated courteously and with dignity and respect.
   2. Professional recommendations for how to address the needs of diverse clients, such as Lesbian, Gay, Bi-sexual, Transgender, Questioning (LGBTQ) persons or persons with disabilities should be consulted and integrated into procedures, as appropriate. Providers should avoid making assumptions about a client's gender identity, sexual orientation, race, or ethnicity; all requests for services should be treated without regard to these characteristics. Similarly, services for adolescents should be provided in a "youth-friendly" manner.
   3. Assurance of confidentiality and the provision of privacy.
   4. Opportunity to participate in planning their own medical treatment.
   5. Encouraging clients to voice any questions or concerns they may have.
   6. Materials and/or interpreter available for those with limited ability to read or understand English and for those who may be blind or hearing impaired.
   7. Explanation of all procedures, range of available services, agency fees and financial arrangements.

B. Individual client education **must** be offered.

C. Individual counseling (A client-centered, interactive process to assist the client in making an informed choice) **must** be offered and/or provided prior to the client making an informed choice of family planning services.

D. Adolescent services **must** be offered and should be provided in a “youth-friendly” manner, making services accessible, equitable, comprehensive, and effective for youth. Counseling for minors should include the following:

   1. Title X providers **must** offer confidential services to minors and **must** observe relevant state laws related to mandatory reporting of child abuse and neglect and human trafficking.
      a. Minors **must** be informed that services are confidential, except in special cases (e.g. child abuse) where reporting is required.
      b. Concern with respect to confidentiality of information may not be used as a rationale for noncompliance with laws regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws.
      c. Maintain records to demonstrate compliance with each of the requirements, including records which:
         i. Indicate the age of minor clients.
         ii. Indicate the age of the minor client’s sexual partners if such age is an element of a notification law under which a report is required.
         iii. Document each notification or report made pursuant to such State notification laws.

2. Title X providers **must** encourage and promote communication between the minor and his or her parent(s) or guardian(s) about their decision to seek family planning services. If not completed, the reason for lack of counseling must be documented in the chart.
3. Title X providers **must** provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.
4. Adolescents seeking contraceptive services **must** be provided comprehensive information about how to prevent pregnancy, including sexual risk avoidance (abstinence) as an effective way to prevent pregnancy and STIs.

E. Counseling for all clients **must** address the client's pregnancy intention or reproductive life plan.

F. The client's written general consent for services **must** be obtained prior to receiving any clinical services. (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a) (2))
   1. The general consent for services **must** state that services are confidential and voluntary; provided without coercion to accept services or any particular method of family planning and provided without prerequisite to accept any other service.
   2. The general consent for services **must** be language appropriate or obtained through an interpreter.

G. A medical history **must** be obtained that is appropriate to the type of service provided.

H. A physical examination, including necessary clinical procedures, **must** be provided, as indicated.

I. Laboratory testing **must** be provided, as indicated.

J. Medications and/or supplies **must** be provided, as indicated/requested.
   1. **Must** provide written specific instructions on how to use medications, if dispensed.
   2. **Must** include danger signs and when, where, and how to obtain emergency care, return schedule and follow-up.

K. Follow-up and referral **must** be provided, as indicated.
   1. Provision of referrals as needed
   2. Planned mechanism of client follow-up
      a. Suggested return visit date
      b. Contact information for emergencies after hours
      c. Discuss access to primary care services

L. Emergency arrangements **must** be available for after-hours and weekend care and should be posted, given to, available on clinic website, and/or explained to clients.

M. Return visits should assess the ongoing plan of care and needed family planning related services

## CLIENT ENCOUNTERS

A. The client's general consent for services **must** be obtained prior to receiving any clinical services. (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a) (2)). With telehealth, consent may be verbal or electronic.

B. Client encounters with women and men of reproductive age may require different services (i.e., contraceptive services, pregnancy testing and counseling, achieving pregnancy, STI services and related preventive health services). For all clients, the following questions **must** be asked and documented to help determine what family planning services are most appropriate for the visit:

1. **What is the client's reason for the visit?**
2. **Does the client have another source of primary health care?**
3. **Does the client have a reproductive life plan or want a pregnancy in the next year?**
    a. Providers should assess the client's pregnancy intention or reproductive life planning by asking questions like: "Would you like to become pregnant in the next year?", "Have you thought about goals for having or not having children?", or "Do you plan to have children (or more children) in the future?", "How long would you like to wait before you become pregnant?" See One Key Question guidance at https://powertodecide.org/one-key-question or CDC Guidance at: https://www.cdc.gov/preconception/overview.html.

    b. Providers should encourage family involvement/partner participation in reproductive life planning and family planning decisions where possible and appropriate.

## FAMILY PLANNING AND RELATED PREVENTATIVE HEALTH SERVICES FOR WOMEN

| | | Family planning services (provide services in accordance with the appropriate clinical recommendation) | | | | | |
|---|---|---|---|---|---|---|---|
| | Screening components | Contraceptive services[1] | Pregnancy testing and counseling | Basic infertility services | Preconception health services | STD services[2] | Related preventive health services |
| History | Reproductive life plan | √ | √ | √ | √ | √ | |
| | Medical history | √ | √ | √ | √ | √ | √ |
| | Current pregnancy status | √ | | | | | |
| | Sexual health assessment | √ | | √ | √ | √ | |
| | Intimate partner violence | | | | √ | | |
| | Alcohol & other drug use | | | | √ | | |
| | Tobacco use | √ (combined hormonal methods for clients ≥35 years) | | | √ | | |
| | Immunizations | | | | √ | √[4] (HPV & HBV) | |
| | Depression | | | | √ | | |
| | Folic acid | | | | √ | | |
| Physical examination | Height, weight & BMI | √ (hormonal methods)[3] | | √ | √ | | |
| | Blood pressure | √ (combined hormonal methods) | | | √[4] | | |
| | Clinical breast exam | | | √ | | | √[4] |
| | Pelvic exam | √ (initiating diaphragm or IUD) | √ (if clinically indicated) | √ | | | |
| | Signs of androgen excess | | | √ | | | |
| | Thyroid exam | | | √ | | | |
| Laboratory testing | Pregnancy test | √ (if clinically indicated) | √ | | | | |
| | Chlamydia | √[5] | | | | √[4] | |
| | Gonorrhea | √[5] | | | | √[4] | |
| | Syphilis | | | | | √[4] | |
| | HIV/AIDS | | | | | √[4] | |
| | Hepatitis C | | | | | √[4] | |
| | Diabetes | | | | √[4] | | |
| | Cervical cytology | | | | | | √[4] |
| | Mammography | | | | | | √[4] |

**Source:** Centers for Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: Recommendations CDC and the U.S. Office of Population Affairs. *MMWR. Morbidity and Mortality Weekly Report.* Retrieved for http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

## FAMILY PLANNING AND RELATED PREVENTATIVE HEALTH SERVICES FOR MEN

| | | Family planning services (provide services in accordance with the appropriate clinical recommendation) | | | | |
|---|---|---|---|---|---|---|
| | Screening components | Contraceptive services[1] | Basic infertility services | Preconception health services[2] | STD services[3] | Related preventive health services |
| History | Reproductive life plan | ✓ | ✓ | ✓ | ✓ | |
| | Medical history | ✓ | ✓ | ✓ | ✓ | |
| | Sexual health assessment | ✓ | ✓ | ✓ | ✓ | |
| | Alcohol & other drug use | | | ✓ | | |
| | Tobacco use | | | ✓ | | |
| | Immunizations | | | ✓ | ✓ *(HPV & HBV)*[4] | |
| | Depression | | | ✓ | | |
| Physical examination | Height, weight & BMI | | | ✓ | | |
| | Blood pressure | | | ✓[4] | | |
| | Genital exam | | ✓ *(if clinically indicated)* | | ✓ *(if clinically indicated)* | ✓[4] |
| Laboratory testing | Chlamydia | | | | ✓[4] | |
| | Gonorrhea | | | | ✓[4] | |
| | Syphilis | | | | ✓[4] | |
| | HIV/AIDS | | | | ✓[4] | |
| | Hepatitis C | | | | ✓[4] | |
| | Diabetes | | | ✓[4] | | |

**Source:** Centers for Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: Recommendations of CDC and the U.S. Office of Population Affairs. *MMWR. Morbidity and Mortality Weekly Reports*. Retrieved from http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

**Abbreviations:** BMI = body mass index; HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus; STD = sexually transmitted disease.

[1] No special evaluation needs to be done prior to making condoms available to males. However, when a male client requests advice on pregnancy prevention, he should be provided contraceptive services as described in the section "Provide Contraceptive Services."

[2] The services listed here represent a sub-set of recommended preconception health services for men that were recommended and for which there was a direct link to fertility or infant health outcomes (Source: Frey K, Navarro S, Kotelchuck M, Lu M. The clinical content of preconception care: preconception care for men. Am J Obstet Gynecol 2008;199 [6 Suppl 2):S389-95).

[3] STD services also promote preconception health, but are listed separately here to highlight their importance in the context of all types of family planning visit. The services listed in this column are for men without symptoms suggestive of an STD.

[4] Indicates that screening is suggested only for individuals at highest risk or for a specific subpopulation with high prevalence of infection or other condition.

Note: These two charts provide a checklist of recommended family planning and related preventive health services (QFP pages 22, 23).

# Family Planning Services

## CONTRACEPTIVE SERVICES

Written protocols and operating procedures **must** be current and in place for contraceptive services. Sub-recipient agencies must **offer** at least one family planning method to clients who z cxwish to delay or prevent pregnancy. The delivery of preconception, STI, and related preventive health services **must** not be a barrier to a client's ability to receive services related to preventing or achieving pregnancy. Receiving services related to preventing or achieving pregnancy is the priority; if other family planning services cannot be delivered at the initial visit, follow-up visits should be scheduled.

Contraceptive services must include:

1. A broad range of family planning methods, including contraceptives, natural family planning or other fertility awareness-based methods, should be provided. All methods of contraception **must** have written protocols in place.
   a. Current CDC Medical Eligibility Criteria (MEC) **must** be followed when prescribing contraceptives.
   b. More than one method may be used simultaneously by the client (for example, a hormonal method and condoms or FABM and barrier method during the fertile period). Clients with high-risk sexual behavior patterns should be encouraged to use condoms correctly and consistently in addition to any other chosen method to reduce the risks of STIs/HIV and pregnancy.

### Broad Range of Contraceptives

A. Broad Range Contraceptives includes:

1. Hormonal Contraceptives
   a. At least one delivery method of combined hormonal contraceptive should be available on site.
   b. At least one delivery method of progestin-only contraceptive should be available on site.
2. Condoms
   a. At least male condoms should be available on site.
3. At least one type of long-acting reversible contraceptive (LARC) method should be provided, either on site or by paid referral, and should be offered for same-day insertion.
4. At least one type of fertility awareness-based method (FABM) should be provided at each clinical site.
5. Education materials and information regarding all methods including, hormonal contraceptives, abstinence, fertility awareness-based methods, barrier methods, intrauterine devices, sterilization, and emergency contraception.
6. The agency formulary **must** indicate:
   a. Methods maintained and available on site
   b. Methods available on site within two weeks of client request
   c. Methods available by paid referral.
   d. Methods available by unpaid referral (i.e., sterilization)
7. Agencies should maintain a formal referral agreement for any required broad range method not provided on site.
8. A referral resource list should be provided for contraceptives not available in the clinic.
9. Agencies are encouraged to review current practices, needs and preferences of their client population and maintain the most frequently chosen methods where feasible.
10. Agencies are strongly encouraged to provide emergency contraception and maintain supplies on site.

11. Prescriptions may be written for contraceptives on the clinic formulary or on the client's insurance plan formulary. Accepting a prescription **must** not pose a barrier for the client.

B. Emergency Contraception

Emergency contraception has been found by the FDA to be safe and effective for use when initiated after unprotected intercourse. The provision of emergency contraception is strongly encouraged but not required for delegate agencies. Emergency Contraception education and referral **must** be provided to all female clients when not provided on site. When delegate agencies provide emergency contraception, the following **must** occur:

1. Written protocol must be in place.
2. If indicated by the client's history, a negative, highly sensitive pregnancy test is necessary to exclude a pre-existing pregnancy.
3. Birth control counseling should accompany or follow any method used for emergency contraception purpose in order to discourage women from using emergency contraception as a routine method of contraception.
4. Chlamydia testing should be offered to females <25 years of age and to females > 25 years with risk factors.

C. Permanent Contraception (Sterilization)

1. Education and information regarding sterilization **must** be provided for both male and female clients, if indicated.
2. Sub-recipient agencies **must** have a list of community providers where clients can be referred for sterilization. Paid referrals for sterilization are not required.
3. Sub-recipient agencies performing sterilization procedures **must** meet Federal regulations for sterilization informed consent.

**The Clinic Visit**

A medical history **must** be taken prior to prescribing contraception to ensure that methods of contraception are safe for the client.

1. For a female client, the medical history **must** include:
   a. Reproductive life plan
   b. Menstrual history
   c. Gynecologic history
   d. Obstetrical/reproductive history
   e. Contraceptive use
   f. Allergies
   g. Medications
   h. Immunizations
   i. Recent intercourse
   k. Infectious or chronic health condition (present)
   n. Other characteristics and exposures (e.g., age, postpartum, breastfeeding) that might affect the client's medical eligibility criteria (MEC) for contraceptive methods.
   n. Social history/risk behaviors
   o. Sexual history and risk assessment

p. Mental health
q. Intimate partner violence
r. Interest in sterilization if age appropriate (≥ 21 per federal law requirement)

2. For a male client, the medical history **must** include:
   a. Reproductive life plan
   b. Use of condoms
   c. Allergies (i.e., condoms)
   d. Medications
   e. Immunizations
   f. Recent intercourse
   g. Partner history (use of contraception, pregnant, has children, had a miscarriage or termination)
   h. Infectious or chronic health condition (present)
   j. Contraceptive experiences and preferences
   k. Sexual history and risk assessment
   l. Interest in sterilization if age appropriate (≥ 21 per federal law requirement)

NOTE: Obtaining a medical history **must** not be a barrier to making condoms available in the clinical setting (i.e., a formal visit **must** not be a prerequisite for a client to obtain condoms).

### Physical and Laboratory Assessment

1. For a female client the following **must** be provided:
   a. BP (when providing combined hormonal method and screening for hypertension)
      1) All clients — screen yearly
      2) If BP <120/80 — screen yearly, continue yearly.
      3) If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit if average BP >140/90 recheck at next visit or in 1 week and refer if sustained BP >140/90.
   b. Bimanual exam and cervical inspection (prior to IUD insertion, fitting diaphragm or cervical cap)
   c. Pap screening and clinical breast exam (based on current recommendations for timing and testing components). See Related Preventive Health Services section.
   d. Chlamydia testing **must** be offered annually for all females < 25 years, sexually active women ≥25 years with risk factors (new partner, infected partner, partner with other concurrent partners, symptoms, history of STI or multiple partners in the last year)
   e. CT and GC testing **must** be available for clients requesting IUD insertion, if indicated.
2. For a male client, laboratory tests are not required unless indicated by history.

### Client-Centered Counseling and Education

Contraceptive counseling is to help a client choose a method of contraception and understand how to use is correctly and consistently. Clients (adolescents and adults) should participate in client- centered counseling and learn about methods that can be used safely based on the 2016 CDC Medical Eligibility Criteria and that best fit their needs. When educating clients about the broad range of contraceptive methods, information **must** be medically accurate, balanced, and provided in a nonjudgmental manner. To assist clients in making informed decisions, providers should educate clients in a way that is readily understood and retained. Documentation of counseling **must** be in the client's medical record

1. When educating clients about contraceptive methods they can use safely, clients must be taught the following:
    a. Method effectiveness
    b. Correct and consistent use of the method
    c. Benefits and Risks
    d. Potential Side effects
    e. Protection from STIs, including HIV
    f. Starting the method
    g. Danger signs
    h. Availability of emergency contraception (provide on-site or by prescription)
    i. Follow-up visit (as needed to obtain or maintain the selected method)

2. Quality client-centered contraceptive counseling includes the following:
    a. Establish and maintain rapport.
    b. Assess the client's need and personalize the discussion.
    c. Work with the client to establish a plan.
    d. Provide information in a manner that can be understood by the client.
    e. Confirm the client's understanding.
        i. The teach-back method may be used to confirm the client's understanding by asking the client to repeat back messages about effectiveness, risks, benefits, method use, protection from STIs and follow-up (QFP pages 45-46).
3. Contraceptive counseling **must** be documented in the client record (i.e., checkbox or written statement).
4. Client information sheets should be used for education.
5. When counseling male clients, discussion should include information about female-controlled methods where appropriate (including emergency contraception), encourage discussion of contraception with partners, and provide information about how partners can access contraceptive services. Male clients should also be reminded that condoms should be used correctly and consistently to reduce risk of STIs, including HIV.
6. Encourage partner communication about contraception, including understanding partner barriers (e.g., misperceptions) and general support for using a chosen method.
7. A procedure consent form **must** be signed by the client prior to inserting an IUD or implant.
8. Clinical evaluation of a client electing permanent sterilization should be guided by the provider who performs the procedure.

## Contraceptive Counseling to Adolescent Clients

Comprehensive information **must** be provided to adolescent clients about how to prevent pregnancy. Adolescent services should be provided in a "youth friendly" manner, which means that they are accessible, equitable, acceptable, appropriate, comprehensive, effective, and efficient for you

Information should clarify that:

1. It should not be assumed that adolescent clients seeking family planning services are sexually active. Avoiding sex (abstinence) is an effective way to prevent pregnancy and STIs and can be chosen as a method at any time in life.
2. If the adolescent indicates that she or he will be sexually active, provide information about contraception and help her or him choose a method that best meets her or his individual needs, including the use of condoms to reduce the risk of STIs/HIV. Long-acting reversible contraception (LARCs) are a safe and effective option for many adolescents, including those who have not been pregnant or given birth.
3. Title X providers **must** offer confidential services to minors and must observe state mandatory reporting laws related to child abuse, neglect, and human trafficking.
    a. Minors **must** be informed that services are confidential, except that in special cases (e.g. child abuse) reporting is required.
    b. Concern with respect to confidentiality of information may not be used as a rationale for noncompliance with laws regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws.
    c. Maintain records to demonstrate compliance with each of the requirements, including records which:
        i. Indicate the age of minor clients.
        ii. Indicate the age of the minor client's sexual partners **if** such age is an element of a state notification law under which a report is required.
        iii. Document each notification or report made pursuant to such State notification laws.
4. Title X providers **must** encourage communication between the minor and his or her parent(s) or guardian(s) about sexual and reproductive health and his or her decision to seek services, except that documentation of such encouragement is not to be required if the Title X provider has documented in the medical record:
    a. (i) That it suspects the minor to be the victim of child abuse or incest; and
    b. (ii) That it has, consistent with, and if permitted or required by, applicable State or local law, reported the situation to the relevant authorities.
5. Title X providers **must** provide counseling to adolescents on how to resist attempts to coerce them into engaging in sexual activities.

## Counseling Returning Clients

When providing contraceptives for returning clients, an assessment should include the following:

1. Method concerns
2. Method use (consistent, correct)
3. Any changes in client's history (i.e., risk factors, medications)

If appropriate, provide additional contraceptives and discuss a follow-up plan.

## Preventive Health Promotion and Referral

1. Title X providers should refer pregnant, parenting, and postpartum adolescents to home visiting and other programs that have been demonstrated to provide needed support and reduce rates of repeat teen pregnancy

2. Title X providers should provide referral resources for mental health, domestic or intimate partner violence, and behavioral health including alcohol, tobacco, substance use as indicated.
3. Title X providers should provide a referral resource for immunizations as indicated.

## PRECONCEPTION HEALTH SERVICES

Preconception describes anytime that a client of reproductive potential is not pregnant but at risk of becoming pregnant, or when a client is at risk for impregnating their partner. A written protocol and procedure **must** be current, available, and consistent with national standards of care. Agencies **must** offer preconception health services to females and males as part of core family planning services. Preconception health services promote health before conception thereby reducing pregnancy-related adverse outcomes (low birth weight, premature birth, and infant mortality), promote birth outcomes and improve the health of clients even if they choose not to have children. All clients of childbearing status should have an annual reproductive life plan documented in the chart.

### Medical history for females must include:

1. Reproductive life plan
2. Sexual risk and health assessment
3. Reproductive history
4. Pregnancy history (gestational diabetes or HTN, pre-eclampsia, eclampsia, pregnancy outcomes)
5. Chronic disease management
6. Environmental exposures
7. Medications
8. Genetic conditions
9. Family history
10. Intimate partner violence
11. Social history/risk behaviors
12. Immunizations status
13. Depression

### Medical history of males must include:

1. Reproductive life plan
2. Sexual risk and health assessment
3. Past medical and surgical history that impairs reproductive health
4. Genetic conditions
5. History of reproductive failures, or conditions that can reduce sperm quality (obesity, diabetes, varicocele)
6. Social history/risk behaviors
7. Environmental exposures
8. Immunization status
9. Depression

### Physical Examination for all clients:

1. Height, weight, BMI (screen for obesity)
2. BP (screen for hypertension- based on American Heart Association recommendations)
    a. All clients — screen yearly

b. If BP <120/80 --- screen yearly, continue yearly
c. If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit and if average BP >140/90 recheck at next visit or in 1 week and refer if sustained BP >140/90.

3. Additional vital signs: temperature, heart rate, respiration, pain

Laboratory testing **must** be recommended based on risk assessment:

1. The USPSTF recommends screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity. Clinicians should offer or refer patients with prediabetes to effective preventive interventions.(USPSTF)

**Client Plan/Education**

1. Discuss relevant medications that are contraindicated in pregnancy, and review current medications taken during pregnancy.
2. Encourage to take a daily supplement containing (400-800 mcg) of folic acid (or a prenatal vitamin).
3. Avoid smoking, alcohol, and other drugs.
4. Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish).
5. Offer/Refer for any needed STI screening (including HIV) and appropriate vaccinations, if indicated.
6. Recommend keeping immunization up to date, including COVID-19 vaccination, while taking into consideration vaccines that are safe to administer near or during pregnancy.
7. Discuss prior pregnancy history complications and refer if necessary.

**Referral**

1. If client desires, refer for further diagnosis and treatment.
2. Refer male and female clients for additional services if screening results indicate presence of a health condition or as indicated (i.e., tobacco cessation, obesity, diabetes, depression, immunizations).

## ACHIEVING PREGNANCY SERVICES

A written protocol and procedure **must** be current, available, and consistent with national standards of care. Agencies **must** offer services on achieving pregnancy to people who want to become pregnant as part of their core family planning services. The goal is to address the needs of clients who wish to become pregnant in accordance with current standards of practice.

Achieving Pregnancy services will be offered to clients who respond to the reproductive life plan questions stating they desire to become pregnant. Achieving pregnancy services include identifying and assessing clients who desire pregnancy; providing counseling and education (including key messages on achieving pregnancy) and addressing misperceptions that many women, men and adolescents have about fertility and infertility. Clients who have been trying to achieve pregnancy for 12 months or longer with regular unprotected intercourse should be offered basic infertility services.

## Client Assessment

A. Client assessment includes:
1. Reproductive Life Plan
2. Time frame for desired pregnancy
    a. If less than 1 year, provide counseling on maximizing fertility success
3. Length of time she or they have been trying to become pregnant.
4. History of pregnancies or infertility
5. Partner involvement and support system issues
    a. Support system issues may include family and community support, LGBTQ considerations, single parent considerations, cultural/familial considerations, and awareness of other concerns or influences.

B. Medical history includes:
1. Immunizations
2. Medications
3. Present infectious
4. Chronic health conditions
5. Genetic conditions
6. Environmental exposures
7. Social history/risk behaviors
8. Sexual health assessment and risk assessment
9. Mental health
10. Medical history for **females must** Include:
    a. Reproductive history
    b. Obstetrical/Gynecology history
    c. Family history
    d. Intimate partner violence

10. Medical history for **males must** include:
    a. Past medical or surgical history that might impair reproductive health
    b. Medical conditions associated with reproductive failure that could reduce sperm quality

C. Assessing and updating the client's physical, sexual, and medical history may reveal additional issues in the person's health history that need to be addressed. The results can also help determine the need for additional information like fertility awareness or other health services such as: STI screening, preconception care, infertility services, possible need for Zika screening, and other preventative health services.

## Client Education and Counseling

Important information to include:

1. Importance of regular preventive health and chronic disease management
2. Some medications might be contraindicated in pregnancy and current medications will need to be reviewed.
3. Encourage daily supplement containing (400-800 mcg) of folic acid or a prenatal vitamin.
4. Avoid smoking, alcohol, and other drugs.
5. Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish)
6. Offer/refer for any needed STI screening, including HIV.
7. Offer/refer for age-appropriate vaccinations, as indicated.
8. Nutritional counseling and recommended weight loss if client is overweight.
9. The counseling provided **must** be documented in the record.

## Maximizing Fertility Awareness

Education to provide on maximizing fertility awareness and success:

1. Fertility awareness/techniques to predict ovulation
   a. Education about peak days and signs of fertility (including the 6-day interval ending on the day of ovulation that is characterized by slippery, stretchy cervical mucus and other possible signs of ovulation)
   b. Education on methods or devices designed to determine or predict the time of ovulation (e.g., over- the-counter ovulation kits, digital telephone applications, or cycle beads) should be discussed

2. Lifestyle influences
   a. Advise that vaginal intercourse every 1-2 days beginning soon after the menstrual period ends can increase the likelihood of becoming pregnant (women with regular menstrual cycles)
   b. Information that fertility rates are lower among women who are very thin or obese, and those who consume high levels of caffeine (e.g., more than five cups a day)
   c. Discourage smoking, alcohol, recreational drugs, and use of commercially available vaginal lubricants that may reduce fertility.
   d. Encourage a daily supplement containing folic acid or prenatal vitamins.
   e. Encourage males to avoid hot tubs.

## Referral

If desired, clients should be provided with a current referral listing for further diagnosis and treatment.

## PREGNANCY DIAGNOSIS AND COUNSELING

Agencies should provide pregnancy testing and diagnosis to all clients in need of this service. Pregnancy testing is one of the most common reasons for a first visit to a family planning agency. It is therefore important to use this occasion as an entry point for providing education and counseling about family planning services. A written protocol and procedure **must** be current, available, and consistent with national standards of care.

### Pregnancy diagnosis services include:

1. General Consent for Services
2. Reproductive Life Plan Discussion
3. Medical history (including chronic medical illnesses, physical disability, psychiatric illness)
4. Pregnancy testing (qualitative urine with high sensitivity)
5. Pregnancy test results **must** be given to the client
6. Counseling and referral resource list as appropriate
7. Chlamydia testing **must** be offered to females < 25 years of age and to females ≥ 25 years with risk factors.

If the **pregnancy test is positive**, the clinical visit should include:

1. A referral to prenatal care, if desired, and an estimation of gestational age. If a woman is uncertain about the date of her last normal menstrual period, a pelvic examination might be needed to help assess gestational age.
2. Information about the normal signs and symptoms of early pregnancy
3. Instructions on when to report any concerns to a provider for further evaluation.
4. If an ectopic pregnancy or other pregnancy abnormalities or problems are suspected, the client **must** be referred for immediate diagnosis and management.

### Nondirective Pregnancy Counseling and Referrals

Title X grantees and sub recipients **must** be in full compliance with Section 1008 of the Title X statute and 42 CFR 59.5(a)(5), which permits nondirective pregnancy counseling, including nondirective counseling on abortion to be provided when requested by the client. No Title X project may provide abortion as a method of family planning, (§ 59.5(a)(5)).

A. The Title X clinic may provide the following counseling and/or information to the client:
    a. Offer pregnant clients the opportunity to be provided nondirective information and counseling regarding each of the following options:
        i. Prenatal care and delivery;
        ii. Infant care, foster care, or adoption; and
        iii. Pregnancy termination (42 CFR 59.5(a)(5)(i)).
    b. If requested to provide such information and counseling, provide neutral, factual information, and nondirective counseling on each of the options, and referral upon request, except with

respect to any of the options the pregnant client indicates they do not wish to receive such information and counseling (42 CFR 59.5(a)(5)(ii)).

i. While a Title X project may provide a referral for abortion, which may include providing a client with the name, address, telephone number, and other relevant factual information (such as whether the provider accepts Medicaid, charges, etc.) about an abortion provider, the project **may NOT take further affirmative action (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the client. (65 FR at 41281 (July 3, 2000).**

ii. A Title X project may not use the provision of any prenatal, social service, emergency medical, or other referral, of any counseling, or of any provider lists, as an indirect means of encouraging or promoting abortion as a method of family planning.

c. Referral to social services or adoption agencies; and/or
d. Information about maintaining the health of the mother and unborn child during pregnancy.

B. In cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of medical services needed to address the emergency. A Title X project must provide for medical services related to family planning (including consultation by a clinical services provider, examination, prescription and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, and necessary referral to other medical facilities when medically indicated and provide for the effective usage of contraceptive devices and practices. (§ 59.5(b)(1)).

C. Providers also should assess the client's social support and refer her to appropriate counseling or other supportive services, as needed.

D. For clients who are considering or choose to continue the pregnancy, a prenatal care referral should be provided, and initial prenatal counseling should be provided that includes:
   a. Pregnant women with risk factors should be tested for STIs (including HIV) at the time of their positive pregnancy test if there will be delays in obtaining prenatal care (more than 2 months).
   b. Advise that some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (if current provider is unqualified).
   c. Encourage to take a daily supplement containing (400-800 mcg) of folic acid (or a prenatal vitamin).
   d. Avoid smoking, alcohol, and other drugs.
   e. Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish).
   f. Refer for age-appropriate vaccinations if indicated.

g. Risk assessment for adverse maternal or fetal outcomes should be performed. If the pregnant client is deemed high risk for such outcomes, prenatal care at the appropriate level should be expedited.

**Negative Test Visit**

Clients with a **negative pregnancy diagnosis** and do not want to become pregnant **must** be offered information about family planning services as indicated, such as:

1. The value of making a reproductive life plan.
2. Contraceptive services (Ideally provided the same day).
3. Counseling to explore why the client thought she was pregnant and sought pregnancy testing services.
4. Assessed for difficulties using her current method of contraception, if indicated.

Women who are not pregnant and who are trying to become pregnant **must** be offered information about family planning, as indicated, such as:

1. Services to help achieve pregnancy or basic infertility services.
2. Preconception health education.
3. STI services.
4. Reproductive life plan.

## BASIC INFERTILITY SERVICES

A written protocol and procedure **must** be current, available, and consistent with national standards of care. Agencies **must** offer basic infertility care as part of core family planning services. Infertility is defined as the failure of a couple to achieve pregnancy after 12 months or longer of regular unprotected intercourse.

### The Clinic Visit

An infertility visit to a family planning clinic focuses on determining potential causes of the inability to achieve pregnancy and making any needed referrals for specialist care.

Evaluation of both partners should begin at the same time. Earlier evaluation (6 months of regular unprotected intercourse) is justified for:

1. Women aged > 35 years
2. Those with a history of oligomenorrhea (infrequent menstruation)
3. Those with known or suspected uterine or tubal disease or endometriosis
4. Those with a partner known to be sub-fertile (the condition of being less than normally fertile though still capable of effecting fertilization).

An early evaluation may be warranted if risk factors of male infertility are known to be present or if there are questions regarding the male partner's fertility potential.

### Basic Infertility Care for Women.

The infertility visit should focus on:

1. Understanding the client's reproductive life plan and difficulty in achieving pregnancy.
2. The medical history **must** include:
    a. Past surgeries
    b. Previous hospitalizations
    c. Serious illnesses or injuries
    d. Medical conditions associated with reproductive failure (e.g., thyroid disorders, hirsutism, or other endocrine disorders)
    e. Childhood disorders
    f. Cervical cancer screening results and any follow-up treatment
    g. Medication
    h. Allergies
    i. Social history/risk behaviors
    j. Family history of reproductive failures
    k. Reproductive history (i.e., time trying to achieve pregnancy, coital frequency and timing)
    l. Level of fertility awareness
    m. Previous evaluation and treatment results; gravidity, parity, pregnancy outcome(s), and associated complications; age at menarche, cycle length and characteristics, and onset/severity of dysmenorrhea
    n. Sexual history (pelvic inflammatory disease, history of/exposure to STIs)

o. Review of systems (symptoms of thyroid disease, pelvic or abdominal pain, dyspareunia, galactorrhea, and hirsutism)

3. A physical examination **must** be offered if clinically indicated:
   a. Height, weight, and body mass index (BMI) calculation
   b. Thyroid examination (i.e., enlargement, nodule, or tenderness)
      c. Clinical breast examination (CBE)
      d. Signs of androgen excess
      e. A pelvic examination (i.e., pelvic or abdominal tenderness, organ enlargement/mass; vaginal or cervical abnormality, secretions, discharge; uterine size, shape, position, and mobility; adnexal mass or tenderness; and cul-de-sac mass, tenderness, or nodularity).

## Basic Infertility Care for Men

Infertility services provided to the male partner of an infertile couple should include:

1. Client's reproductive life plan
2. Medical history **must** include:
   a. Reproductive history (methods of contraception, coital frequency and timing; duration of infertility, prior fertility; sexual history; and gonadal toxin exposure, including heat).
   b. Medical illnesses (e.g., diabetes mellitus)
   c. Prior surgeries
   d. Past infections
   e. Medications (prescription and nonprescription)
   f. Allergies
   g. Lifestyle exposures
   h. Sexual health assessment.
   i. Female partners' history (pelvic inflammatory disease, STIs, and problems with sexual dysfunction)

3. A physical examination **must** be offered if clinically indicated:
   a. Examination of the penis (including the location of the urethral meatus)
   b. Palpation of the testes and measurement of their size
   c. Presence and consistency of both the vas deferens and epididymis
   d. Presence of a varicocele
   e. Secondary sex characteristics
   f. Digital rectal exam

Male clients concerned about their fertility should be offered a semen analysis. If this test is abnormal, they should be referred for further diagnosis (i.e., second semen analysis, endocrine evaluation, post-ejaculate urinalysis, or others deemed necessary) and treatment. The semen analysis is the first and most simple screen for male fertility.

### Infertility Counseling

Counseling provided during the clinic visit is guided by information elicited from the client during the medical and reproductive history and findings from the physical exam.

### Referral

1. Clients (female and male) **must** be referred for further diagnosis and treatment if indicated or requested.
2. Counseling provided during the clinic visit is guided by information elicited from the client during the medical and reproductive history and findings from the physical exam.
3. Referral for Zika testing if indicated

## SEXUALLY TRANSMITTED INFECTION SERVICES

Written protocols and operating procedures for sexually transmitted infections **must** be in place when STI/HIV services are provided. Screening and treatment **must** follow current Centers for Disease Control and Prevention (CDC) STI Treatment and HIV testing guidelines.

### The Clinic Visit

Initial steps of the clinic visit include:

A. Assess client's Reproductive Life Plan

B. Medical history
   1. Allergies
   2. Medications
   3. Medical conditions
   4. Sexual health assessment, based on gender identity, current anatomy and sexual behavior (partners, practices, protection, history of STIs, pregnancy prevention)
   5. Immunizations (Hep.B, HPV)

C. Physical exam as indicated (based on history or symptoms)

D. Laboratory testing including the following:

   1. Chlamydia:
      a. Testing **must** be offered annually for all females < 25 years. Sexually active women ≥25 years with risk factors (new partner, infected partner, partner with other concurrent partners, symptoms, history of STI or multiple partners in the last year) should be offered testing. Pregnant women should be screened for chlamydia at the time of the pregnancy test if there might be a delay in obtaining prenatal care.

b. Clients who test positive for Chlamydia should be re-tested 3 months following treatment for early detection of re-infection. Clients who do not present at 3 months for re-test should be re-tested the next time they present for services in the 12 months following treatment of the initial infection. Pregnant women should have a test-of-cure 3-4 weeks following treatment.
c. Chlamydia screening for males can be considered at sites with high prevalence (adolescent clinics, correctional facilities, STI clinics) or males who have sex with males (MSM). Males with Chlamydia should be re-tested 3 months following treatment.

2. Gonorrhea
   a. Testing **must** be offered annually to sexually active women <25 and for older women at increased risk of infection (previous gonorrhea, presence of other STIs, new or multiple sex partners, inconsistent condom use, commercial sex work, drug use) and those who reside in high prevalence areas. Other risk factors that place women at increased risk include infected partner, symptoms, history of STI or multiple partners in past year. Pregnant women should be screened for chlamydia at the time of the pregnancy test if there might be a delay in obtaining prenatal care.
   b. All males with symptoms suggestive of gonorrhea (urethral discharge or dysuria or whose partner has gonorrhea) should be tested and empirically treated.
   c. Males who have sex with males (MSM) should be tested at sites of exposure.
   d. Clients with uncomplicated urogenital or rectal gonorrhea infection should be re-tested for re- infection 3 months after treatment. Clients who do not present at 3 months for re-test should be re- tested the next time they present for services in the 12 months following treatment of the initial infection. Test of cure should occur between 7-14 days after initial treatment for pharyngeal gonorrhea.

3. Syphilis
   a. Testing should be offered to male and female clients at high risk:
      (a) MSM,
      (b) Commercial sex workers,
      (c) Persons who exchange sex for drugs,
      (d) Those in adult correctional facilities,
      (e) Living in high prevalence areas.
      (f) Pregnant women should be screened for chlamydia at the time of the pregnancy test if there might be a delay in obtaining prenatal care.

4. HIV/AIDS
   a. Testing should be routinely recommended for all male and female clients seeking STI evaluation
   b. HIV testing should be performed at time of STI diagnosis if not initially performed
   c. HIV screening is recommended at least once for all persons 15-65 years of age.
   d. High risk individuals should be screened for HIV at least annually. Annual testing is recommended for high-risk individuals:
      (a) injection drug users and their partners
      (b) persons who exchange sex for money or drugs
      (c) sex partners of HIV infected persons
      (d) MSM or heterosexual persons who themselves or whose sex partner have had more than one sex partner since their most recent HIV test

e. Opt out screening can be provided if included in the general medical consent.

5. Hepatitis C
   a. According to the CDC,
      a. Hepatitis C screening at least once in a lifetime for all adults aged ≥18 years, except in settings where the prevalence of HCV infection is <0.1% and
      b. Hepatitis C screening for all pregnant women during each pregnancy, except in settings where the prevalence of HCV infection is <0.1%.
      c. The recommendation for HCV testing that remains unchanged is regardless of age or setting prevalence, all persons with risk factors should be tested for hepatitis C, with periodic testing while risk factors persist.
      d. For persons with HIV, serologic testing should occur at initial evaluation and annual HCV testing in MSM with HIV infection.
      e. Risk factors for hepatitis C include people who currently or have ever used injection drugs; with HIV infection; with certain medical conditions, including those who ever received hemodialysis and those with persistently abnormal ALT levels; who have received transfusions or organ transplants; health care, emergency medical, and public safety personnel who have been exposed to the blood of someone who has hepatitis C; and children born to mothers who have hepatitis C.
      f. Any person who requests hepatitis C testing should receive it, regardless of disclosure of risk, because many persons might be reluctant to disclose stigmatizing risks.
   b. If testing is positive, refer for additional care and management of HCV infection and related conditions. Assess alcohol use and refer for intervention if indicated.
   c. With a grade B recommendation, the USPSTF recommends screening for HCV infection in all adults aged 18-79 years. [Chou, R., Dana, T., Fu, R. et al. (2020). Screening for Hepatitis C virus infection in adolescence and adults: Updated evidence report and systematic review for the US Preventative Services Task Force. *JAMA, 323*(10), 976-991. doi:10.1001/jama.2019.20788]
   d. Clients with high-risk behaviors /conditions (e.g., past or current injection of illegal drugs, HIV infected) should be recommended to have annual testing.

6. Hepatitis B
   1. Screening is not recommended for the general population.
      a. Screen women at increased risk (having had more than one sex partner in the previous six months, evaluation or treatment for an STI, past or current injection -drug use, and an HBsAg-positive sex partner)
      b. Screen men who have sex with women at increased risk (i.e., by sexual or percutaneous exposure)
   2. Testing should be recommended for high-risk populations (persons from high prevalence areas, HIV positive, IV drug users, MSM, Hep.B household contacts.)
      a. Test pregnant women for HBsAg at first prenatal visit of each pregnancy regardless of prior testing; retest at delivery if at high risk.
      b. Test all MSM for HBsAg, HBV core antibody, and HBV surface antibody.

c. Test all persons with HIV for HBsAg and anti-HBc and/or anti-HBs.

7. Zika Virus
    1. Risk assessment questions should be asked of all clients. Has the client or partner(s) traveled to a Zika impacted area in the past 8 months?
        a. Zika testing is only recommended for persons with Zika symptoms and who have traveled to a country with an active Zika outbreak.
        b. Check here https://wwwnc.cdc.gov/travel/page/zika-information for countries with active outbreaks.
    2. All clients should be educated regarding Zika risks and prevention strategies

**Treatment**

1. STI treatment should be provided on-site.
2. When treatment for any STI is provided on-site, the sub-recipient **must** follow current Centers for Disease Control and Prevention STI Treatment Guidelines ensure all clients are treated in a timely manner and appropriate follow-up measures are provided.
3. Behavioral counseling for all sexually active adolescents and adults who are at an increased risk for STIs is recommended. [US Preventive Services Task Force. (2020). Behavioral counseling interventions to prevent sexually transmitted infections. *JAMA, 324*(7). doi:10.1001/jama.2020.13095]
    a. Examples of behavioral interventions include individual or group counseling, media-based interventions, written materials, phone and text messages, websites, and videos.

**Expedited Partner Therapy**

Expedited Partner Therapy (EPT) should be offered as indicated for clients testing positive for chlamydia, gonorrhea, and trichomoniasis.

1. The ORC § 4723.4810 authorizes the use of expedited partner therapy (EPT) for certain sexually transmitted diseases as designated by the state board of nursing.

**Counseling**

1. Educate on risk reduction and available testing or referral for testing.
2. Encourage vaccination for HPV and Hepatitis B if indicated.
3. Encourage condom use to prevent STI/HIV infection.
4. Encourage clients with STIs to:
    a. Notify their sex partners and urge them to seek medical evaluation and treatment.
    b. Refrain from unprotected sexual intercourse during the period of STI treatment.
    c. Return for re-testing in 3 months if indicated.
4. Initiate behavioral counseling
5. Educate on Zika risks and prevention strategies

**Referral**

1. Clients with Hepatitis C and HIV infection should be linked to medical care and treatment.

2. Clients should be referred for needed immunizations.

### Mandatory Reporting

Sub-recipient agencies **must** comply with state and local STI reporting requirements.

All material from the above Sexually Transmitted Infection section was referenced from Workowski, K.A., Bachmann, L.H., Xhan, P.A. et al. Sexually Transmitted Infections Treatment Guidelines, 2021, *Morbidity and Mortality Weekly Report, (4)* 1-178. doi: http://dx.doi.org/10.15585/mmwr.rr7004a1

## GYNECOLOGIC SERVICES

Family planning agencies should provide for the diagnosis and treatment of minor gynecologic problems to avoid fragmentation or lack of health care for clients with these conditions. Written protocols and operating procedures **must** be available, current, and consistent with national standards of care. Problems such as vaginitis or urinary tract infection may be amenable to on-the-spot diagnosis and treatment, following microscopic examination of vaginal secretions or urine dip stick testing.

## RELATED PREVENTIVE HEALTH SERVICES

Written protocols and operating procedures **must** be available, current, and consistent with national standards of care.

Sub-recipient agencies are encouraged to participate in the Breast and Cervical Cancer (BCCP) project for diagnostic services (i.e., breast ultrasound, mammogram, and colposcopy) for uninsured or underinsured clients.

A. Clinics **must** offer and/or provide and stress the importance of the following to all clients:

1. Clinical Breast Exam (CBE)
   a. According to ACOG, the CBE may be offered to asymptomatic, average risk women in the context of an informed, shared decision-making approach. If performed for screening, intervals of every 1-3 years for women aged 25-39 years and annually for women 40 years and older are reasonable.
   b. ACOG continues to recommend the CBE as part of the evaluation for high-risk women with symptoms.
   c. The ACS and USPSTF do not recommend CBE due to no evidence that benefits outweigh the harm.

2. Pap testing as indicated:
   a. Age 21 to 65, every 3 years if Pap test is negative, OR
   b. Age 30 to 65, every 5 years if using co-testing (pap and HPV) and both are negative

c. Abnormal results should be treated in accordance with professional standards of care (for example, http://www.asccp.org/guidelines)

3. The Pelvic examination (including vulvar evaluation and bimanual exam) should be performed with routine pap testing and should be provided if medically indicated.

B. Clinics **must** stress the importance of:
1. The National Comprehensive Cancer Network recommends annual screening mammograms starting at age 40.
2. ACOG recommends offering average-risk women beginning at age 40 years and to initiate mammography by no later than 50. Screenings may be every 1 or 2 years. Biennial screenings after age 55. Mammography screenings should continue until at least age 75.
3. ACS recommends offering mammogram screenings annually at age 40 and biennially at 55 years. Screening should continue as long as the woman is in good health and is expected to live at least 10 more years.
4. USPSTF recommends starting biennial mammography screening at age 50.

C. Clinics should conduct a genital examination for adolescent males and document:
1. Skin and hair distribution (observation)
2. Hydrocele, varicocele, (observation and palpation)
3. Signs of STI (observation and/or palpation)

## QUALITY MANAGEMENT

### A. Referrals and Follow-up

Title X projects should offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site to promote holistic health and provide seamless care.

Written protocols and operating procedures for referrals and follow-up **must** be in place for the following:
- referrals that are made as a result of abnormal physical exams or laboratory findings,
- referrals for required services, and
- referrals for services determined to be necessary but beyond the scope of family planning.

1. Referral procedures **must** be sensitive to clients' concerns for confidentiality and privacy.

2. Client consent for release of information to providers **must** be obtained, except as may be necessary to provide care or as required by law.

3. Protocols and operating procedures for referrals and follow-up made because of abnormal physical examination or laboratory test findings within the scope of Title X that impact contraceptive management **must** include the following:
   a. A system to document referrals and follow-up procedures **must** be in place.
   b. Follow-up procedures **must** include the following:

1) A method to identify clients needing follow-up.
2) A method to track follow-up results on necessary referrals (such as, Pap and breast follow-up).
3) Documentation in the client record of contact and follow-up.
4) Documentation of reasons, actions, and follow-up where recommendations were not followed and/or protocols not acted upon.

c. Referral procedures should include that the client be given an explanation of the referral and need for follow-up including:
   1) Reason and importance of the referral
   2) Services to be received from the referral agency
   3) Address of the referral provider/agency
   4) Any instructions needed to follow through with the referral
   5) When to return to the family planning clinic Sub-recipient agencies **must** provide all Quality Family Planning Service components either on-site or by referral. When required services are provided by referral, the agency **must** have in place formal arrangements with a referral provider that includes a description of the services provided and includes cost reimbursement information.

4. For services determined to be necessary but which are beyond the scope of the project (such as thyroid abnormalities), clients **must** be referred to other providers for care. When a client is referred for non-family planning or emergency clinical care, agencies **must**:
   a. Document that the client was advised of the referral and the importance of follow-up.
   b. Document that the client was advised of their responsibility to comply with the referral.

5. Sub-recipients **must** maintain a current referral list that includes healthcare providers, local health and human service departments, hospitals, voluntary agencies, and health service projects supported by other federal programs.
   a. Referral lists **must** be current and updated annually.
   b. When possible, clients should be given a choice of providers.

## Pharmaceuticals

Agencies **must** operate in accordance with federal and state laws relating to security and record keeping for drugs and devices. The inventory, supply, and provision of pharmaceuticals **must** be conducted in accordance with state pharmacy laws and professional practice regulations.

It is essential that each facility maintain an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients. Projects should also ensure access to other drugs or devices that are necessary for the provision of other medical services included within the scope of the Title X project. Agencies can write prescriptions for Title X clients who choose and can conveniently obtain their contraceptives and medications from a pharmacy. Prescriptions may be written for contraceptives/medications on the clinic formulary or on the client's insurance plan formulary.

According to the OAC § 4723-9-09, a dispensing prescriber, except as authorized for expedited partner therapy (EPT), shall only dispense drugs to his/her clients with a valid prescriber-patient relationship.

Written protocols and operating procedures for the distribution, security and record keeping of pharmaceuticals and supplies **must** meet the following required standards:

1. The medical director is responsible for all policies and procedures pertaining to the general handling of pharmaceuticals.

2. Prescription of pharmaceuticals is done under the direction of a physician (who **must** have a drug control license for each location in which the storage and the dispensing of prescription drugs occur). The physician may dispense indirectly under his/her delegated authority to a R.N. or certified mid-level clinician. Pre-labeled, pre-packaged oral contraceptives may be distributed if delegated by a dispensing prescriber.
   a. All medications dispensed in Title X clinics **must** be pre-packaged.
   b. Prescription medications dispensed (including samples) **must** be labeled and labels **must** contain the following information:
      1) Name and address of location from which the prescription drug is dispensed
      2) Name of the client, unless prescription is authorized for EPT
      3) Date the prescription drug is dispensed
      4) Name, strength, and quantity of drug dispensed
      5) Directions for use, including frequency of use
      6) Prescriber's name (medical director/prescribing practitioner)
      7) Expiration date of prescription drug
      8) Record number of client
   c. All clients **must** receive verbal and written instructions for each drug. Medication education sheets should be kept current annually reviewed and revised as needed. The nature of drug education should be documented in medical records.
   d. There **must** be documentation that in-service training pertaining to the nature and safety aspects of pharmaceuticals is provided at least every two years to staff involved in the provision of medications to clients (i.e., new staff orientation, staff meeting, and quiz).

3. The inventory, supply and provision of pharmaceuticals may be delegated to appropriately qualified health professionals.
   a. Family planning health professionals delegated to deliver prescriptions drugs **must** be trained in all aspects of pharmaceutical and supply distribution.
   b. Delegate agencies **must** have proper segregation between requisition, procuring, receiving and payment functions for pharmaceuticals and supplies.
   c. Delegate agencies **must** have an inventory system to control purchase, use, reordering of pharmaceuticals and supplies.
   d. Delegate agencies **must** have adequate controls over access to medications and supplies including:
      1) Contraceptive and therapeutic pharmaceuticals **must** be kept in a secure place, either under direct observation or locked.
      2) Access to pharmaceuticals **must** be limited to health care professionals responsible for distributing these items.
      3) Safeguards **must** be in place to ensure that supplies purchased through the 340 B program are provided only to clients of the Converge Title X network.

e. A system **must** be in place to monitor the expiration date on drugs and ensure disposal of all expired drugs.
f. A system for silent notification in case of drug recall **must** be in place.
g. Inventory levels should not exceed a six-month supply.

4. A current formulary, listing all drugs available for Title X clients, **must** be maintained, and reviewed at least annually. Formularies should be retained for three years.

5. An adequate supply and variety of drugs and devices **must** be available to meet their client's contraceptive needs.
   a. Purchase and use of generic drugs based on therapeutic equivalence as published by the FDA or in the Formularies of Therapeutic Equivalence accepted by the State Board of Pharmacy is acceptable.
   b. Sub-recipient agencies may elect to identify certain supplies on the formulary, such as more expensive or infrequently used methods, that will be ordered upon client request and be available within two weeks of the request.

6. At a minimum, each site that provides medical services **must** have the following:
   a. Emergency drugs and supplies for treatment of vaso-vagal reaction.
   b. Emergency drugs and supplies for treatment of anaphylactic shock.

7. Prescriptive Methods for Transfer Clients
   a. An informed (general) consent form **must** be obtained, and a client history **must** be completed/reviewed. A BP **must** be taken if the client desires to continue a combined hormonal contraceptive. The provider will review the transfer records and decide if current prescription can be continued. The provider **must** document the prescription in the client's record.

## Medical Emergencies

Emergency situations involving clients and/or staff may occur at any time; therefore, all agencies **must** have written plans and protocols/ operating procedures for the management of on-site medical and non-medical emergencies.

1. At a minimum, written protocols **must** address:
   a. Vaso-vagal reactions/Syncope (fainting)
   b. Anaphylaxis
   c. Cardiac arrest
   d. Shock
   e. Hemorrhage
   f. Respiratory difficulties

2. Protocols **must** also be in place for emergencies requiring EMS transport, after-hours management of contraceptive emergencies and clinic emergencies.

3. All staff **must** be trained in emergency procedures and **must** be familiar with the plans. Licensed medical staff providing direct patient care services **must** be trained in CPR and hold current certification.

4. There **must** be a procedure in place for maintenance of emergency resuscitative drugs, supplies, and equipment.

## Medical Records

1. General Policy
   a. A medical record **must** be established for each client who receives clinical services, including pregnancy testing/counseling clients and emergency contraception clients.
   b. Title X requires the use of an electronic health record.
   **c.** Medical records are maintained in accordance with the accepted medical standards and state laws regarding record retention. Records **must** be**:**
      1) Complete, legible, and accurate
      2) Signed and dated by the clinician/health professional making each entry
         a) Each entry includes date, name, and title of the clinician/health professional
         b) Each entry is a permanent part of the record
      3) Readily accessible
      4) Confidential
      5) Safeguarded against loss or use by unauthorized persons
      6) Available upon request to the client
   d. HIPAA regulations regarding personal health information **must** be followed.

2. Record Contents
   The client's medical record **must** contain sufficient information to identify the client, indicate where and how the client can be contacted, justify the clinical diagnosis, and warrant the treatment and end results. Records **must** include the following:
   a. Personal data:
      1) Name
      2) Address, phone number(s), and how to contact
      3) Age
      4) Sex
      5) Marital status
      6) Income Assessment
      7) Unique client number
      8) Race and ethnicity (as required for FPAR)
      9) Medical history
      10) Allergies recorded in a prominent, consistent location
   b. Physical exam
   c. Documentation of clinical findings, diagnostic/therapeutic orders
      1) Laboratory test results and follow-up done for abnormal results
      2) Treatments and special instructions
      3) Documentation of continuing care, referral, and follow-up

4) Documentation of scheduled revisits

d. Contraceptive method chosen by the client
e. Informed consents
f. Documentation of all counseling, education, and social services given
g. Documentation of deferrals, reason for deferral, and refusal of services
h. Date and signature of clinician or health professional for each entry, including documentation of telephone encounters of a clinical nature.
   1) Signature includes name and title of provider
   2) A signature log if full name and title are not used in medical record
i. A confidentiality assurance statement in the client's record.
j. A list of identified problems should be maintained to facilitate continuing management and follow- up.

3. Confidentiality and Release of Records

   A system **must** be in place to maintain confidentiality of client records.
   a. A confidentiality assurance statement **must** appear in the client's record.
   b. HIV, mental health, and substance use information **must** be handled according to state law.
   c. The written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality.
      1) Consent form for release of information, signed by the client, specifies to whom information may be disclosed.
      2) Only the specific information requested may be released.
   d. Information collected for reporting purposes **must** be disclosed only in summary, statistical, or other form which does not identify individuals.
   e. Upon request, clients transferring to other providers **must** be provided with a copy or summary of their record to expedite continuity of care.
   f. Upon request, clients **must** be given access to their medical record

## Quality Improvement

Sub-recipient agencies **must** have a system in place that provides for the ongoing evaluation for conducting quality improvement.

1. The quality improvement system should include the selection and measurement of activities of at least one quality measure such as suggested measures on Table 4 in the QFP on page 24.

2. The quality improvement system **must** include the following elements:
   a. A tracking system that identifies clients in need of follow-up and/or continuing care **must** be in place. (Referrals and Follow-up)
   b. A system to assure that professional licenses and CPR certifications are current **must** be in place. (Personnel & Emergencies)
   c. Medical Audits to determine conformity with agency protocols, current standards, and acceptable medical practices **must** be conducted quarterly by the medical director.
      1) Minimum of two to three charts per clinician **must** be reviewed by the medical director biannually.
   d. Chart Audits/ Record Monitoring to determine completeness and accuracy of the medical record **must** be conducted at least biannually by the quality assurance committee or identified personnel.
      1) Chart audits **must** represent a minimum of three percent (3%) of the agency's *quarterly* caseload, or a minimum of 10 charts, whichever is more, randomly selected and reviewed by staff.
      2) All clinical sites should be represented in the sampling.
   e. Clinical protocols and procedures **must** be reviewed and signed annually by the medical director.
   f. Infection control policies and procedures reflecting current CDC recommendations and OSHA regulations **must** be in place.
   g. Laboratory audits to ensure quality and CLIA compliance **must** be in place.
   h. Equipment maintenance and calibration **must** be documented. (Equipment and Supplies)
   i. A process to implement corrective actions when deficiencies are noted **must** be in place.

3. Sub-recipient agency quality improvement systems should include:
   a. Annual peer review of all clinician/providers should be conducted. (Personnel)
   b. Regularly scheduled staff meetings to update and/or review medical or service delivery topics. Minutes should be kept of these meetings.
   c. Routine check of emergency drugs and supplies.
   d. A process to elicit consumer feedback should be in place.
   e. Periodic review of forms used by the agency for completeness and applicability.
   f. Routine monitoring of critical incident/occurrence reports.
   g. Periodic review of credentials of contracted laboratories.
   h. Periodic patient flow analysis.
   i. Periodic review of provider liability insurance coverage.
   j. Periodic monitoring for reliability and accuracy of the client data system to assure program performance, reporting, quality care, and generation of revenues. The following components should be monitored:
      1) Missing user data

2) Coding errors
3) Data outcome

4. A Quality Improvement Committee should be in place. This committee should meet quarterly, or as deemed necessary by the Project Director, to discuss quality assurance issues and to make recommendations for corrective action when deficiencies have been noted.
   a. If a formal Quality Improvement Committee is in place, minutes should be kept of all committee meetings.
   b. The function of the Quality Improvement Committee may be assumed by an in-house nursing or medical advisory committee with ongoing documentation of quality improvement activities.

## Reference

Centers for Disease Control and Prevention (CDC). (2014). Providing quality family planning services: Recommendations of the CDC and the U.S. Office of Population Affairs. *MMWR, 63*(4). https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

**SECTION 2**
**Program Monitoring**

## PROGRAM REVIEWS

The following resources are consistent in these program expectations: The Federal Register Title X [42 CFR Part 59, Subpart A], the Family Planning Statute which defines the legislative requirements for the program. The OPA Title X Program Guidelines, consisting of The Title X Handbook and Providing Quality Family Planning Services 2014 (QFP) is the guidance issued to grantees to assist with implementation of these requirements. These are available on the OPA website and in the federal resource section of this document.

### Reviews for Converge Subrecipients

All Title X subrecipients undergo a comprehensive program review conducted by the clinical services team every three years. The program site review is conducted to assure that Converge supported family planning service sites are managed effectively and are in compliance with federal Title X regulations. All program areas are reviewed: administration, finance, clinical services and community outreach and education.

### Methods

At least four weeks prior to the review, Converges staff will work with subrecipients to schedule the comprehensive site review (on site or virtually). If requested, subrecipients submit their required pre- materials directly to the Clinical Services team at least four weeks prior to the site review.

The clinical reviewer is responsible for reviewing the clinic service portion of the program including clinic protocols, contraceptive supplies, clinic observation and medical review. The administrative reviewer examines administrative portions of the program including policy review, observation, community outreach and education, and staff training. The financial reviewer analyzes billing, collections, collection processes and financial records.

## Process

The following are steps in the site review process:

1. Converge Clinical services teams work with subrecipients to identify review date/s and provide needed documentation lists.
2. Pre-Materials are to be submitted to the Medical Direct at least four weeks prior to the scheduled review. The materials should be submitted electronically.
3. Unless otherwise requested by the program, the family planning lead serves as the contact for the review process.
4. Subrecipients have the option to request a pre-review conference call or meeting to ask questions as they prepare for the site review.
5. Programs **must** have at least one clinic session scheduled during the visit to facilitate the evaluation of administrative and clinical components of the program. If review is conducted virtually, calls will be scheduled to access through role play.
    a. Upon request, an **entrance pre-conference** can be scheduled. The pre-conference occurs immediately at the beginning of the review to enable reviewers and program staff to meet prior to beginning the review. The program may include any staff person who will be able to provide information regarding clinical, administrative, education or financial aspects of the program. This is an opportunity for the reviewers to meet program personnel and get acquainted with the building, schedules, etc. It is a time for program staff to make reviewers aware of individual characteristics of the program and organization, as well as clarify the review process.
    b. The **exit conference** is an opportunity for discussion between the reviewers and the program staff regarding the general findings of the review.
    c. Completed **program review reports** are sent to the sub recipient within 30 days of the review. Any requirement that was not met is identified in the report with recommendations for correction. The report may also include recommendations for program improvement. Corrective plans of action **must** be submitted and accepted for all unmet requirements.
6. A **corrective plan of action (CPA)** must be submitted after the receipt of the program review report.
    a. CPAs are due within sixty days of the final day of the review.
    b. Plan may be approved with no further action needed, with conditions such as subsequent site visit or submission of support materials or may be rejected with revisions required.
    c. Implementation of CPA **must** be completed within one year of the review to continue accreditation.

## TECHNICAL ASSISTANCE AND MONITORING VISITS

Subrecipient agencies are visited in person or through a technical assistance call at least once every grant year. These visits are to provide technical assistance and to monitor progress in areas needing improvement identified during the previous site review, grant review or other means. This is done to ensure that those areas have been corrected to confirm Title X and Converge compliance.

In addition, program issues and changes are discussed at these visits and any technical assistance requested by the agency is provided.

## FINANCIAL PROGRAM AUDITS

An audit is a systematic review or appraisal to determine whether internal accounting and other control systems assure the following:

1. Financial operations are properly conducted.
2. Financial reports are timely, fair, and accurate.
3. The subrecipient has complied with applicable laws, regulations, and the terms and conditions of the award.
4. Resources are managed efficiently.
5. Desired results and objectives are being achieved


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## SECTION 4

### Clinical Protocol Review by Clinicians

The following clinical protocols provide a consistent approach to the provision of quality family planning services. A clinical protocol is a written plan of clinical management for an identified health condition. It is used to guide the clinician in the provision of health care to a client in an ambulatory healthcare setting. Clinical protocols incorporate standards of healthcare and reflect compliance with appropriate laws and regulations.
Clinicians include nurse practitioners, certified nurse midwives, physician's assistants, and physicians.

All clinicians must review each clinical protocol during orientation to the agency and prior to the provision of family planning medical services. Acceptance and agreement to use the clinical protocols in their entirety as practice guidelines is documented by clinician signature below. Each clinician must repeat this procedure annually. Knowledge, skills and legal scope of practice of each clinician must be assessed by the medical director prior to use of a clinical protocol that includes medically delegated responsibility to the clinician. In the event that a clinician cannot accept medically delegated responsibilities as included in all the medically delegated clinical protocols, the clinician and medical director must document which clinical protocols that the clinician is permitted to use. This may happen if the clinician is new to the agency or during clinician preceptorship. One approach is for both to sign or initial the individual clinical protocols that by mutual agreement the clinician is permitted to use.

On an appropriate line below, each clinician must: print name, sign name, sign initials and date signature. This information also provides a legal record of clinician signatures. Additional lines will be added as necessary.

| | |
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| Medical Director | Date |
| Physician | Date |
| Physician | Date |
| Nurse Practitioner | Date |
| Nurse Practitioner | Date |
| Certified Nurse Midwife | Date |
| Physician's Assistant | Date |

## SECTION 5
## General

### What are clinical lab services?

This policy is to provide guidance for staff providing clients with accurate, efficient, and confidential laboratory testing through compliance with the CLIA, Federal and State rules and regulations, HIPAA regulations regarding confidentiality, and ongoing development, implementation, and evaluation of quality control methods.

A clinical laboratory is defined by CLIA as any facility which performs laboratory testing on specimens obtained from humans for providing information for health assessment and for the diagnosis, prevention, or treatment of disease.

There are four types of CLIA certifications for laboratories which include:

- Certification of Waiver;
- Certification for Provider-Performed Microscopy Procedures (PPMP);
- Certification of Compliance; and
- Certification of Accreditation.

Reproductive Health clinic laboratories performing *only* "waived" tests must apply for a Certificate of Waiver.

Reproductive Health clinics performing *only* tests indicated as "waived" and "provider-performed microscopy procedures" (PPM) must apply for a Certification of PPM.

Reproductive Health clinics laboratories that perform a higher level of complexity testing must adapt this protocol to reflect their certification.

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| **Protocol** | All staff performing any laboratory test will be provided an orientation when hired, as well as ongoing competency assessment on laboratory policies, and procedures at least annually, and additional training when laboratory tests are added or changed.<br><br>Certification:<br>• A CLIA certificate is required in order to operate a clinical laboratory.<br>o Applications and renewals are submitted to ODH Office of Health Assurance and Licensing CLIA Program.<br>o The fee is determined by CMS according to the complexity level of testing.<br>o The CLIA certificate will be displayed in a prominent place in view of the public.<br><br>CLIA Laboratories: Waived and PPM<br>• Are subjected to inspections only: |

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| | ○ If a complaint is made;<br>○ To validate that:<br>▪ Only waived categorized tests are performed under a waived lab certificate; and<br>▪ Only waived and PPM tests are performed under a PPM certificate; or<br>○ If there is a risk of harm to client due to inaccurate testing.<br>• Waived laboratories may perform only those tests categorized as waived.<br>• PPM laboratories may perform only tests classified as waived and PPM.<br>• Written Orders:<br>○ Waived tests may be performed at the written request of a:<br>▪ Medical Doctor;<br>▪ Doctor of Osteopathy;<br>▪ Naturopathic Doctor;<br>▪ Physician Assistant;<br>▪ Certified Nurse Practitioner; or<br>▪ Certified Nurse Midwife.<br>○ Written protocols, policies, and procedures cover the use of standing orders when specific guidance is provided.<br>• Waived tests may be performed by any individual following appropriate training and documentation.<br>• PPM testing may be performed only by a:<br>○ Medical Doctor;<br>○ Doctor of Osteopathy;<br>○ Physician's Assistant;<br>○ Certified Nurse Practitioner; or<br>○ Certified Nurse Midwife.<br>• Written procedures will be developed and maintained for all tests performed in the waived and PPM laboratory and will be approved by the laboratory director and/or health officer.<br>• A PPM laboratory must have a lab director who is legally liable and responsible for all aspects of testing and must be a:<br>○ Physician (MD or DO) licensed to practice in Mississippi;<br>○ Nurse practitioner or nurse midwife licensed and certified by the Mississippi Board of Nursing; or<br>○ Physician's assistant licensed by Mississippi Board of Medical Examiners.<br>• Maintain:<br>○ Complete records on each test kit/device per manufacturer's recommendations, for 2 years, including:<br>▪ Quality control;<br>▪ Calibration; and<br>▪ Instrument maintenance. |

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| | ○ Records on all testing personnel indicating laboratory training and competency assessment.<br>○ Meet department standards for safety, disposal of hazardous and infectious waste.<br>○ Refer specimens only to laboratories operating in compliance with CLIA.<br>▪ To determine if a referred lab is CLIA compliant staff may access information at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Laboratory_Demographic_Information.html.<br>▪ Staff may call the laboratory directly to ask about their CLIA status.<br>▪ Laboratory staff will reevaluate the CLIA status when the referred labs certificate expiration date is due.<br><br>• Laboratory will not revise results or information directly related to interpretation of results provided by the testing laboratory.<br>• Inform Laboratory Compliance Section of changes in laboratory name, owner, director, or address within 30 days after a change occurs. |
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| **Procedure** | Test Preparation:<br><br>• Tests will be performed in an area with adequate space while maintaining client privacy.<br><br>• Testing and storage must meet specific environmental requirements per manufacturer's instructions.<br><br>• Clinical equipment will be maintained, and calibration checks performed as directed in manufacturer's instructions. Points to consider:<br><br>○ Clean work area before and after testing;<br>○ Perform testing in well-lit area;<br>○ Check and record temperatures of the testing and reagent storage areas;<br>○ Check and record expiration dates of reagents/kits, discard when expired;<br>○ Do not mix reagents;<br>○ Inspect reagents for damage, discoloration, or contamination and discard if found;<br>○ Prepare reagents according to manufacturer's instructions; and<br>○ Allow time for refrigerated reagents/samples to come to room temperature.<br>• External quality control (QC) per manufacturer's instructions.<br>○ Will be performed at a minimum:<br>▪ With each new shipment of kits/reagents;<br>▪ With a change in lot numbers; and<br>▪ By each new testing staff before conducting testing. |

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| | o Results will be recorded on the lab's results log; and records kept for 2 years.<br><br>Performing Tests:<br>• Staff will:<br>o Confirm test order;<br>o Confirm client's identification;<br>o Confirm client is aware of what test(s) is/are being done;<br>o Confirm client has followed pretest instructions, if indicated;<br>o Wear appropriate personal protective equipment;<br>o Use the proper specimen collection device;<br>o Follow the testing steps in the exact order per manufacturer's instructions;<br>o Use a timer to follow the required timing intervals;<br>o Interpret test results according to the manufacturer's instructions;<br>o In-house test results will be given to the client at the time of testing;<br>o If test results are invalid, compromised, or disagree with client's clinical information, the test will be repeated; and<br>o Record test results in client's chart and on the lab's results log.<br><br>• Any test not performed in this laboratory will be referred to a licensed reference laboratory.<br>o Specimens sent out will be documented on a specimen tracking log.<br>o The original report form from the reference laboratory will be filed in the client's chart.<br>o Abnormal cervical cytology results will be entered into a client management tracking system. (see *Management of Abnormal Cervical Cytology Policies and Procedures*)<br><br>Critical Values:<br>o Establish critical values which require immediate treatment or evaluation from an ordering provider;<br>o Define which tests have critical values;<br>o Ensure staff are aware of the critical values;<br>o Provide staff directions in how to alert the provider in a timely manner; and<br>o Document when and to whom the critical values are reported.<br><br>Notification of Lab Test Result(s):<br>o All clients will be notified of test results.<br>o Clients with special requests will be notified per client preference. |

- Clinics providing confidential services will designate a code name or code word (e.g., "Annie") that can be used when calling or leaving a message for clients who need confidential services (e.g., "Hi, this is Annie, please call me back").
- Client will be notified of normal test results by mail within 7 days.
  - Inform the client to call the clinic for results if they have not received any notification within 10-14 days.
- Client with abnormal test results will be contacted by:
  - Phone:
    - First attempt shall occur when lab results are received.
    - Second attempt will be done within 1 week of the first attempt.
  - If unable to contact by phone, a letter will be sent.
  - If no response is received within 1 month, a registered letter will be sent.
  - If no response is received, the client will be assumed to be lost to follow-up.
- Client notification process will be documented in client's chart.

Quality Assurance (QA) Requirements:

- All laboratories will have a mechanism in place to monitor, assess, and when indicated, correct problems identified in the pre-analytic phase of testing.
- The pre-analytic phase begins from the time a test is ordered by the provider until the sample is ready for analysis. Type of errors include:
  - Client identification and preparation;
  - Test collection procedures;
  - Specimen handling and processing; and
  - Specimen transport.

- PPM labs must monitor and evaluate the total testing process (pre-analytic, analytic, and post-analytic).
  - Pre-analytic phase - see above.
  - Analytic phase consists of two procedures:
    - Confirmation of specimen and corresponding procedure to be done; and
    - The process in which the specimen sample is analyzed.
      - Error types consist of equipment malfunction and sample mix- up.
  - Post-analytic phase is the process of declaring the outcome of the tests performed.
    - Error types consist of erroneous validation of analytical data, failure in reporting/addressing the report, excessive turn-around time, improper data entry, and failure/delay in reporting critical values.

- Staff will assure the accurate, reliable, and prompt reporting of test results.

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| | • All QA activities and corrective action will be documented and discussed with the staff.<br><br>Microscope Maintenance for PPM Lab:<br>• Clean objective lenses, eyepieces, and condenser daily, or after use;<br>• Use a high-quality lens paper dampened with approved lens cleaner;<br>• Keep the 10X and 40X objectives oil-free;<br>• Cover microscope when not in use; and<br>• Ensure annual service is performed by a trained technician. |
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| **Training** | Competency Assessment Requirements:<br>• Will be done semiannually during the first year of employment and annually thereafter.<br>• Can be done throughout the entire year by coordinating it with routine practices and procedures to minimize impact on workload.<br>• Consists of six elements:<br>o Direct observations of routine client test performance, including client preparation, if applicable, specimen handling, processing, and testing;<br>o Monitoring the recording and reporting of test results;<br>o Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records;<br>o Direct observation of performance of instrument maintenance and function checks;<br>o Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and<br>o Assessment of problem-solving skills.<br><br>PPM Test Performance:<br>o Perform either proficiency testing or quality assurance (split sampling or an external quality assurance program) bi-annually. |
| | |

**References**


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Centers for Disease Control and Prevention. (2014). *Clinical laboratory improvement amendments (CLIA).* http://wwwn.cdc.gov/clia/Regulatory/default.aspx

U.S. Government Publishing Office. (2003). *Electronic code of federal regulations*. http://www.ecfr.gov/cgi- bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#se42.5.493_137

Centers for Medicare & Medicaid Services. (2014). *Clinical laboratory improvement amendments (CLIA).* http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html

Centers for Disease Control and Prevention. (2005). *Good laboratory practices for waived testing sites*. http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf

Centers for Medicare & Medicaid Services. (2012). *What do I need to do to assess personnel competency?* http://www.cms.gov/Regulations-and Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf

**Resources**

1. CLIA application for certification: http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf
2. Centers for Disease Control and Prevention. 2011. Ready? Set? Test! Patient Testing is Important booklet: http://wwwn.cdc.gov/clia/Resources/WaivedTests/pdf/ReadySetTestBooklet.pdf
3. Tests granted waived status under CLIA: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/waivetbl.pdf
4. Centers for Medicare & Medicaid Services– list of PPM (Provider Performed Microscopy Procedures): http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ppmplist.pdf

## What is autoclave pre-sterilization, operation, and maintenance?

This policy provides guidance on the sterilization process to ensure client safety and best practice in the sterilization of equipment and use of the autoclave as well as preventative and scheduled maintenance procedures.

Autoclaving is a process used to destroy microorganisms and decontaminate biohazardous waste from instruments by using high pressure and high temperature steam for sterilization. There are potential risks to the operators which include:

- Heat burns from hot materials and autoclave chamber walls and door;
- Steam burns from residual steam coming from autoclave and materials on completion of cycle;
- Hand and arm injuries when closing the door; and
- Body injury if there is an explosion.

To ensure the health and safety of staff using the autoclave, it is important for each department to maintain their autoclave per manufacturer's instructions and to train staff in their proper use.

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| **Protocol** | Clinical staff will be trained in the operation of the autoclave and follow the manufacturer's recommendations for proper maintenance to ensure not only their safety, but also to ensure that equipment is correctly sterilized. |
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| **Procedure** | Safety Practices of the Autoclave:<br>• Follow manufacturer's instructions for loading, operating, maintaining, cleaning, and performing quality assurance checks.<br>• Before using the autoclave, check inside the autoclave for any items left by the previous user that could pose a hazard.<br>• Clean the drain strainer before loading the autoclave.<br>• Load the autoclave properly as per the manufacturer's instructions(do not overload).<br>• Make sure the door of the autoclave is fully closed and latched when in use.<br>• Make sure the correct cycle for the material is selected.<br>• When the cycle is complete, open the door slowly. Keep your head, face, and hands away from the opening.<br>• ***Do not*** autoclave items containing corrosives, solvents or volatiles, or radioactive materials.<br><br>Prepare and Package Items Needing Sterilization:<br>• Thoroughly clean instruments first by rinsing with water. |

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| | o Use of personal protective equipment (PPE) shall be worn for handling and cleaning contaminated instruments.<br><br>• Pre-clean with appropriate cleaning product.<br>o If detergent based, ensure that it is mixed to the correct in-use dilution.<br>o Avoid prolonged soaking; soak for the amount of time recommended by the cleaning agent's manufacturer.<br><br>• Clean.<br>o Completely submerge items during the cleaning process to minimize aerosolizing of microorganisms and assist in cleaning.<br>o Remove gross soil using tools such as brushes and cloths.<br>o Inspect brushes and other cleaning equipment for damage after each use, and discard if necessary.<br>o Clean, disinfect, dry, and store tools used to assist in cleaning after each use, or else discard.<br><br>• Rinse.<br>o Rinse all equipment thoroughly with water after cleaning to remove residues which may react with the disinfectant/sterilant.<br><br>• Dry.<br>o Follow manufacturer's instructions for drying of the device.<br>o Instruments may be air-dried or dried by hand with a clean, lint- free towel.<br>o Dry stainless-steel instruments immediately after rinsing to prevent spotting.<br><br>• Post cleaning.<br>o Visually inspect instruments to ensure cleanliness and integrity of the device.<br>o Repeat cleaning on any item that is not clean.<br>o Follow the manufacturer's guidelines for lubrication.<br>o Those instruments requiring lubrication shall be lubricated prior to sterilization.<br><br>• Package in autoclave wrap or pouches.<br>o Use of heat-sensitive tape on the autoclave wrap provides monitoring which indicates the load has undergone an effective steam sterilization process and indicates the proper temperature has been reached.<br>o If the heat-sensitive tape does not turn brown (indicating the load did not undergo proper sterilization process) the load must be reprocessed.<br>o Autoclave pouches have a color sensor strip on the outside of the pouch which also must turn brown to indicate the package was effectively sterilized. |

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| | o Write the date, batch number that day, employee initials, and label contents on the wrap or pouches to be sterilized.<br><br>Loading the Autoclave:<br>• Do not mix unwrapped and wrapped items or sterilized and non-sterilized items.<br>• Do not overload.<br>• Close and latch door firmly.<br><br>Operating the Autoclave:<br>• Follow individual autoclave manufacturer's operating instructions.<br>• Press ON/Standby button.<br>• Refer to Standard Cycle Parameters to select the proper sterilization program time and temperature.<br>• Select and press the appropriate sterilization program button.<br>• Press the START button.<br>• If the autoclave is not working properly discontinue using immediately.<br>o Post sign alerting others not to use the autoclave.<br>o Contact the service company responsible for maintenance of the autoclave.<br>• Address any error messages; make corrections and reprocess the instruments.<br><br>Unloading the Autoclave:<br>• Allow the load to cool down to room temperature.<br>• Examine the load items for:<br>o Any signs of compromised packaging integrity; and<br>o Change to brown color of the heat-sensitive tape or pouch color strip.<br><br>Recordkeeping:<br>• Entries must be placed on the log form each time the autoclave is used.<br>• Entries should include operator's name, date, and time.<br>• Log forms should be kept by the autoclave for easy access.<br>• Log maintenance and repairs into log forms.<br><br>Monitoring:<br>• Monitoring of the autoclave should be performed routinely using:<br>o Mechanical indicators;<br>▪ Assessment of cycle time and temperature after each load.<br>o Chemical indicators; and<br>▪ Affixed to the outside of each pack; changes color when sterilization parameters are present for each package. |

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| | ○ Biological indicators (e.g., Attest™ biological indicators, spore-strip biological indicators).<br>▪ Sterilizer should be monitored at least weekly.<br>▪ If sterilizer is used frequently (several loads per day) daily use of biological indicators may be indicated.<br>▪ Consider sending a processed pack or pouch to a laboratory for culture to verify sterility.<br><br>Contingency Plans:<br>• If autoclave does not operate as expected, do not attempt to fix the problem.<br>○ Record the problem on the log form.<br>○ Notify **(insert name)** to report the problem.<br>• Burn emergency.<br>○ If you are burned, seek medical treatment as soon as possible.<br>○ Burns to the face, third degree burns, or burns over large area should be treated as emergencies.<br>○ Minor burns should be treated using first aid procedures.<br>○ Regardless of the degree of severity, report the burn to (**insert name**) as an occupational injury.<br>Maintenance:<br>• Preventative and scheduled.<br>○ Follow the manufacturer's recommendations for routine maintenance and cleaning.<br>○ Daily: clean door gasket with a soft cloth.<br>○ Weekly:<br>▪ Clean the tray holder and trays with a cleaning agent and water and a soft sponge.<br>▪ Clean and descale the chamber and reservoir with a descaling agent.<br>○ Clean the outer parts of the autoclave with a soft cloth. |
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| **Training** | • All users must become familiar with the manufacturer's operation manual prior to the use of the autoclave.<br>• All users must be trained before operating an autoclave.<br>• All training should be documented, and records should be maintained in the lab with other safety training records. |
| | |

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BC Ministry of Health. (2013). *Best practices for cleaning, disinfection and sterilization of medical equipment/devices in all health care settings*. http://www.publichealthontario.ca/en/eRepository/PIDAC_Cleaning_Disinfection_and_Sterilization_2013.pdf

## What is cleaning and disinfection for healthcare settings?

This policy provides guidance for Reproductive Health clinic staff in reducing the risk of infection through cleaning and disinfection of environmental surfaces in patient-care areas and common-use areas.

All healthcare settings, regardless of the level of care provided, must make infection prevention a priority and must be equipped to observe Standard Precautions. Outpatient facilities have been identified as vectors for transmission of infectious agents among patients. Vulnerable patient populations rely on frequent and intensive use of ambulatory care to maintain or improve their health. It is critical that all this care be provided under conditions that minimize or eliminate risks of healthcare-associated infections.

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| **Protocol** | All staff will follow the Standard Precautions for disinfection and sterilization of patient-care areas and common-use areas. |
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| **Procedure** | Those surfaces in proximity to the patient and those that are touched frequently in the exam room will be cleaned between each patient and disinfected daily.<br>These include surfaces such as:<br>• Exam tables;<br>• Countertops;<br>• Mayo stand;<br>• Chairs;<br>• Stools; and<br>• Tabletops.<br><br>Select EPA-registered disinfectants or detergents/disinfectants with label claims for use in healthcare.<br><br>Follow the manufacturer's recommendations for use of cleaners and EPA-registered disinfectants (this includes):<br>• Amount;<br>• Dilution;<br>• Contact time;<br>• Safe use; and<br>• Disposal.<br><br>Use appropriate personal protective equipment (PPE), as indicated.<br><br>Change the paper covering the exam table between patient use. |

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| | Place any used linens (e.g., exam gowns, sheets) in a designated container located in each exam room after each patient use.<br><br>Clean personal and diagnostic equipment regularly; disinfect if equipment becomes contaminated with blood or body fluids.<br><br>Proper Hand Hygiene:<br>• Use of alcohol-based hand rub with emollient is the preferred method.<br>• Use soap and water when hands are visibly soiled or in contact with suspected infectious material.<br>• Decontaminate hands with alcohol-based hand rub before and after each patient encounter.<br>• Decontaminate hands with alcohol-based hand rub after contact with body fluids or excretions, mucous membranes, and nonintact skin if hands not visibly soiled.<br>• Decontaminate hands with alcohol-based hand rub after removing gloves.<br>• Wash hands with soap and water before eating and after using a restroom.<br><br>Clean floors in exam rooms, lab, and bathrooms daily.<br><br>Promptly clean and decontaminate spills of blood and other potentially infectious materials.<br><br>If reusable cleaning cloths or mops are used, they should be decontaminated regularly to prevent surface contamination.<br><br>Cleaning Common Areas:<br>• Floors in common areas shall be cleaned daily.<br>• Common area surfaces (e.g., counters, doorknobs, telephones) will be disinfected daily or more frequently, using an EPA-registered disinfectant. |
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| **Training** | • Job- or task-specific infection prevention education and training will be provided to all healthcare providers.<br>• Training will focus on both healthcare staff safety and patient safety.<br>• Training on Bloodborne Pathogens will be provided upon orientation and repeated at least annually for all staff whose assigned tasks may lead to occupational exposure. |

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| | • Competencies will be documented upon orientation to clinic, should be repeated annually, and any time policies or procedures are updated or revised.<br>• Assessments of current infection prevention measures and update as needed will be performed annually. |
| | |

**References**


Occupational Safety and Health. (2005). *Bloodborne pathogen regulations*. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

Centers for Disease Control and Prevention. (2016). *Guide to infection prevention for outpatient settings: Minimum expectations for safe care.* https://www.cdc.gov/infectioncontrol/pdf/outpatient/guide.pdf

American Academy of Family Physicians. (2001). *AAP issues recommendations on infection control in physicians' offices.* http://www.aafp.org/afp/2001/0215/p787.html

## What is a reproductive life plan?

The CDC recommends all people of reproductive age should have a reproductive health plan as part of providing quality family planning services. A reproductive life plan is a set of personal goals and subsequent plans about having or not having children. All clients need to make a reproductive life plan based on their own values, goals, and resources. Clients need to think about when and under what conditions they want to become pregnant. If pregnancy is not desired, contraceptive options should be discussed.

The provider should avoid making assumptions about the client's needs based on his or her characteristics, such as sexual orientation or disabilities. For clients whose initial reason for coming to the service site was not related to preventing or achieving pregnancy, asking questions about his or her reproductive life plan might help identify unmet reproductive health-care needs. Identifying a need for contraceptive services might be particularly important given the high rate of unintended pregnancy in the United States.

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| **Subjective Data** | History must include:<br>• All clients of reproductive age must be assessed at least annually as to their reproductive plans<br>• Discussing a reproductive life plan enhances the family planning aspects of the visit. |
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| **Clinical Pathway of family planning services for men and women of reproductive age (*See* Figure 2)** | Client encounters with women and men of reproductive age may require different service needs (i.e., contraceptive services, pregnancy testing and counseling, achieving pregnancy, STI services and related preventive health services). The following questions will determine what family planning services are most appropriate for a given visit and must be asked and documented:<br><br>• What is the client's reason for the visit?<br>• Does the client have another source of primary healthcare?<br>• What is the client's reproductive life plan? |
| | |
| **Reproductive Life Plan** | **Providers should assess the client's reproductive life plan by asking the client questions such as:**<br>• Do you have any children?<br>• Do you want to have (more) children?<br>• How many (more) children would you like to have and when?<br>*Or*<br>• Would you or your partner like to become pregnant in the next 12 months?<br>*And*<br>• Do you want to prevent a pregnancy now? |
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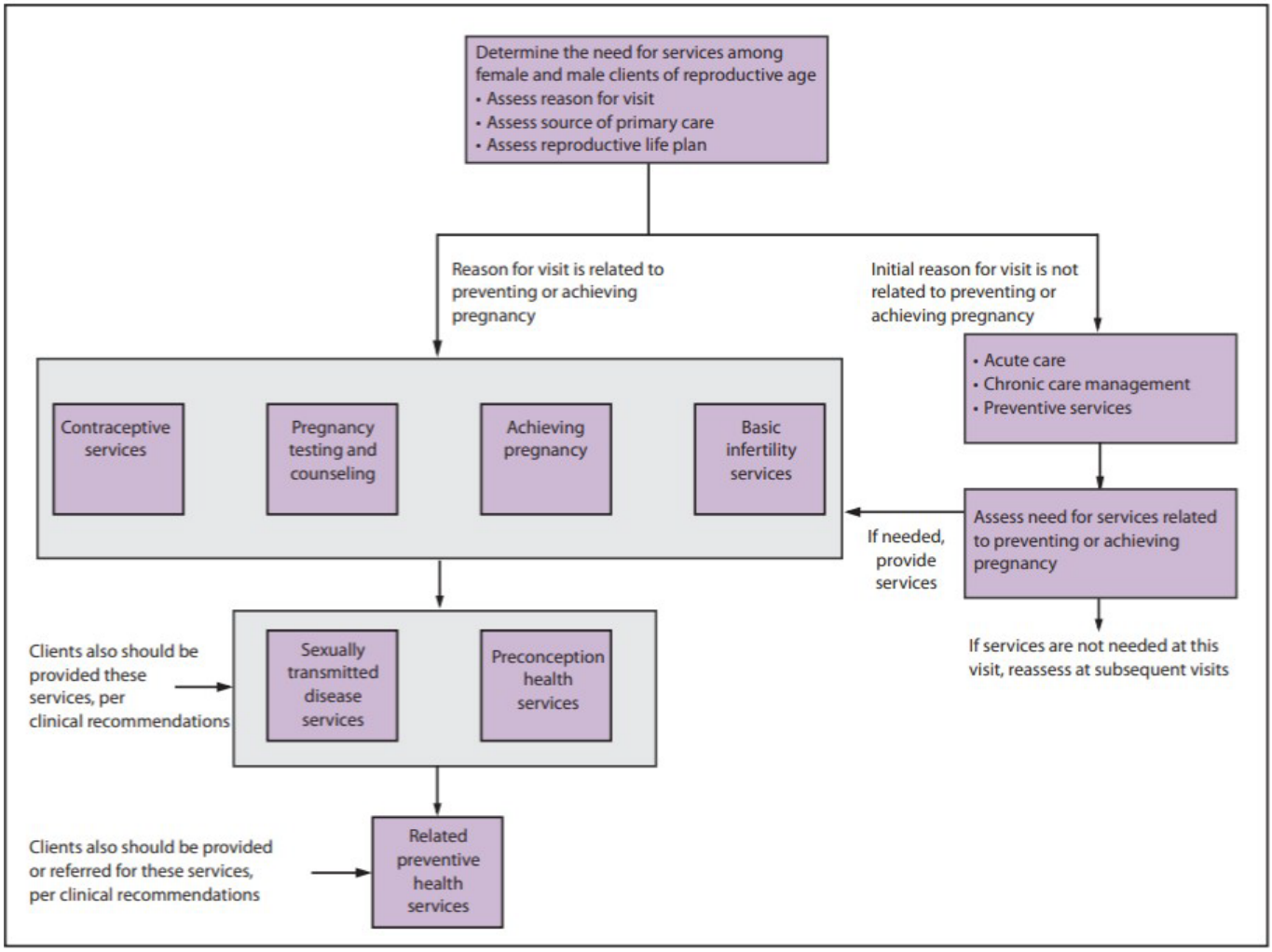
| **Plan**<br>**(*See* Figure 2)** | • If the client does not want a child currently and is sexually active, then offer **Contraceptive Services**<br>• If the client desires pregnancy testing, then provide **Pregnancy Testing and Counseling Services**<br>• If the client wants to have a child within the next twelve months, then provide **Achieving Pregnancy Services**<br>• If the client wants to have a child and is experiencing difficulty conceiving, then provide **Basic Infertility Services**<br>• If the female client of reproductive potential is not pregnant but at risk of becoming pregnant, or the male client is at risk for impregnating his female partner, then provide **Preconception Health Services**<br>• If the client is at risk for STI exposure, provide **STI Services** |
| | |
| **Patient Education/Counseling** | • Nearly half of pregnancies are unintended.<br>• Risks associated with unintended pregnancies<br>  o Late entry to prenatal care<br>  o Maternal depression<br>  o Increased rates of abortion<br>  o Exposure to potentially harmful substances during pregnancy<br>  o Poor pre-pregnancy disease control<br>  o Reduced school completion and lower income attainment (for an unmarried woman)<br>• Preconception, contraception, STI prevention counseling etc.<br>• Importance of planning and goal setting.<br>• Importance of birth spacing. Women with interpregnancy intervals of less than 18 months are more likely to have premature infants and low birthweight babies<br>• Reproductive life plans are fluid and are never right or wrong.<br>• If the client does not have a plan to prevent pregnancy, the client has a plan to get pregnant.<br>• Benefits of a reproductive life plan<br>  o Choose contraceptive methods that best fit the plan<br>  o Decrease risks for unintended and short interval pregnancies<br>  o Increase likelihood of achieving life goals (e.g., graduating school or college, obtaining a certain job) |
| | |
| **Consultation/Referral** | • Based upon client's need. |
| | |

**FIGURE 2. Clinical pathway of family planning services for women and men of reproductive age**

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Moos, M.K., & Johnson, F. (2015). *Reproductive life planning: From concept to practice* [PowerPoint Slides]. http://www.healthystartepic.org/wpcontent/uploads/2015/08/MoosReproductiveLifePlanningSlides.pdf

## Clinic Emergencies

1. Syncope
    a. Symptoms (sudden onset of one or more of the following):
        i. Nausea and/or vomiting
        ii. Diaphoresis
        iii. Weakness
        iv. Dizziness
        v. Pallor
    b. Clinical Signs
        i. Weakness, sweaty, possible decreased level of consciousness
        ii. Pulse < 60/min. or >110
        iii. BP < 80 systolic
    c. Laboratory
        i. Consider checking a Hgb/HCT
        ii. Consider finger stick glucose
    d. Plan
        i. Check vital signs and perform physical examination
        ii. Lie client flat with legs elevated
        iii. Treat symptomatically; supportive care only
            1.) Aromatic spirits of ammonia may be helpful (Do not use if patient is asthmatic) 2.) Offer juice or cola with sugar for clients with hypoglycemic episode
        iv. If cardiovascular collapse is suggested by examination activate EMS system and begin basic life support

2. Anaphylactic Shock
    a. Symptoms (Sudden onset of one or more of the following):
        i. Hives
        ii. Pruritus
        iii. Swelling
        iv. Red, watery eyes
        v. Rhinorrhea
        vi. Dizziness or syncope
        vii. Change of voice
        viii. Coughing or wheezing
        ix. Throat tightness or closing
        x. Difficulty with breathing or swallowing
        xi. Sense of doom
        xii. Change of color

    b. Plan
        i. If cardiovascular collapse, respiratory distress, or facial/oral swelling is suggested by examination, activate EMS system and begin basic life support if needed

ii. Monitor vital signs frequently (every 2 to 5 minutes)
iii. Medications (below), as available:
    i. If available, give Aqueous Epinephrine 1:1,000, 0.5 ml subcutaneously, with a dose for adults of 0.01 mL/kg up to a maximum dose of 0.2 to 0.5 mL. Repeat q 10-15 min. as needed if available
    ii. Administer oxygen by facial mask at 8-10 liters/min if available
    iii. Give Benadryl (diphenhydramine) 25-50 mg I.M.
    iv. If anaphylaxis is due to an injection, give aqueous epinephrine, 0.15-0.3 ml, into injection site to inhibit further absorption

3. Cardio-Pulmonary Arrest (Basic Life Support for Health Care Providers)
    a. Establish unresponsiveness
        i. Activate Emergency Medical System (EMS) or appropriate resuscitation team.
        ii. Get AED and emergency equipment or send someone to do so. (All clinics and facilities should have an AED on the premises.)
    b. Evaluate the airway and check for breathing
        i. Look, listen and feel
        ii. If unresponsive and not breathing, open the airway (person needs to be in a supine position)
        iii. Head tilt-chin lift or jaw thrust
        iv. If victim is breathing or resumes effective breathing, place in the recovery position
        v. If victim is not breathing, give 2 slow breaths (1 second each) while using pocket mask or bag-mask. Allow for exhalation between breaths.
    d. Check for signs of circulation (breathing, coughing, movement), including pulse. (Carotid)
        i. If signs of circulation/pulse present but breathing is absent, provide rescue breathing (1 breath every 5 seconds for adult, 10-12 breaths per minute)
        ii. If signs of circulation/pulse absent, begin chest compressions interposed with breaths
            1) Compression depth of at least 2 inches in adults and at least 1/3 the AP dimension of the chest in infants and children
            2) Compression rate: 100-120/min
            3) Compression/Breath Ratio (1 Person): 30:2 – 5 cycles (about 2 minutes)
            4) Compression/Breath Ratio (2 people): 30:2 – 5 cycles (check pulse and switch roles every 2 minutes)
    1. Defibrillation
        i. If CPR is in progress, continue CPR until the AED is turned on, the AED pads are applied, and the AED is ready to analyze the heart rhythm.
        ii. If you are alone and an AED is available, you should use it once you have determined the person in in cardiac arrest.

    2. For an AED to be effective, you MUST use it properly by doing the following:
        i. Turn it on first.
        ii. Make sure the patient's chest is clearly exposed and dry.
            1) Remove any medication patches with a gloved hand.
            2) If necessary, remove or cut any undergarments that may be in the way. The pads need to be adhered to the skin for the shock to be delivered to the heart.

iii. Apply the appropriate-sized pads for the patient's age in the proper location on the bare chest.
    1) Use adult pads for adults and children over the age of 8 years or over 55 pounds.
    2) Place one pad on the upper right chest below the right clavicle to the right of the sternum; place the other pad on the left side of the chest on the mid-axillary line a few inches below the left armpit.
iv. Plug in the connector, and push the analyze button, if necessary. (Most AEDs available today have their pads pre-connected and will automatically analyze once the pads are applied to the chest. Make sure you understand how the AED within your organization operates.)
v. Tell everyone to "clear" while the AED is analyzing to ensure accurate analysis. Ensure no one is touching the patient during the analysis or shock.
vi. When "clear" is announced, have the rescuer performing the compressions stop compressions and hover a few inches above the chest, but remain in position to resume compressions immediately after a shock is delivered or the AED advises that a shock is not indicated.
vii. Observe the AED analysis and prepare for a shock to be delivered if advised.
    1) Ensure that everyone is clear of the patient before the shock is delivered.
    2) Remember that the AED delivers an electrical current that could injure anyone in contact with the patient.
    3) Have the rescuer in the hover position ready to resume compressions immediately after a shock is delivered or the AED advises that a shock is not indicated.
viii. Deliver the shock by pressing the shock button, if indicated.
ix. After the shock is delivered, immediately start compressions and perform about 2 minutes of CPR (about 5 cycles of 30:2) until the AED prompts that it is reanalyzing, the patient shows signs of return of spontaneous circulation, or you are instructed by the team leader or more advanced personnel to stoop.
x. Do not wait for the AED to prompt to begin CPR after a shock or no shock advised message.

CPR information taken from:
American Red Cross. (2015). *Basic life support for healthcare providers*. https://www.redcross.org/content/dam/redcross/atg/Landing_Pages/BLS/BLS_Handbook Final_.pdf

American Heart Association. (2019). *CPR & ECC guidelines*. https://eccguidelines.heart.org/circulation/cpr-ecc-guidelines/

4. Shock/Hemorrhage
    a. Symptoms (sudden onset of one or more of the following):
        i. Uncontrolled, profuse bleeding
        ii. Pallor, weakness, diaphoresis, fainting
    b. Clinical Signs
        i. Client may appear weak and may exhibit disorientation

ii. Pulse may be weak, shallow, rapid, or slow
iii. Blood pressure may be decreased (hypotension)
iv. Skin may appear pale and cold

c. Plan
i. Place client in Trendelenburg position
ii. Activate EMS system
iii. Monitor vitals as indicated
iv. If able, start intravenous line and infusion
v. If etiology identified, attempt to control bleeding

5. General Emergency Information
a. Staff should be trained in emergency procedures and must be familiar with the emergency plans. All licensed medical staff should be trained in CPR and hold current certification.
i. All client medical emergencies requiring referral to another provider should have referral results documented in client's record.
ii. If appropriate, copy pertinent records to send with emergency personnel.
iii. Staff should engage in periodic drills; if multiple use facility, coordinate drills with other personnel.

b. After Hours Emergencies (all facilities must have in place at least one of the following for the management of afterhours contraceptive emergencies):
i. Answering service that can direct a client to either an on-call staff nurse or the nearest ED.
ii. Message left on clinic phone with clear instructions to the nearest ED.
iii. Call-forwarding to the on-call staff nurse.
iv. In addition to the above, written instructions must be provided to every client during the initial and subsequent visits detailing the facilities after-hour policies or be posted on the clinic website.

c. Emergency situations (fire, natural disaster, vandalism, power failure, harassment, bomb/terrorism, earthquake, and tornado) may occur at any time. All projects must therefore have written plans and procedures for the management of emergencies.
i. Disaster plans must be developed and made available to all staff.
ii. Staff must understand all assigned emergency escape routes.
iii. Staff must complete training and understand their role in an emergency or natural disaster.
iv. All exits must be recognizable and free from barriers.

## Latex

Latex allergy is caused by a reaction to certain proteins found in natural rubber latex. A latex allergy may cause minor symptoms, such as itchy skin, to hives or anaphylaxis.

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| **Subjective Data/Symptoms** | *History may include:*<br>• Rash with latex exposure<br>• Swollen lips with blowing up a latex balloon<br><br>*Symptoms may include:*<br>• Itchy, stuffy, or runny nose<br>• Watery eyes<br>• Scratchy throat<br>• Hives or swelling<br>• Nausea or vomiting<br>• Dizziness, confusion<br>• Wheezing, cough, chest tightness, and difficulty breathing |
| | |
| **Objective Data** | *Physical Findings:*<br>• Rash or redness<br>• Hives or swelling<br>• Hypotension<br>• Confusion, loss of consciousness<br>• Weak or rapid pulse<br>• Cough<br>• Wheezing |
| | |
| **Plan / Pharmacologic Treatment** | *Medication:*<br><br>• If person is having an anaphylactic reaction, the person needs an immediate injection of epinephrine. See Section 3, Anaphylactic Shock<br>• For less severe reactions, antihistamines or corticosteroids should control the reaction and relieve discomfort |
| | |
| **Latex Allergy Precautions** | Latex allergy precautions include:<br>• Remove all latex gloves from the area and replace with:<br>o Nonsterile latex free gloves, powder free, low protein, or vinyl gloves for non-sterile procedures. |

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| | ○ Sterile latex free gloves for sterile procedures.<br>• Remove all items containing latex.<br>• A facility-wide strategy to manage latex allergies in the health care environment should be in place.<br>• Latex free materials should be readily available for those patients with allergies. |
| | |

**References**


Centers for Disease Control and Prevention. (2012). *Home healthcare workers: How to prevent latex allergies.* https://www.cdc.gov/niosh/docs/2012-119/pdfs/2012-119.pdf

Premier. (2020). *Latex: Allergy prevention.* https://www.premiersafetyinstitute.org/safety-topics-az/latex-allergies/latex-allergy-prevention-control-strategies-healthcare/

Tang, M. (2013). *Latex management of a patient at risk of or with a known latex allergy.* https://www.rch.org.au/rchcpg/hospital_clinical_guideline_index/Latex_management_of_a_patient_at_risk_of_or_with_a_known_latex_allergy/

## What are medical records, personal health information, and confidentiality?

Agencies must maintain complete medical records for every client, in accordance with accepted professional standards. The medical records must be completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information. Each entry must be signed.

A record must be maintained of every client encounter with the staff. All staff, including non-medical workers, should record every encounter (including telephone calls), reason for encounter, and any action taken.

Concern with respect to confidentiality of information may not be used as a rationale for noncompliance with state laws regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws.

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| **Custody of Records** | The agency is the legal custodian of client records. It is responsible for the provision of a safe place for storage of client records to prevent disclosure to unauthorized persons.<br><br>Client records should be kept in locked files when not in use and must not be left where individuals other than authorized persons have access to them. EMRs must be password protected and should have an automatic time out when not in use. Users should lock the EMR when not in use to ensure against unauthorized access. Also, consider that portable laptops should not be left in a room with a client. An additional layer of security can be provided with the use of biometrics. |
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| **Confidentiality and HIPAA** | Agencies must be compliant with HIPAA regulations. HIPAA covered entities are expected to have adequate administrative, technical, and physical safeguards in place to protect personal health information under its control.<br><br>A summary of the HIPAA privacy rule is available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html<br><br>A summary of the HIPAA security rule is available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html<br><br>In January 2013, HHS announced a final rule that implements a number of provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act to strengthen the privacy and security protections for health information established under HIPAA. See http://www.hhs.gov/ocr/privacy/hipaa/administrative/omnibus/index.html for the press release and a link to the final rule. |

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| | Clients must be informed of agency privacy practices and a signed acknowledgment of receipt of the notice must be part of the medical record. Model notices of privacy practices that reflect 2013 regulatory changes are available at http://www.hhs.gov/ocr/privacy/hipaa/modelnotices.html |
| | |
| **Some Considerations in Maintaining Confidentiality** | All staff must be oriented to the importance of safeguarding the confidential nature of the record and any other client information.<br><br>Privacy and confidentiality in gathering client information by interview or any other means is essential.<br><br>Office and clinic facilities should be such that client information is not inadvertently revealed to persons in the waiting room or any place else.<br><br>Use discretion in engaging a client in discussion in his home or on the street while neighbors, relatives, or other persons are present.<br><br>Electronic email exchanges with clients should be encrypted. |
| | |
| **Accessibility of Medical Records** | The records must be systematically organized to facilitate retrieval and compiling of information.<br><br>Funding agencies, such as the U.S. Department of Health and Human Services, have the right to review charts of those individuals whose care is supported by their funds.<br><br>The original medical record is the property of the clinic. However, the client or her/his attorney, upon presentation of appropriate documentation, is entitled to copies of the record. |
| | |
| **Retention of Records** | Each agency should have an established written policy regarding the length of time for retention of records and the method of disposing of client records. This is usually done by obtaining a ruling from the agency or county attorney.<br><br>It is recommended that all client records be retained for a minimum of 7 years plus current year after discharge; or, in the case of a minor, 7 years after their 18th birthday. |
| | |
| **Destruction of Records** | When materials no longer need to be retained, in order to ensure the confidentiality of records, they should be destroyed. Agencies that use EMRs should establish a business plan that addresses how and when records will be deleted or moved to a secure network drive. |
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| **Content of Client Record** | The medical record must contain sufficient information to identify the client, justify the diagnosis or clinical impression, and warrant the treatment and end results.<br><br>The record should contain the following:<br><br>• Personal Data<br>  o Client identification.<br>  o Name, address, and telephone number.<br>  o Name of someone who may be contacted to reach client.<br>  o Name, address, telephone number, and relationship to client of a person who may be contacted in the event of a medical emergency. For the client under 18, the parent or guardian should be listed.<br>  o Dates of visits.<br>  o Identification of other sources of medical care.<br><br>• Clinical data<br>  o Medical history, which must be updated at least annually or more often as indicated.<br>  o Documentation of physical examination.<br>  o Documentation of laboratory tests ordered, results, and follow-up.<br><br>• Diagnostic and therapeutic orders, observations, clinical findings, and action taken<br>  o Indication of treatments and/or medications given, observations, and action taken.<br>  o Progress notes.<br>  o Special instructions.<br>  o Follow-up contact when applicable.<br>  o Any telephone calls to or from a client regarding medical problems.<br>  o Referral forms.<br>  o Follow-up of referrals.<br>  o Whenever possible, a summary of relevant health-related encounters in other health facilities should be included in the client's family planning medical record. |
| | |
| **Record Audit** | Internal record audits should be performed at least monthly, to determine completeness of records, e.g., blanks filled in, releases and consent signed appropriately, physician and staff signatures, etc.<br><br>Chart audits for the Title X funding should be completed twice a year. |
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## SECTION 6
## Psychosocial

### Human Trafficking

## Mandated Reporting

**Policy:**

Title X projects shall comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking (collectively, "State notification laws") (Legislative mandate and OPA's Notice of Funding Opportunity)

A. Must have in place and implement a plan to comply with State notification laws. Such plan shall include, at a minimum, policies and procedures that include:
    a. A summary of obligations of the project or organizations and individuals carrying out the project under State notification laws, including any obligation to inquire about or determine the age of a minor client or of a minor client's sexual partner(s)
    b. Timely and adequate annual training of all individuals (whether or not they are employees) serving clients for, or on behalf of, the project regarding State notification laws; policies and procedures of the Title X project and/or provider with respect to notification and reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence and human trafficking; appropriate interventions, strategies, and referrals to improve the safety and current situation of the patient; and compliance with State notification laws."

B. Ensure that every minor who presents for treatment is provided counseling on how to resist attempts to coerce them into engaging in sexual activities.

C. Projects may conduct a preliminary screening of any minor who presents with a sexually transmitted disease (STI), pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor. Projects are permitted to diagnose, test for, and treat STIs.

D. Projects should maintain records to demonstrate compliance with each of the requirements, including which:
    a. Indicate the age of minor clients.
    b. Indicate the age of the minor client's sexual partners if such age is an element of a State notification law under which a report is required.
    c. Document each notification or report made pursuant to such State notification laws.

E. Refer to *Minor Consent, Confidentiality, and Reporting Child Sexual Abuse: A Guide for Title XFamily Planning Providers* in Mississippi for full details and procedures.

## What is mandated reporting?

Agencies must be compliant with all applicable state laws regarding the mandatory reporting of child abuse, child molestation, sexual abuse, rape, incest, or domestic violence. Agencies must have written procedures in place demonstrating compliance.

Program Directors must assure that all staff members are trained annually and familiar with Mississippi law regarding mandatory reporting / human trafficking. Documentation must be kept.

Family Planning agencies must develop written internal procedures for staff on how to address mandatory reporting incidents**.** It is expected that the Project Director will solicit input from local agencies involved in the issue before writing up a local procedure. Local agencies include law enforcement, child protective services, etc. Your clinic's procedure must detail how you will respond to any reportable or potentially reportable situation as outlined in this policy. All Family Planning Program staff must be familiar with the policy and procedures outlined in this section.

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| **Who are mandated reporters?** | Mississippi law specifies the persons or professions that are required to report child abuse or neglect. Mississippi mandatory reporters are listed in MississippRev. Code § 2151.421(A)(1)(b).<br><br>Mandatory reporters include (selected sample):<br>• Attorney<br>• Physician, including a hospital intern or resident<br>• Dentist<br>• Podiatrist<br>• Practitioner of a limited branch of medicine as specified in Mississippi Rev. Code 4731.15<br>• Registered nurse, licensed practical nurse, visiting nurse<br>• Other healthcare professional<br>• Person engages in social work or the practice of professional counseling<br>• Employee of a county department of job and family services who is a professional and works with children and families |
| | |
| **How is a report made?** | The person making the report shall make it to the public children services agency or a municipal or county peace office in the county in which the child resides or in which the abuse or neglect is occurring. (Mississippi Rev. Code § 2151.421)<br><br>Mandated reported must immediately report. The report can be made by phone or in person. If requested, the mandated reporter must submit a written report. |
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| **What information should be included** | • The names and addresses of the child and the child's parents or theperson or persons having custody of the child, if known. |

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| **in a mandatory report?** | • The child's age and the nature and extent of the child's injuries, abuse or neglect that is known or reasonably suspected or believed, as applicable, to have occurred or of the threat of injury, abuse, or neglect that is known or reasonably suspected or believed, as applicable, to exist, including any evidence of previous injuries, abuse, or neglect.<br>• Any other information that might be helpful in establishing the cause of the injury, abuse, or neglect that is known or reasonably suspected or believed, as applicable, to have occurred or of the threat of injury, abuse, or neglect that is known or reasonably suspected or believed, as applicable, to exist. Mississippi Rev. Code § 2151.421(C). |
| | |
| **When must abuse be reported?** | "A mandated reporter who is acting in an official or professional capacity and knows or suspects that a child under eighteen years of age or a mentally retarded, developmentally disabled, or physically impaired child under twenty- one years of age has suffered or faces a threat of suffering any physical or mental wound, injury, disability, or condition of a nature that reasonably indicates abuse or neglect of the child, shall immediately report that knowledge or suspicion." ORC § 2151.421.<br><br>Confirmation of abuse is not required. Reporters must report whenever they "suspect" that abuse has occurred. |
| | |
| **What sexual activity must be reported?** | Sexual activity that must be reported includes any sexual activity that would constitute any of the following offenses:<br><br>• Rape (defined at 2907.02)<br>• Sexual Battery (defined at 2907.03)<br>• Unlawful Sexual Conduct with a Minor (defined at 2907.04)<br>• Sexual Imposition (defined at 2907.06)<br>• Gross Sexual Imposition (defined at 2907.05)<br><br>ORC § 2151.421.<br><br>**Am I ever required to report a minor's *consensual* sexual activity as child abuse?**<br>Consensual acts that **must** be reported as child abuse include:<br>• Sexual conduct with a minor under 13 years old, irrespective of partner's age. (2907.02)<br>• Sexual contact with a minor under 13 years old, irrespective ofpartner's age. (2907.05) |

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| | • Sexual conduct with a minor 13 years old or older but under 16, if the partner is 18 or older and knew or was reckless about the minor's age. (2907.04)<br>• Causing sexual contact between others, if one of the parties is under 13 years old. (2907.05)<br>• Sexual contact with a minor 13 or older but under 16 if the partner is 18 or older and at least 4 years older than the minor (sexual contact between a 13 or 14 year old and someone 18 or older, or a 15 year old and someone 19 or older).(2907.06)<br>• Causing sexual contact between others if one of the parties is a minor 13 or older but under 16, if the instigator is 18 or older and at least 4 years older than the minor (13 year old/18 or older, 14 year old/at least 18, 15 year old/at least 19).(2907.06)<br>• Sexual conduct with a minor under 18 years old who is a primary, secondary, or higher education school student if the partner is a teacher, administrator, coach, or other person in authority employed by the school. (2907.03)<br>• Sexual conduct with a minor under 18 years old if the partner is a coach, instructor, leader of a scouting troop or a person with temporary or occasional disciplinary control over the minor. (2907.03)<br><br>"'Sexual conduct' means vaginal intercourse between a male and female; anal intercourse, fellatio, and cunnilingus between persons regardless of sex; and without privilege to do so, the insertion, however slight, of any part of the body or any instrument, apparatus, or other object into the vaginal or anal cavity of another. Penetration, however slight, is sufficient to complete vaginal or anal intercourse." ORC § 2907.01<br><br>"'Sexual contact' means any touching of an erogenous zone of another, including without limitation the thigh, genitals, buttock, pubic region, or if the person is a female, a breast, for the purpose of sexually arousing or gratifying either person." ORC § 2907.01.<br><br>**In general, the following consensual acts do not require reporting:**<br>• Sexual conduct or contact when both partners are 13 years old or older and under 18 years old.<br>• Sexual contact with a minor 15 or older if the partner is under 19 years old.<br>• Sexual contact or conduct with a minor 16 or older, irrespective of partner age, (unless partner is a teacher, coach or other specially identified category as described above). |
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| **What is abuse or neglect?** | Mississippi law defines an "abused child" to include any child who: |

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| | "(A) Is the victim of "sexual activity" as defined under Chapter 2907 of the Revised Code, where such activity would constitute an offense under that chapter;<br>(B) Is endangered;<br>(C) Exhibits evidence of any physical or mental injury or death, inflicted other than by accidental means, or an injury or death which is at variance with the history given of it. Except as provided in division (D) of this section, a child exhibiting evidence of corporal punishment or other physical disciplinary measure by a parent, guardian, custodian, person having custody or control, or person in loco parentis of a child is not an abused child under this division if the measure is not prohibited under section 2919.22 of the Revised Code.<br>(D) Because of the acts of his parents, guardian, or custodian, suffers physical or mental injury that harms or threatens to harm the child's health or welfare.<br>(E) Is subjected to out-of-home care child abuse." ORC § 2151.031.<br><br>Mississippi defines a "neglected child" as any child:<br><br>"(1) Who is abandoned by the child's parents, guardian, or custodian;<br>(2) Who lacks adequate parental care because of the faults or habits of the child's parents, guardian, or custodian;<br>(3) Whose parents, guardian, or custodian neglects the child or refuses to provide proper or necessary subsistence, education, medical or surgical care or treatment, or other care necessary for the child's health, morals, or well-being;<br>(4) Whose parents, guardian, or custodian neglects the child or refuses to provide the special care made necessary by the child's mental condition;<br>(5) Whose parents, legal guardian, or custodian have placed or attempted to place the child in violation of sections 5103.16 and 5103.17 of the Revised Code;<br>(6) Who, because of the omission of the child's parents, guardian, or custodian, suffers physical or mental injury that harms or threatens to harm the child's health or welfare;<br>(7) Who is subjected to out-of-home care child neglect." ORC § 2151.03. |
| | |
| **When mandated reporters in Mississippi must report consentual sexual activity as child abuse** | If a minor engages in consentual sexual conduct* with an older (or younger) partner, is a report mandated?** |

| Age of Partner⇒ | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Age of Patient ⇓ | | | | | | | | | | | |
| 11 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 12 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 13 | Y | N | N | N | N | N | Y | Y | Y | Y | Y |
| 14 | Y | N | N | N | N | N | Y | Y | Y | Y | Y |
| 15 | Y | N | N | N | N | N | Y | Y | Y | Y | Y |
| 16 | Y | N | N | N | N | N | N | N | N | N | N |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 17 | Y | N | N | **N** | N | N | N | N | N | N | N |
| 18 | Y | Y | Y | Y | N | N | N | N | N | N | N |

If a minor engages in sexual contact,* is a report required?**

| Age of Partner⇒ | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Age of Patient ⇓ | | | | | | | | | | | |
| 11 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 12 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 13 | Y | N | N | N | N | N | Y | Y | Y | Y | Y |
| 14 | Y | N | N | N | N | N | Y | Y | Y | Y | Y |
| 15 | Y | N | N | N | N | N | N | Y | Y | Y | Y |
| 16 | Y | N | N | N | N | N | N | N | N | N | N |
| 17 | Y | N | N | **N** | N | N | N | N | N | N | N |
| 18 | Y | Y | Y | N | N | N | N | N | N | N | N |

Is sexual activity when both partners are 16 or older ever reportable?

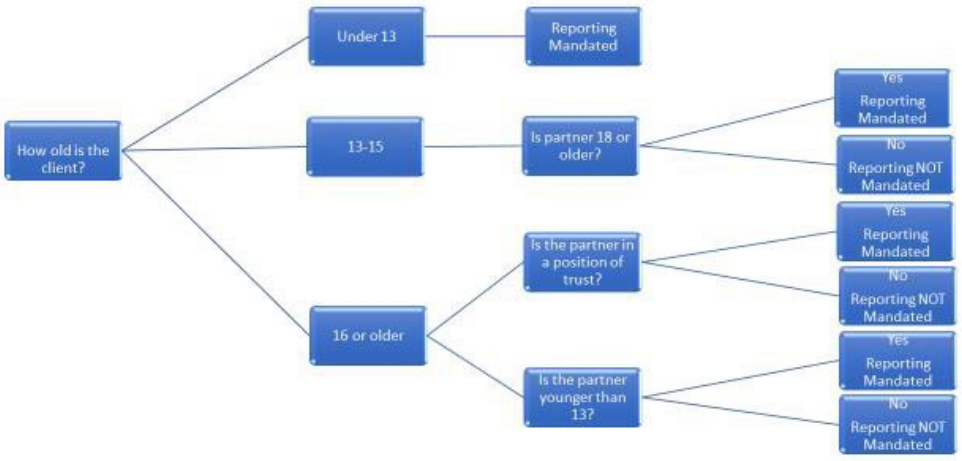
Mandated reporters must report sexual conduct with a minor under 18 years old who is a primary, secondary, or higher education school student if the partner is a teacher, administrator, coach, or other person in authority employed by the school. They also must report sexual conduct with a minor under 18 years old if the partner is a coach, instructor, leader of a scouting troop or a person with temporary or occasional disciplinary control over the minor.

*In addition, mandated reporters must report any sexual activity that appears coerced, exploitative, based on intimidation, or in any other way resembles abuse -- regardless of claimed consent by the minor and regardless of partner age.*

**References**

Gudeman, R. (2011). *Minor Consent, Confidentiality, and Child Abuse Reporting in Title X Funded Family Planning Settings in Ohio*. (3rd ed.). National Center for Youth Law. Oakland: CA.

# Mandated Reporting Algorithm




Source: http://codes.ohio.gov/orc/2907
ORC 2907.02, 2907.03, 2907.04

Ohio Department of Health, Reproductive Health and Wellness Program
July, 2017

## What is family and intimate partner violence?

Intimate partner violence (IPV) is a serious, preventable public health problem that affects millions of Americans. The term "intimate partner violence" describes physical violence, sexual violence, stalking, or psychological harm by a current or former partner or spouse. This type of violence can occur among heterosexual or same-sex couples and does not require sexual intimacy.

IPV is abuse or aggression that occurs in a close relationship. "Intimate partner" refers to both current and former spouses and dating partners. IPV can vary in how often it happens and how severe it is. It can range from one episode of violence that could have lasting impact to chronic and severe episodes over multiple years. IPV includes four types of behavior:

- **Physical violence** is when a person hurts or tries to hurt a partner by hitting, kicking, or using another type of physical force.
- **Sexual violence** is forcing or attempting to force a partner to take part in a sex act, sexual touching, or a non-physical sexual event (e.g., sexting) when the partner does not or cannot consent.
- **Stalking** is a pattern of repeated, unwanted attention and contact by a partner that causes fear or concern for one's own safety or the safety of someone close to the victim.
- **Psychological aggression** is the use of verbal and non-verbal communication with the intent to harm another person mentally or emotionally and/or to exert control over another person.

Several types of IPV behaviors can occur together. IPV is connected to other forms of violence and causes serious health issues and economic consequences. By using a public health approach that addresses risk and protective factors for multiple types of violence, IPV and other forms of violence can be prevented.

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| **Screening** | ACOG recommends that physicians screen ALL patients for intimate partner violence. Be sure to inform patients of any legal reporting requirements prior to screening. For women who are not pregnant, screening should occur:<br>• At routine OB-GYN visits<br>• At family planning visits<br>• At pre-pregnancy visits<br><br>Domestic violence screening can be conducted by making the following statement and asking these three simple questions:<br>• Within the past year — or since you have been pregnant — have you been hit, slapped, kicked or otherwise physically hurt by someone?<br>• Are you in a relationship with a person who threatens or physically hurts you?<br>• Has anyone forced you to have sexual activities that made you feel uncomfortable?" |
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| **If Abuse is Denied** | If abuse is denied and no indicators of abuse are present, document the findings in the medical record and offer referral information for future reference. |

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| | What to do if a patient says "no":<br>• Respect her/his response;<br>• Let the patient know that you are available should the situation ever change;<br>• Assess again at regular intervals as an indication that it is safe to disclose to you;<br>• Display information and resources in exam and waiting rooms, or bathrooms;<br>• If patient says "no" but you believe she/he may be at risk, discuss the specific risk factors and offer information and resources;<br>• Let patient know that experts and help are available. Offer a crisis card/safety card. Tell them that even if they don't need it that they can give it to a friend or family member who might use it. Discuss possible repercussions if their partner finds the card.<br>• Do not write any domestic violence referral on discharge papers that will be taken home with the patient.<br><br>If patient has obvious or suspected abuse but cannot communicate to acknowledge abuse (i.e. unconscious or impaired), schedule a follow-up appointment or initiate appropriate social work consult to ensure follow up. |
| | |
| **If Abuse is Identified** | If a patient discloses that they are currently being abused, at a minimum their immediate safety should be assessed. This could include asking:<br><br>• Are you in immediate danger?<br>• Is your partner in the facility now?<br>• Has the violence escalated or gotten worse over the past year?<br>• Has your partner threatened to kill you or your children?<br>• Does your partner have access to guns or other deadly weapons?<br><br>If the patient answers yes to any of these, encourage her/him to speak with a domestic violence advocate to develop a safety plan even if the patient does not intend to leave her/his abuser.<br><br>Provide a phone and a safe place for her/him to contact an advocate. Offer to make the call for them if they would prefer that. Be mindful that your phone may be the only link a survivor has to a domestic violence advocate since cell phones and land lines are easily traceable. |
| | |
| **Resources** | • National Domestic Violence Hotline<br>o Call 1-800-799-7233 and TTY 1-800-787-3224<br><br>• Love is Respect National Teen Dating Abuse Helpline<br>o Call 1-866-331-9474 or TTY 1-866-331-8453 |

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| | • Rape, Abuse & Incest National Network's (RAINN) National Sexual Assault Hotline<br>  ○ Call 800-656-HOPE (4673) to be connected with a trained staff member from a sexual assault service provider in your area.<br>• National Resource Center on Domestic Violence<br>• Mississippi Coaltition Against Domestic Violence<br>  ○ Has created a publication with protocols for healthcare providers |
| | |
| **Indicators** | General signs and symptoms of family and intimate partner violence<br>• Conditions such as chronic fatigue or headaches, abdominal and/or pelvic pain, frequent use of pain medication, sexual dysfunction, frequent vague complaints of physical discomfort, or gastrointestinal problems<br>• Drug and alcohol abuse by the patient or her partner<br>• History or signs of depression or anxiety, or use of sedatives and/or tranquilizers<br>• Attempts or thoughts of suicide<br>• Self-injury<br>• Signs of post-traumatic stress disorder<br>• Suspicious injuries that are explained in ways that are inconsistent with the type or severity of the injury<br>• Multiple sites of injury and/or a pattern of repeated injury<br>• Delay in seeking medical care including delayed prenatal care<br>• Description of a partner as jealous, controlling or domineering, prone to anger, and/or frustrated with the patient and/or children |
| | |
| **Sample Safety Planning Guide for a Patient** | We are concerned about your safety and strongly encourage you to talk to an advocate who can help you devise a safety plan. In the meantime, here are some steps you can take to prepare for emergencies and reduce your risk of injury.<br><br>1. Prepare an emergency kit containing items you will need if you must leave suddenly. You may wish to include:<br>• Identification for you and your children<br>• Money, credit cards, checkbook, and bankbook<br>• Green card, custody papers, restraining orders, car registration, health insurance card, and any other important papers<br>• Keys, medications, address book, and a change of clothes. It may be helpful to keep a packed bag at a friend's house |

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| | 2. Let neighbors know you want them to call 911 when they hear an argument. Set a code phrase you can use with a friend to signal that you are asking for help.<br><br>3. Teach your children what to do if you and your partner are fighting. You should tell your children to stay out of the argument and arrange for them to have a safe, nearby place where they can go in an emergency.<br><br>4. Plan for a place where you can stay if you must leave home.<br><br>5. Design and practice escape routes from the house with your children in case of an emergency.<br><br>6. Make sure weapons are not easily accessible. Knives should be removed from the kitchen counter and guns should be kept in a locked box separate from ammunition.<br><br>7. During an argument, you should stay in an area where you can quickly exit. Stay away from the kitchen (where there are knives) and the bathroom (where you can hit your head easily).<br><br>Additional steps if separating from a potentially violent partner:<br><br>1. Put a safety plan in place before discussing your desire to separate. Discuss your plan with your children.<br><br>2. Change the locks on your doors and install locks on windows.<br><br>3. Get the police and court system involved. If possible, obtain a protective order (e.g. restraining order). Always keep a copy with you and give a copy to someone that you trust. Call the police immediately if your partner violates the protective order.<br><br>4. Inform others—your neighbors, especially—that you have a restraining order in effect and encourage them to call the police for you if your partner violates it. Provide a picture of your partner if necessary.<br><br>5. Make sure that your children's caregivers know who has permission to pick them up. |
| | |

## References

Centers for Disease Control and Prevention. (2018). *Intimate partner violence*. https://www.cdc.gov/violenceprevention/intimatepartnerviolence/index.html

## What is Substance Abuse?

The U.S. Department of Health & Human Services reports providing the tools necessary for the inclusion of substance abuse disorder screening into family planning services offered by Title X applicants as a key issue.

Substance use, including alcohol, tobacco, marijuana, illicit drugs, and misuse of prescription drugs, has significant negative health effects on women, especially during the reproductive years.

Screening, brief intervention, and referral to treatment (SBIRT) decreases substance use, health care services, and costs to society. Screening using a validated screening tool quickly gauges a patient's level of substance use risk.

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| **General Screening** | General Screening<br>• Clinic staff should utilize face to face time with proven screening instruments<br>• Agencies need to have policies and procedures in place to assist the client when further assessment is indicated<br>• Agencies should consult their legal counsel for processes when a minor warrants referral for a professional substance abuse assessment |
| | |
| **Drug Abuse** | To screen patients, first use a statement like the following:<br><br>"Substance use is so common in our society that I now ask all my patients, what, if any substances they are using?"<br><br>Then, ask questions from a tool or provide them with a tool. |
| | |
| **Assessment Tools examples** | • The Short Michigan Alcohol Screening Test (SMAST) may be administered in less than 5 Minutes<br><br>• CRAFFT Screening Instrument for Adolescents<br>  ○ Have you ever ridden in a car driven by someone (including yourself) who was high or had been using alcohol or drugs?<br>  ○ Do you ever use alcohol or drugs to relax, feel better about yourself, or fit in?<br>  ○ Do you ever use alcohol or drugs while you are by yourself or alone?<br>  ○ Do you ever forget things you did while using alcohol or drugs?<br>  ○ Do your family or friends ever tell you that you should cut down on your drinking or drug use?<br>  ○ Have you ever gotten into trouble while you were using drugs or alcohol?<br><br>• CAGE AID – 5-question tool to screen for drug and alcohol use |

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| | ○ Have you ever felt you ought to cut down on your drinking or drug use?<br>○ Have people annoyed you by criticizing your drinking or drug use?<br>○ Have you ever felt bad or guilty about your drinking or drug use?<br>○ Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover?<br><br>• AUDIT-C is a 3-question screen for harmful drinking.<br>○ How often do you have a drink containing alcohol?<br>○ How many standard drinks containing alcohol do you have on a typical day?<br>○ How often do you have six or more drinks on one occasion? |
| | |
| **SBIRT** | Screening, **brief intervention**, and referral to treatment<br><br>• With a positive screening, the provider should provide a brief intervention and be prepaid to make a referral<br>• Brief interventions are evidence-based practices design to motivate individuals at risk of substance abuse and related health problems to change their behavior by helping them understand how their substance use puts them at risk and to reduce or give up their substance use.<br>• Healthcare providers can also use brief interventions to encourage those with more serious dependence to accept more intensive treatment within the primary care setting or a referral to a specialized alcohol and drug treatment agency.<br>• Brief interventions last from 5 minutes of brief advice to 15-30 minutes of brief counseling.<br>• The two most common behavioral therapies used in SBIRT programs are brief versions of cognitive behavioral therapy and motivational interviewing, or some combination of the two. |
| | |
| **Create Resource Area** | • Ideal location in each program's waiting room and screening room<br>• Feature publications on substance abuse and family violence<br>• Post names of local counseling centers: mental health, drug-specific, alcohol-specific. Include pamphlets/magnets for the general public from these agencies<br>• Post meeting schedules from Alcoholics Anonymous and Narcotics Anonymous<br>• Post directory of domestic violence shelters and related local resources |
| | |
| **Tobacco Use** | The Five A's for Brief Tobacco Intervention |

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| | Successful intervention begins with identifying users and is based on the patient's willingness to quit. A brief cessation message of 5-15 minutes should be delivered by a trained provider.<br><br>The five major steps to intervention are the "5 A's": Ask, Advise, Assess, Assist, and Arrange.<br><br>1. Ask all patients about their smoking status at every visit; place a sticker on the patient chart indicating tobacco use (current, former, or never)<br>2. Advise to quit in a clear, strong, personalized manner<br>3. Assess willingness to make a quit attempt<br>4. Assist in quit attempt (counseling and pharmacotherapy as appropriate)<br>5. Arrange follow-up (preferably within the first week after the quit date)<br><br>The same treatments benefit both men and women, but some are less efficacious in women, such as nicotine replacement therapies. Women may face different stresses and barriers to quitting such as depression, weight control concerns, and hormonal cycles.<br><br>Reference:<br><br>U.S. Department of Health & Human Services, Office of the Surgeon General (www.surgeongeneral.gov/tobacco/default.htm) |
| | |
| **National Resource** | Substance Abuse and Mental Health Services Administration<br><br>• SAMHSA's National Helpline, 1-800-662-HELP (4357), (also known as the Treatment Referral Routing Service) or TTY: 1-800-487-4889 is a confidential, free, 24-hour-a-day, 365-day-a-year, information service, in English and Spanish, for individuals and family members facing mental and/or substance use disorders.<br>• This service provides referrals to local treatment facilities, support groups, and community-based organizations. Callers can also order free publications and other information. |
| | |

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Gotham. H., Wilson, K., Carlson, K., Rodriguez, G., Kuofie, A., & Witt, J. (2019). Implementing substance abuse screening in family planning. *The Journal for Nurse Practitioners, 15.* Retrieved from https://www.npjournal.org/article/S1555-4155(18)31140-1/pdf

SAMHSA-HRSA Center for Integrated Health Solutions. (2020). *Screening tools*. https://www.integration.samhsa.gov/

# Converge Clinical Protocols and Procedures 2024

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## SECTION 1
## Providing Quality Family Planning Services

## INTRODUCTION

The Title X Family Planning Program is administered by the Office of Population Affairs (OPA), Office of the Assistant Secretary for Health (OASH), within the U.S. Department of Health and Human Services (HHS). The family planning services grants program is authorized by Title X of the Public Health Service (PHS) Act (42 U.S.C. 300 *et seq.*). Implementing regulations are at 42 CFR part 59, subpart A. The requirements that apply to the direct recipients of Title X funds also apply to sub-recipients (42 CFR 59.1; HHS Grants Policy Statement, 2007). The information outlined in this document applies to the award of family planning services grants under section 1001 of the PHS Act (42 U.S.C. 300(a)), "to assist in the establishment and operation of voluntary family planning projects." These projects "consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children" (42 CFR 59.1(a)).

Family Planning assists individuals in determining the number and spacing of their children through the provision of affordable, voluntary family planning services including the provision of a broad range of contraceptive methods, education, and related preventive health services. By assisting the establishment and operation of voluntary family planning projects throughout Mississippi, the program positively impacts the health and well-being of women, children, and families. Services provided through family planning clinics allow women and men to make well-informed reproductive health choices. Converge funded family planning clinics are designed to address the unmet family planning needs of low-income women and men and provide access to populations with special needs. No one is denied services because of inability to pay.

Quality Title X Family Planning (QFP) includes these attributes: confidentiality, safety, effectiveness, client-centered approach, timeliness, efficiency, accessibility, equity, and cost effectiveness. Quality Family Planning Services include the following clinical elements:

- Contraceptive services
- Pregnancy testing and counseling
- Achieving desired pregnancy (fertility awareness)
- Basic infertility service
- Preconception health services
- Sexually transmitted infection (STI) services
- Adolescent-friendly health services

Title X providers **must** offer all family planning services (listed above), related preventive health services and referral for specialist care, as needed. Other preventive health services that are beyond the scope of Title X may be offered either on-site or by referral. Information about preventive services that are beyond the scope of Title X is available at http://www.uspreventiveservicestaskforce.org.

All family planning projects **must** offer family planning services and related preventive health services to female and male clients, including adolescents. All projects **must** provide for medical services related to family planning and the effective use of contraceptive devices and practices including provider's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies, as well as referral to other medical facilities when medically necessary, consistent with § 59.14(a), and provide for the effective usage of contraceptive devices and practices. This includes, but is not limited to, emergencies that require referral. Efforts may be made to aid the client in finding potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of this care.

## SERVICE PLANS AND PROTOCOLS

The service plan is the component of a sub-recipient's annual healthcare plan, which is developed by staff and the medical director and identifies the services to be provided to clients under Title X.

C. All sub-recipient agencies should offer a broad range of effective family planning methods (including contraceptive, natural family planning or other fertility awareness-based methods) and services (including infertility services, information about or referral for adoption, and services for adolescents) [§ 59.5]. Such projects are not required to provide every acceptable and effective family planning method or service. A participating entity may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services. All sub- recipient agencies **must** have written clinical protocols approved by Converge and signed by the agency's medical director, which outline procedures for the provision of each service offered. Sub-recipient agencies **must** have written protocols available at each clinical site. The clinic staff **must** use approved protocols for the provision of all family planning services.

D. Clinical protocols **must** be written in accordance with the QFP document, State of Mississippi laws and nationally recognized standards for medical care. Clinical Protocols **must** be current (i.e., updated within the past 12 months) and signed annually by the medical director. The Title X Clinical Services & Protocols **must** be available at each clinical site.

## PROCEDURAL OUTLINE

The services provided to family planning clients, and the sequence in which they are provided, will depend upon the type of visit and the nature of the service requested. All the QFP services identified in the introduction **must** be offered to all clients and documented in the medical record.

N. Service delivery to all clients **must** include the following:
   1. Assuring clients are treated courteously and with dignity and respect.
   2. Professional recommendations for how to address the needs of diverse clients, such as Lesbian, Gay, Bi-sexual, Transgender, Questioning (LGBTQ) persons or persons with disabilities should be consulted and integrated into procedures, as appropriate. Providers should avoid making assumptions about a client's gender identity, sexual orientation, race, or ethnicity; all requests for services should be treated without regard to these characteristics. Similarly, services for adolescents should be provided in a "youth-friendly" manner.
   3. Assurance of confidentiality and the provision of privacy.
   4. Opportunity to participate in planning their own medical treatment.
   5. Encouraging clients to voice any questions or concerns they may have.
   6. Materials and/or interpreter available for those with limited ability to read or understand English and for those who may be blind or hearing impaired.
   7. Explanation of all procedures, range of available services, agency fees and financial arrangements.

O. Individual client education **must** be offered.

P. Individual counseling (A client-centered, interactive process to assist the client in making an informed choice) **must** be offered and/or provided prior to the client making an informed choice of family planning services.

Q. Adolescent services **must** be offered and should be provided in a "youth-friendly" manner, making services accessible, equitable, comprehensive, and effective for youth. Counseling for minors should include the following:

   1. Title X providers **must** offer confidential services to minors and **must** observe relevant state laws related to mandatory reporting of child abuse and neglect and human trafficking.
      a. Minors **must** be informed that services are confidential, except in special cases (e.g. child abuse) where reporting is required.
      b. Concern with respect to confidentiality of information may not be used as a rationale for noncompliance with laws regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws.
      c. Maintain records to demonstrate compliance with each of the requirements, including records which:
         i. Indicate the age of minor clients.
         ii. Indicate the age of the minor client's sexual partners if such age is an element of a notification law under which a report is required.
         iii. Document each notification or report made pursuant to such State notification laws.

2. Title X providers **must** encourage and promote communication between the minor and his or her parent(s) or guardian(s) about their decision to seek family planning services. If not completed, the reason for lack of counseling must be documented in the chart.
3. Title X providers **must** provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.
4. Adolescents seeking contraceptive services **must** be provided comprehensive information about how to prevent pregnancy, including sexual risk avoidance (abstinence) as an effective way to prevent pregnancy and STIs.

R. Counseling for all clients **must** address the client's pregnancy intention or reproductive life plan.

S. The client's written general consent for services **must** be obtained prior to receiving any clinical services. (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a) (2))
   1. The general consent for services **must** state that services are confidential and voluntary; provided without coercion to accept services or any particular method of family planning and provided without prerequisite to accept any other service.
   2. The general consent for services **must** be language appropriate or obtained through an interpreter.

T. A medical history **must** be obtained that is appropriate to the type of service provided.

U. A physical examination, including necessary clinical procedures, **must** be provided, as indicated.

V. Laboratory testing **must** be provided, as indicated.

W. Medications and/or supplies **must** be provided, as indicated/requested.
   1. **Must** provide written specific instructions on how to use medications, if dispensed.
   2. **Must** include danger signs and when, where, and how to obtain emergency care, return schedule and follow-up.

X. Follow-up and referral **must** be provided, as indicated.
   1. Provision of referrals as needed
   2. Planned mechanism of client follow-up
      a. Suggested return visit date
      b. Contact information for emergencies after hours
      c. Discuss access to primary care services

Y. Emergency arrangements **must** be available for after-hours and weekend care and should be posted, given to, available on clinic website, and/or explained to clients.

Z. Return visits should assess the ongoing plan of care and needed family planning related services

## CLIENT ENCOUNTERS

C. The client's general consent for services **must** be obtained prior to receiving any clinical services. (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a) (2)). With telehealth, consent may be verbal or electronic.

D. Client encounters with women and men of reproductive age may require different services (i.e., contraceptive services, pregnancy testing and counseling, achieving pregnancy, STI services and related preventive health services). For all clients, the following questions **must** be asked and documented to help determine what family planning services are most appropriate for the visit:

1. **What is the client's reason for the visit?**
2. **Does the client have another source of primary health care?**
3. **Does the client have a reproductive life plan or want a pregnancy in the next year?**
   a. Providers should assess the client's pregnancy intention or reproductive life planning by asking questions like: "Would you like to become pregnant in the next year?", "Have you thought about goals for having or not having children?", or "Do you plan to have children (or more children) in the future?", "How long would you like to wait before you become pregnant?" See One Key Question guidance at https://powertodecide.org/one-key-question or CDC Guidance at: https://www.cdc.gov/preconception/overview.html.

   b. Providers should encourage family involvement/partner participation in reproductive life planning and family planning decisions where possible and appropriate.

## FAMILY PLANNING AND RELATED PREVENTATIVE HEALTH SERVICES FOR WOMEN

| | | Family planning services (provide services in accordance with the appropriate clinical recommendation) | | | | | |
|---|---|---|---|---|---|---|---|
| | Screening components | Contraceptive services[1] | Pregnancy testing and counseling | Basic infertility services | Preconception health services | STD services[2] | Related preventive health services |
| History | Reproductive life plan | √ | √ | √ | √ | √ | |
| | Medical history | √ | √ | √ | √ | √ | √ |
| | Current pregnancy status | √ | | | | | |
| | Sexual health assessment | √ | | √ | √ | √ | |
| | Intimate partner violence | | | | √ | | |
| | Alcohol & other drug use | | | | √ | | |
| | Tobacco use | √ (combined hormonal methods for clients ≥35 years) | | | √ | | |
| | Immunizations | | | | √ | √[4] (HPV & HBV) | |
| | Depression | | | | √ | | |
| | Folic acid | | | | √ | | |
| Physical examination | Height, weight & BMI | √ (hormonal methods)[3] | | √ | √ | | |
| | Blood pressure | √ (combined hormonal methods) | | | √[4] | | |
| | Clinical breast exam | | | √ | | | √[4] |
| | Pelvic exam | √ (initiating diaphragm or IUD) | √ (if clinically indicated) | √ | | | |
| | Signs of androgen excess | | | √ | | | |
| | Thyroid exam | | | √ | | | |
| Laboratory testing | Pregnancy test | √ (if clinically indicated) | √ | | | | |
| | Chlamydia | √[5] | | | | √[4] | |
| | Gonorrhea | √[5] | | | | √[4] | |
| | Syphilis | | | | | √[4] | |
| | HIV/AIDS | | | | | √[4] | |
| | Hepatitis C | | | | | √[4] | |
| | Diabetes | | | | √[4] | | |
| | Cervical cytology | | | | | | √[4] |
| | Mammography | | | | | | √[4] |

**Source:** Centers for Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: Recommendations CDC and the U.S. Office of Population Affairs. *MMWR. Morbidity and Mortality Weekly Report.* Retrieved for http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

## FAMILY PLANNING AND RELATED PREVENTATIVE HEALTH SERVICES FOR MEN

| | | Family planning services (provide services in accordance with the appropriate clinical recommendation) | | | | |
|---|---|---|---|---|---|---|
| | Screening components | Contraceptive services[1] | Basic infertility services | Preconception health services[2] | STD services[3] | Related preventive health services |
| History | Reproductive life plan | ✓ | ✓ | ✓ | ✓ | |
| | Medical history | ✓ | ✓ | ✓ | ✓ | |
| | Sexual health assessment | ✓ | ✓ | ✓ | ✓ | |
| | Alcohol & other drug use | | | ✓ | | |
| | Tobacco use | | | ✓ | | |
| | Immunizations | | | ✓ | ✓ *(HPV & HBV)*[4] | |
| | Depression | | | ✓ | | |
| Physical examination | Height, weight & BMI | | | ✓ | | |
| | Blood pressure | | | ✓[4] | | |
| | Genital exam | | ✓ *(if clinically indicated)* | | ✓ *(if clinically indicated)* | ✓[4] |
| Laboratory testing | Chlamydia | | | | ✓[4] | |
| | Gonorrhea | | | | ✓[4] | |
| | Syphilis | | | | ✓[4] | |
| | HIV/AIDS | | | | ✓[4] | |
| | Hepatitis C | | | | ✓[4] | |
| | Diabetes | | | ✓[4] | | |

**Source:** Centers for Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: Recommendations of CDC and the U.S. Office of Population Affairs. *MMWR. Morbidity and Mortality Weekly Reports*. Retrieved from http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

**Abbreviations:** BMI = body mass index; HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus; STD = sexually transmitted disease.

[1] No special evaluation needs to be done prior to making condoms available to males. However, when a male client requests advice on pregnancy prevention, he should be provided contraceptive services as described in the section "Provide Contraceptive Services."

[2] The services listed here represent a sub-set of recommended preconception health services for men that were recommended and for which there was a direct link to fertility or infant health outcomes (Source: Frey K, Navarro S, Kotelchuck M, Lu M. The clinical content of preconception care: preconception care for men. Am J Obstet Gynecol 2008;199 [6 Suppl 2]:S389-95).

[3] STD services also promote preconception health, but are listed separately here to highlight their importance in the context of all types of family planning visit. The services listed in this column are for men without symptoms suggestive of an STD.

[4] Indicates that screening is suggested only for individuals at highest risk or for a specific subpopulation with high prevalence of infection or other condition.

Note: These two charts provide a checklist of recommended family planning and related preventive health services (QFP pages 22, 23).

# Family Planning Services

## CONTRACEPTIVE SERVICES

Written protocols and operating procedures **must** be current and in place for contraceptive services. Sub-recipient agencies must **offer** at least one family planning method to clients who z cxwish to delay or prevent pregnancy. The delivery of preconception, STI, and related preventive health services **must** not be a barrier to a client's ability to receive services related to preventing or achieving pregnancy. Receiving services related to preventing or achieving pregnancy is the priority; if other family planning services cannot be delivered at the initial visit, follow-up visits should be scheduled.

Contraceptive services must include:

2. A broad range of family planning methods, including contraceptives, natural family planning or other fertility awareness-based methods, should be provided. All methods of contraception **must** have written protocols in place.
    a. Current CDC Medical Eligibility Criteria (MEC) **must** be followed when prescribing contraceptives.
    b. More than one method may be used simultaneously by the client (for example, a hormonal method and condoms or FABM and barrier method during the fertile period). Clients with high-risk sexual behavior patterns should be encouraged to use condoms correctly and consistently in addition to any other chosen method to reduce the risks of STIs/HIV and pregnancy.

### Broad Range of Contraceptives

D. Broad Range Contraceptives includes:

1. Hormonal Contraceptives
    a. At least one delivery method of combined hormonal contraceptive should be available on site.
    b. At least one delivery method of progestin-only contraceptive should be available on site.
2. Condoms
    a. At least male condoms should be available on site.
3. At least one type of long-acting reversible contraceptive (LARC) method should be provided, either on site or by paid referral, and should be offered for same-day insertion.
4. At least one type of fertility awareness-based method (FABM) should be provided at each clinical site.
5. Education materials and information regarding all methods including, hormonal contraceptives, abstinence, fertility awareness-based methods, barrier methods, intrauterine devices, sterilization, and emergency contraception.
6. The agency formulary **must** indicate:
    a. Methods maintained and available on site
    b. Methods available on site within two weeks of client request
    c. Methods available by paid referral.
    d. Methods available by unpaid referral (i.e., sterilization)
7. Agencies should maintain a formal referral agreement for any required broad range method not provided on site.
8. A referral resource list should be provided for contraceptives not available in the clinic.
9. Agencies are encouraged to review current practices, needs and preferences of their client population and maintain the most frequently chosen methods where feasible.
10. Agencies are strongly encouraged to provide emergency contraception and maintain supplies on site.

11. Prescriptions may be written for contraceptives on the clinic formulary or on the client's insurance plan formulary. Accepting a prescription **must** not pose a barrier for the client.

E. Emergency Contraception

Emergency contraception has been found by the FDA to be safe and effective for use when initiated after unprotected intercourse. The provision of emergency contraception is strongly encouraged but not required for delegate agencies. Emergency Contraception education and referral **must** be provided to all female clients when not provided on site. When delegate agencies provide emergency contraception, the following **must** occur:

1. Written protocol must be in place.
2. If indicated by the client's history, a negative, highly sensitive pregnancy test is necessary to exclude a pre-existing pregnancy.
3. Birth control counseling should accompany or follow any method used for emergency contraception purpose in order to discourage women from using emergency contraception as a routine method of contraception.
4. Chlamydia testing should be offered to females <25 years of age and to females > 25 years with risk factors.

F. Permanent Contraception (Sterilization)

1. Education and information regarding sterilization **must** be provided for both male and female clients, if indicated.
2. Sub-recipient agencies **must** have a list of community providers where clients can be referred for sterilization. Paid referrals for sterilization are not required.
3. Sub-recipient agencies performing sterilization procedures **must** meet Federal regulations for sterilization informed consent.

## The Clinic Visit

A medical history **must** be taken prior to prescribing contraception to ensure that methods of contraception are safe for the client.

3. For a female client, the medical history **must** include:
   a. Reproductive life plan
   b. Menstrual history
   c. Gynecologic history
   d. Obstetrical/reproductive history
   e. Contraceptive use
   f. Allergies
   g. Medications
   h. Immunizations
   i. Recent intercourse
   k. Infectious or chronic health condition (present)
   n. Other characteristics and exposures (e.g., age, postpartum, breastfeeding) that might affect the client's medical eligibility criteria (MEC) for contraceptive methods.
   s. Social history/risk behaviors
   t. Sexual history and risk assessment

u. Mental health
v. Intimate partner violence
w. Interest in sterilization if age appropriate (≥ 21 per federal law requirement)

4. For a male client, the medical history **must** include:
   a. Reproductive life plan
   b. Use of condoms
   c. Allergies (i.e., condoms)
   d. Medications
   e. Immunizations
   f. Recent intercourse
   g. Partner history (use of contraception, pregnant, has children, had a miscarriage or termination)
   h. Infectious or chronic health condition (present)
   m. Contraceptive experiences and preferences
   n. Sexual history and risk assessment
   o. Interest in sterilization if age appropriate (≥ 21 per federal law requirement)

NOTE: Obtaining a medical history **must** not be a barrier to making condoms available in the clinical setting (i.e., a formal visit **must** not be a prerequisite for a client to obtain condoms).

## Physical and Laboratory Assessment

3. For a female client the following **must** be provided:
   a. BP (when providing combined hormonal method and screening for hypertension)
      1) All clients — screen yearly
      2) If BP <120/80 — screen yearly, continue yearly.
      3) If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit if average BP >140/90 recheck at next visit or in 1 week and refer if sustained BP >140/90.
   b. Bimanual exam and cervical inspection (prior to IUD insertion, fitting diaphragm or cervical cap)
   c. Pap screening and clinical breast exam (based on current recommendations for timing and testing components). See Related Preventive Health Services section.
   d. Chlamydia testing **must** be offered annually for all females < 25 years, sexually active women ≥25 years with risk factors (new partner, infected partner, partner with other concurrent partners, symptoms, history of STI or multiple partners in the last year)
   e. CT and GC testing **must** be available for clients requesting IUD insertion, if indicated.
4. For a male client, laboratory tests are not required unless indicated by history.

## Client-Centered Counseling and Education

Contraceptive counseling is to help a client choose a method of contraception and understand how to use is correctly and consistently. Clients (adolescents and adults) should participate in client- centered counseling and learn about methods that can be used safely based on the 2016 CDC Medical Eligibility Criteria and that best fit their needs. When educating clients about the broad range of contraceptive methods, information **must** be medically accurate, balanced, and provided in a nonjudgmental manner. To assist clients in making informed decisions, providers should educate clients in a way that is readily understood and retained. Documentation of counseling **must** be in the client's medical record

9. When educating clients about contraceptive methods they can use safely, clients must be taught the following:
    a. Method effectiveness
    b. Correct and consistent use of the method
    c. Benefits and Risks
    d. Potential Side effects
    e. Protection from STIs, including HIV
    f. Starting the method
    g. Danger signs
    h. Availability of emergency contraception (provide on-site or by prescription)
    i. Follow-up visit (as needed to obtain or maintain the selected method)

10. Quality client-centered contraceptive counseling includes the following:
    a. Establish and maintain rapport.
    b. Assess the client's need and personalize the discussion.
    c. Work with the client to establish a plan.
    d. Provide information in a manner that can be understood by the client.
    e. Confirm the client's understanding.
        i. The teach-back method may be used to confirm the client's understanding by asking the client to repeat back messages about effectiveness, risks, benefits, method use, protection from STIs and follow-up (QFP pages 45-46).
11. Contraceptive counseling **must** be documented in the client record (i.e., checkbox or written statement).
12. Client information sheets should be used for education.
13. When counseling male clients, discussion should include information about female-controlled methods where appropriate (including emergency contraception), encourage discussion of contraception with partners, and provide information about how partners can access contraceptive services. Male clients should also be reminded that condoms should be used correctly and consistently to reduce risk of STIs, including HIV.
14. Encourage partner communication about contraception, including understanding partner barriers (e.g., misperceptions) and general support for using a chosen method.
15. A procedure consent form **must** be signed by the client prior to inserting an IUD or implant.
16. Clinical evaluation of a client electing permanent sterilization should be guided by the provider who performs the procedure.

## Contraceptive Counseling to Adolescent Clients

Comprehensive information **must** be provided to adolescent clients about how to prevent pregnancy. Adolescent services should be provided in a "youth friendly" manner, which means that they are accessible, equitable, acceptable, appropriate, comprehensive, effective, and efficient for you

Information should clarify that:

6. It should not be assumed that adolescent clients seeking family planning services are sexually active. Avoiding sex (abstinence) is an effective way to prevent pregnancy and STIs and can be chosen as a method at any time in life.
7. If the adolescent indicates that she or he will be sexually active, provide information about contraception and help her or him choose a method that best meets her or his individual needs, including the use of condoms to reduce the risk of STIs/HIV. Long-acting reversible contraception (LARCs) are a safe and effective option for many adolescents, including those who have not been pregnant or given birth.
8. Title X providers **must** offer confidential services to minors and must observe state mandatory reporting laws related to child abuse, neglect, and human trafficking.
    a. Minors **must** be informed that services are confidential, except that in special cases (e.g. child abuse) reporting is required.
    b. Concern with respect to confidentiality of information may not be used as a rationale for noncompliance with laws regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws.
    c. Maintain records to demonstrate compliance with each of the requirements, including records which:
        i. Indicate the age of minor clients.
        ii. Indicate the age of the minor client's sexual partners **if** such age is an element of a state notification law under which a report is required.
        iii. Document each notification or report made pursuant to such State notification laws.
9. Title X providers **must** encourage communication between the minor and his or her parent(s) or guardian(s) about sexual and reproductive health and his or her decision to seek services, except that documentation of such encouragement is not to be required if the Title X provider has documented in the medical record:
    a. (i) That it suspects the minor to be the victim of child abuse or incest; and
    b. (ii) That it has, consistent with, and if permitted or required by, applicable State or local law, reported the situation to the relevant authorities.
10. Title X providers **must** provide counseling to adolescents on how to resist attempts to coerce them into engaging in sexual activities.

## Counseling Returning Clients

When providing contraceptives for returning clients, an assessment should include the following:

4. Method concerns
5. Method use (consistent, correct)
6. Any changes in client's history (i.e., risk factors, medications)

If appropriate, provide additional contraceptives and discuss a follow-up plan.

## Preventive Health Promotion and Referral

4. Title X providers should refer pregnant, parenting, and postpartum adolescents to home visiting and other programs that have been demonstrated to provide needed support and reduce rates of repeat teen pregnancy

5. Title X providers should provide referral resources for mental health, domestic or intimate partner violence, and behavioral health including alcohol, tobacco, substance use as indicated.
6. Title X providers should provide a referral resource for immunizations as indicated.

## PRECONCEPTION HEALTH SERVICES

Preconception describes anytime that a client of reproductive potential is not pregnant but at risk of becoming pregnant, or when a client is at risk for impregnating their partner. A written protocol and procedure **must** be current, available, and consistent with national standards of care. Agencies **must** offer preconception health services to females and males as part of core family planning services. Preconception health services promote health before conception thereby reducing pregnancy-related adverse outcomes (low birth weight, premature birth, and infant mortality), promote birth outcomes and improve the health of clients even if they choose not to have children. All clients of childbearing status should have an annual reproductive life plan documented in the chart.

### Medical history for females must include:

14. Reproductive life plan
15. Sexual risk and health assessment
16. Reproductive history
17. Pregnancy history (gestational diabetes or HTN, pre-eclampsia, eclampsia, pregnancy outcomes)
18. Chronic disease management
19. Environmental exposures
20. Medications
21. Genetic conditions
22. Family history
23. Intimate partner violence
24. Social history/risk behaviors
25. Immunizations status
26. Depression

### Medical history of males must include:

10. Reproductive life plan
11. Sexual risk and health assessment
12. Past medical and surgical history that impairs reproductive health
13. Genetic conditions
14. History of reproductive failures, or conditions that can reduce sperm quality (obesity, diabetes, varicocele)
15. Social history/risk behaviors
16. Environmental exposures
17. Immunization status
18. Depression

### Physical Examination for all clients:

4. Height, weight, BMI (screen for obesity)
5. BP (screen for hypertension- based on American Heart Association recommendations)
    a. All clients — screen yearly

b. If BP <120/80 --- screen yearly, continue yearly
c. If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit and if average BP >140/90 recheck at next visit or in 1 week and refer if sustained BP >140/90.

6. Additional vital signs: temperature, heart rate, respiration, pain

Laboratory testing **must** be recommended based on risk assessment:

1. Diabetes screening (for type 2 diabetes in asymptomatic adult males and females) with sustained BP (either treated or untreated) >139/80 (USPSTF)

### Client Plan/Education

8. Discuss relevant medications that are contraindicated in pregnancy, and review current medications taken during pregnancy.
9. Encourage to take a daily supplement containing (400-800 mcg) of folic acid (or a prenatal vitamin).
10. Avoid smoking, alcohol, and other drugs.
11. Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish).
12. Offer/Refer for any needed STI screening (including HIV) and appropriate vaccinations, if indicated.
13. Recommend keeping immunization up to date, including COVID-19 vaccination, while taking into consideration vaccines that are safe to administer near or during pregnancy.
14. Discuss prior pregnancy history complications and refer if necessary.

### Referral

3. If client desires, refer for further diagnosis and treatment.
4. Refer male and female clients for additional services if screening results indicate presence of a health condition or as indicated (i.e., tobacco cessation, obesity, diabetes, depression, immunizations).

## ACHIEVING PREGNANCY SERVICES

A written protocol and procedure **must** be current, available, and consistent with national standards of care. Agencies **must** offer services on achieving pregnancy to people who want to become pregnant as part of their core family planning services. The goal is to address the needs of clients who wish to become pregnant in accordance with current standards of practice.

Achieving Pregnancy services will be offered to clients who respond to the reproductive life plan questions stating they desire to become pregnant. Achieving pregnancy services include identifying and assessing clients who desire pregnancy; providing counseling and education (including key messages on achieving pregnancy) and addressing misperceptions that many women, men and adolescents have about fertility and infertility. Clients who have been trying to achieve pregnancy for 12 months or longer with regular unprotected intercourse should be offered basic infertility services.

## Client Assessment

D. Client assessment includes:
   1. Reproductive Life Plan
   2. Time frame for desired pregnancy
      a. If less than 1 year, provide counseling on maximizing fertility success
   3. Length of time she or they have been trying to become pregnant.
   4. History of pregnancies or infertility
   5. Partner involvement and support system issues
      a. Support system issues may include family and community support, LGBTQ considerations, single parent considerations, cultural/familial considerations, and awareness of other concerns or influences.

E. Medical history includes:
   1. Immunizations
   2. Medications
   3. Present infectious
   4. Chronic health conditions
   5. Genetic conditions
   6. Environmental exposures
   7. Social history/risk behaviors
   8. Sexual health assessment and risk assessment
   9. Mental health
   10. Medical history for **females must** Include:
      a. Reproductive history
      b. Obstetrical/Gynecology history
      c. Family history
      d. Intimate partner violence

   11. Medical history for **males must** include:
      a. Past medical or surgical history that might impair reproductive health
      b. Medical conditions associated with reproductive failure that could reduce sperm quality

F. Assessing and updating the client's physical, sexual, and medical history may reveal additional issues in the person's health history that need to be addressed. The results can also help determine the need for additional information like fertility awareness or other health services such as: STI screening, preconception care, infertility services, possible need for Zika screening, and other preventative health services

## Client Education and Counseling

Important information to include:

1. Importance of regular preventive health and chronic disease management
2. Some medications might be contraindicated in pregnancy and current medications will need to be reviewed.
3. Encourage daily supplement containing (400-800 mcg) of folic acid or a prenatal vitamin.
4. Avoid smoking, alcohol, and other drugs.
5. Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish)
6. Offer/refer for any needed STI screening, including HIV.
7. Offer/refer for age-appropriate vaccinations, as indicated.
8. Nutritional counseling and recommended weight loss if client is overweight.
9. The counseling provided **must** be documented in the record.

## Maximizing Fertility Awareness

Education to provide on maximizing fertility awareness and success:

3. Fertility awareness/techniques to predict ovulation
    a. Education about peak days and signs of fertility (including the 6-day interval ending on the day of ovulation that is characterized by slippery, stretchy cervical mucus and other possible signs of ovulation)
    b. Education on methods or devices designed to determine or predict the time of ovulation (e.g., over- the-counter ovulation kits, digital telephone applications, or cycle beads) should be discussed

4. Lifestyle influences
    a. Advise that vaginal intercourse every 1-2 days beginning soon after the menstrual period ends can increase the likelihood of becoming pregnant (women with regular menstrual cycles)
    b. Information that fertility rates are lower among women who are very thin or obese, and those who consume high levels of caffeine (e.g., more than five cups a day)
    c. Discourage smoking, alcohol, recreational drugs, and use of commercially available vaginal lubricants that may reduce fertility.
    d. Encourage a daily supplement containing folic acid or prenatal vitamins.
    e. Encourage males to avoid hot tubs.

## Referral

If desired, clients should be provided with a current referral listing for further diagnosis and treatment.

## PREGNANCY DIAGNOSIS AND COUNSELING

Agencies should provide pregnancy testing and diagnosis to all clients in need of this service. Pregnancy testing is one of the most common reasons for a first visit to a family planning agency. It is therefore important to use this occasion as an entry point for providing education and counseling about family planning services. A written protocol and procedure **must** be current, available, and consistent with national standards of care.

### Pregnancy diagnosis services include:

8. General Consent for Services
9. Reproductive Life Plan Discussion
10. Medical history (including chronic medical illnesses, physical disability, psychiatric illness)
11. Pregnancy testing (qualitative urine with high sensitivity)
12. Pregnancy test results **must** be given to the client
13. Counseling and referral resource list as appropriate
14. Chlamydia testing **must** be offered to females < 25 years of age and to females ≥ 25 years with risk factors.

If the **pregnancy test is positive**, the clinical visit should include:

5. A referral to prenatal care, if desired, and an estimation of gestational age. If a woman is uncertain about the date of her last normal menstrual period, a pelvic examination might be needed to help assess gestational age.
6. Information about the normal signs and symptoms of early pregnancy
7. Instructions on when to report any concerns to a provider for further evaluation.
8. If an ectopic pregnancy or other pregnancy abnormalities or problems are suspected, the client **must** be referred for immediate diagnosis and management.

### Nondirective Pregnancy Counseling and Referrals

Title X grantees and sub recipients **must** be in full compliance with Section 1008 of the Title X statute and 42 CFR 59.5(a)(5), which permits nondirective pregnancy counseling, including nondirective counseling on abortion to be provided when requested by the client. No Title X project may provide abortion as a method of family planning, (§ 59.5(a)(5)).

E. The Title X clinic may provide the following counseling and/or information to the client:
    a. Offer pregnant clients the opportunity to be provided nondirective information and counseling regarding each of the following options:
        i. Prenatal care and delivery;
        ii. Infant care, foster care, or adoption; and
        iii. Pregnancy termination (42 CFR 59.5(a)(5)(i)).
    b. If requested to provide such information and counseling, provide neutral, factual information, and nondirective counseling on each of the options, and referral upon request, except with

respect to any of the options the pregnant client indicates they do not wish to receive such information and counseling (42 CFR 59.5(a)(5)(ii)).

i. While a Title X project may provide a referral for abortion, which may include providing a client with the name, address, telephone number, and other relevant factual information (such as whether the provider accepts Medicaid, charges, etc.) about an abortion provider, the project **may NOT take further affirmative action (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the client. (65 FR at 41281 (July 3, 2000).**

ii. A Title X project may not use the provision of any prenatal, social service, emergency medical, or other referral, of any counseling, or of any provider lists, as an indirect means of encouraging or promoting abortion as a method of family planning.

c. Referral to social services or adoption agencies; and/or

d. Information about maintaining the health of the mother and unborn child during pregnancy.

F. In cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of medical services needed to address the emergency. A Title X project must provide for medical services related to family planning (including consultation by a clinical services provider, examination, prescription and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, and necessary referral to other medical facilities when medically indicated and provide for the effective usage of contraceptive devices and practices. (§ 59.5(b)(1)).

G. Providers also should assess the client's social support and refer her to appropriate counseling or other supportive services, as needed.

H. For clients who are considering or choose to continue the pregnancy, a prenatal care referral should be provided, and initial prenatal counseling should be provided that includes:

a. Pregnant women with risk factors should be tested for STIs (including HIV) at the time of their positive pregnancy test if there will be delays in obtaining prenatal care (more than 2 months).

b. Advise that some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (if current provider is unqualified).

c. Encourage to take a daily supplement containing (400-800 mcg) of folic acid (or a prenatal vitamin).

d. Avoid smoking, alcohol, and other drugs.

e. Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish).

f. Refer for age-appropriate vaccinations if indicated.

g. Risk assessment for adverse maternal or fetal outcomes should be performed. If the pregnant client is deemed high risk for such outcomes, prenatal care at the appropriate level should be expedited.

**Negative Test Visit**

Clients with a **negative pregnancy diagnosis** and do not want to become pregnant **must** be offered information about family planning services as indicated, such as:

5. The value of making a reproductive life plan.
6. Contraceptive services (Ideally provided the same day).
7. Counseling to explore why the client thought she was pregnant and sought pregnancy testing services.
8. Assessed for difficulties using her current method of contraception, if indicated.

Women who are not pregnant and who are trying to become pregnant **must** be offered information about family planning, as indicated, such as:

5. Services to help achieve pregnancy or basic infertility services.
6. Preconception health education.
7. STI services.
8. Reproductive life plan.

## BASIC INFERTILITY SERVICES

A written protocol and procedure **must** be current, available, and consistent with national standards of care. Agencies **must** offer basic infertility care as part of core family planning services. Infertility is defined as the failure of a couple to achieve pregnancy after 12 months or longer of regular unprotected intercourse.

### The Clinic Visit

An infertility visit to a family planning clinic focuses on determining potential causes of the inability to achieve pregnancy and making any needed referrals for specialist care.

Evaluation of both partners should begin at the same time. Earlier evaluation (6 months of regular unprotected intercourse) is justified for:

5. Women aged > 35 years
6. Those with a history of oligomenorrhea (infrequent menstruation)
7. Those with known or suspected uterine or tubal disease or endometriosis
8. Those with a partner known to be sub-fertile (the condition of being less than normally fertile though still capable of effecting fertilization).

An early evaluation may be warranted if risk factors of male infertility are known to be present or if there are questions regarding the male partner's fertility potential.

### Basic Infertility Care for Women.

The infertility visit should focus on:

4. Understanding the client's reproductive life plan and difficulty in achieving pregnancy.
5. The medical history **must** include:
    a. Past surgeries
    b. Previous hospitalizations
    c. Serious illnesses or injuries
    d. Medical conditions associated with reproductive failure (e.g., thyroid disorders, hirsutism, or other endocrine disorders)
    e. Childhood disorders
    f. Cervical cancer screening results and any follow-up treatment
    g. Medication
    h. Allergies
    i. Social history/risk behaviors
    j. Family history of reproductive failures
    k. Reproductive history (i.e., time trying to achieve pregnancy, coital frequency and timing)
    l. Level of fertility awareness
    m. Previous evaluation and treatment results; gravidity, parity, pregnancy outcome(s), and associated complications; age at menarche, cycle length and characteristics, and onset/severity of dysmenorrhea
    n. Sexual history (pelvic inflammatory disease, history of/exposure to STIs)

o. Review of systems (symptoms of thyroid disease, pelvic or abdominal pain, dyspareunia, galactorrhea, and hirsutism)

6. A physical examination **must** be offered if clinically indicated:
   a. Height, weight, and body mass index (BMI) calculation
   b. Thyroid examination (i.e., enlargement, nodule, or tenderness)
   c. Clinical breast examination (CBE)
   d. Signs of androgen excess
   e. A pelvic examination (i.e., pelvic or abdominal tenderness, organ enlargement/mass; vaginal or cervical abnormality, secretions, discharge; uterine size, shape, position, and mobility; adnexal mass or tenderness; and cul-de-sac mass, tenderness, or nodularity).

## Basic Infertility Care for Men

Infertility services provided to the male partner of an infertile couple should include:

4. Client's reproductive life plan
5. Medical history **must** include:
   a. Reproductive history (methods of contraception, coital frequency and timing; duration of infertility, prior fertility; sexual history; and gonadal toxin exposure, including heat).
   b. Medical illnesses (e.g., diabetes mellitus)
   c. Prior surgeries
   d. Past infections
   e. Medications (prescription and nonprescription)
   f. Allergies
   g. Lifestyle exposures
   h. Sexual health assessment.
   i. Female partners' history (pelvic inflammatory disease, STIs, and problems with sexual dysfunction)

6. A physical examination **must** be offered if clinically indicated:
   a. Examination of the penis (including the location of the urethral meatus)
   b. Palpation of the testes and measurement of their size
   c. Presence and consistency of both the vas deferens and epididymis
   d. Presence of a varicocele
   e. Secondary sex characteristics
   f. Digital rectal exam

Male clients concerned about their fertility should be offered a semen analysis. If this test is abnormal, they should be referred for further diagnosis (i.e., second semen analysis, endocrine evaluation, post-ejaculate urinalysis, or others deemed necessary) and treatment. The semen analysis is the first and most simple screen for male fertility.

### Infertility Counseling

Counseling provided during the clinic visit is guided by information elicited from the client during the medical and reproductive history and findings from the physical exam.

### Referral

4. Clients (female and male) **must** be referred for further diagnosis and treatment if indicated or requested.
5. Counseling provided during the clinic visit is guided by information elicited from the client during the medical and reproductive history and findings from the physical exam.
6. Referral for Zika testing if indicated

## SEXUALLY TRANSMITTED INFECTION SERVICES

Written protocols and operating procedures for sexually transmitted infections **must** be in place when STI/HIV services are provided. Screening and treatment **must** follow current Centers for Disease Control and Prevention (CDC) STI Treatment and HIV testing guidelines.

### The Clinic Visit

Initial steps of the clinic visit include:

E. Assess client's Reproductive Life Plan

F. Medical history
   1. Allergies
   2. Medications
   3. Medical conditions
   4. Sexual health assessment, based on gender identity, current anatomy and sexual behavior (partners, practices, protection, history of STIs, pregnancy prevention)
   5. Immunizations (Hep.B, HPV)

G. Physical exam as indicated (based on history or symptoms)

H. Laboratory testing including the following:

   1. Chlamydia:
      a. Testing **must** be offered annually for all females < 25 years. Sexually active women ≥25 years with risk factors (new partner, infected partner, partner with other concurrent partners, symptoms, history of STI or multiple partners in the last year) should be offered testing. Pregnant women should be screened for chlamydia at the time of the pregnancy test if there might be a delay in obtaining prenatal care.

b. Clients who test positive for Chlamydia should be re-tested 3 months following treatment for early detection of re-infection. Clients who do not present at 3 months for re-test should be re-tested the next time they present for services in the 12 months following treatment of the initial infection. Pregnant women should have a test-of-cure 3-4 weeks following treatment.
c. Chlamydia screening for males can be considered at sites with high prevalence (adolescent clinics, correctional facilities, STI clinics) or males who have sex with males (MSM). Males with Chlamydia should be re-tested 3 months following treatment.

2. Gonorrhea
   a. Testing **must** be offered annually to sexually active women <25 and for older women at increased risk of infection (previous gonorrhea, presence of other STIs, new or multiple sex partners, inconsistent condom use, commercial sex work, drug use) and those who reside in high prevalence areas. Other risk factors that place women at increased risk include infected partner, symptoms, history of STI or multiple partners in past year. Pregnant women should be screened for chlamydia at the time of the pregnancy test if there might be a delay in obtaining prenatal care.
   b. All males with symptoms suggestive of gonorrhea (urethral discharge or dysuria or whose partner has gonorrhea) should be tested and empirically treated.
   c. Males who have sex with males (MSM) should be tested at sites of exposure.
   d. Clients with uncomplicated urogenital or rectal gonorrhea infection should be re-tested for re- infection 3 months after treatment. Clients who do not present at 3 months for re-test should be re- tested the next time they present for services in the 12 months following treatment of the initial infection. Test of cure should occur between 7-14 days after initial treatment for pharyngeal gonorrhea.

3. Syphilis
   a. Testing should be offered to male and female clients at high risk:
      (a) MSM,
      (b) Commercial sex workers,
      (c) Persons who exchange sex for drugs,
      (d) Those in adult correctional facilities,
      (e) Living in high prevalence areas.
      (f) Pregnant women should be screened for chlamydia at the time of the pregnancy test if there might be a delay in obtaining prenatal care.

4. HIV/AIDS
   a. Testing should be routinely recommended for all male and female clients seeking STI evaluation
   b. HIV testing should be performed at time of STI diagnosis if not initially performed
   c. HIV screening is recommended at least once for all persons 15-65 years of age.
   d. High risk individuals should be screened for HIV at least annually. Annual testing is recommended for high-risk individuals:
      (a) injection drug users and their partners
      (b) persons who exchange sex for money or drugs
      (c) sex partners of HIV infected persons
      (d) MSM or heterosexual persons who themselves or whose sex partner have had more than one sex partner since their most recent HIV test

e. Opt out screening can be provided if included in the general medical consent.

5. Hepatitis C
   a. According to the CDC,
      g. Hepatitis C screening at least once in a lifetime for all adults aged ≥18 years, except in settings where the prevalence of HCV infection is <0.1% and
      h. Hepatitis C screening for all pregnant women during each pregnancy, except in settings where the prevalence of HCV infection is <0.1%.
      i. The recommendation for HCV testing that remains unchanged is regardless of age or setting prevalence, all persons with risk factors should be tested for hepatitis C, with periodic testing while risk factors persist.
      j. For persons with HIV, serologic testing should occur at initial evaluation and annual HCV testing in MSM with HIV infection.
      k. Risk factors for hepatitis C include people who currently or have ever used injection drugs; with HIV infection; with certain medical conditions, including those who ever received hemodialysis and those with persistently abnormal ALT levels; who have received transfusions or organ transplants; health care, emergency medical, and public safety personnel who have been exposed to the blood of someone who has hepatitis C; and children born to mothers who have hepatitis C.
      l. Any person who requests hepatitis C testing should receive it, regardless of disclosure of risk, because many persons might be reluctant to disclose stigmatizing risks.
   e. If testing is positive, refer for additional care and management of HCV infection and related conditions. Assess alcohol use and refer for intervention if indicated.
   f. With a grade B recommendation, the USPSTF recommends screening for HCV infection in all adults aged 18-79 years. [Chou, R., Dana, T., Fu, R. et al. (2020). Screening for Hepatitis C virus infection in adolescence and adults: Updated evidence report and systematic review for the US Preventative Services Task Force. *JAMA, 323*(10), 976-991. doi:10.1001/jama.2019.20788]
   g. Clients with high-risk behaviors /conditions (e.g., past or current injection of illegal drugs, HIV infected) should be recommended to have annual testing.

6. Hepatitis B
   3. Screening is not recommended for the general population.
      a. Screen women at increased risk (having had more than one sex partner in the previous six months, evaluation or treatment for an STI, past or current injection -drug use, and an HBsAg-positive sex partner)
      b. Screen men who have sex with women at increased risk (i.e., by sexual or percutaneous exposure)
   4. Testing should be recommended for high-risk populations (persons from high prevalence areas, HIV positive, IV drug users, MSM, Hep.B household contacts.)
      a. Test pregnant women for HBsAg at first prenatal visit of each pregnancy regardless of prior testing; retest at delivery if at high risk.
      b. Test all MSM for HBsAg, HBV core antibody, and HBV surface antibody.

c. Test all persons with HIV for HBsAg and anti-HBc and/or anti-HBs.

7. Zika Virus
    3. Risk assessment questions should be asked of all clients. Has the client or partner(s) traveled to a Zika impacted area in the past 8 months?
        a. Zika testing is only recommended for persons with Zika symptoms and who have traveled to a country with an active Zika outbreak.
        b. Check here https://wwwnc.cdc.gov/travel/page/zika-information for countries with active outbreaks.
    4. All clients should be educated regarding Zika risks and prevention strategies

## Treatment

4. STI treatment should be provided on-site.
5. When treatment for any STI is provided on-site, the sub-recipient **must** follow current Centers for Disease Control and Prevention STI Treatment Guidelines ensure all clients are treated in a timely manner and appropriate follow-up measures are provided.
6. Behavioral counseling for all sexually active adolescents and adults who are at an increased risk for STIs is recommended. [US Preventive Services Task Force. (2020). Behavioral counseling interventions to prevent sexually transmitted infections. *JAMA, 324*(7). doi:10.1001/jama.2020.13095]
    a. Examples of behavioral interventions include individual or group counseling, media-based interventions, written materials, phone and text messages, websites, and videos.

## Expedited Partner Therapy

Expedited Partner Therapy (EPT) should be offered as indicated for clients testing positive for chlamydia, gonorrhea, and trichomoniasis.

1. The ORC § 4723.4810 authorizes the use of expedited partner therapy (EPT) for certain sexually transmitted diseases as designated by the state board of nursing.

## Counseling

5. Educate on risk reduction and available testing or referral for testing.
6. Encourage vaccination for HPV and Hepatitis B if indicated.
7. Encourage condom use to prevent STI/HIV infection.
8. Encourage clients with STIs to:
    a. Notify their sex partners and urge them to seek medical evaluation and treatment.
    b. Refrain from unprotected sexual intercourse during the period of STI treatment.
    c. Return for re-testing in 3 months if indicated.
6. Initiate behavioral counseling
7. Educate on Zika risks and prevention strategies

## Referral

3. Clients with Hepatitis C and HIV infection should be linked to medical care and treatment.

4. Clients should be referred for needed immunizations.

### Mandatory Reporting

Sub-recipient agencies **must** comply with state and local STI reporting requirements.

All material from the above Sexually Transmitted Infection section was referenced from Workowski, K.A., Bachmann, L.H., Xhan, P.A. et al. Sexually Transmitted Infections Treatment Guidelines, 2021, *Morbidity and Mortality Weekly Report, (4)* 1-178. doi: http://dx.doi.org/10.15585/mmwr.rr7004a1

## GYNECOLOGIC SERVICES

Family planning agencies should provide for the diagnosis and treatment of minor gynecologic problems to avoid fragmentation or lack of health care for clients with these conditions. Written protocols and operating procedures **must** be available, current, and consistent with national standards of care. Problems such as vaginitis or urinary tract infection may be amenable to on-the-spot diagnosis and treatment, following microscopic examination of vaginal secretions or urine dip stick testing.

## RELATED PREVENTIVE HEALTH SERVICES

Written protocols and operating procedures **must** be available, current, and consistent with national standards of care.

Sub-recipient agencies are encouraged to participate in the Breast and Cervical Cancer (BCCP) project for diagnostic services (i.e., breast ultrasound, mammogram, and colposcopy) for uninsured or underinsured clients.

D. Clinics **must** offer and/or provide and stress the importance of the following to all clients:

1. Clinical Breast Exam (CBE)
    a. According to ACOG, the CBE may be offered to asymptomatic, average risk women in the context of an informed, shared decision-making approach. If performed for screening, intervals of every 1-3 years for women aged 25-39 years and annually for women 40 years and older are reasonable.
    b. ACOG continues to recommend the CBE as part of the evaluation for high-risk women with symptoms.
    c. The ACS and USPSTF do not recommend CBE due to no evidence that benefits outweigh the harm.

2. Pap testing as indicated:
    a. Age 21 to 65, every 3 years if Pap test is negative, OR
    b. Age 30 to 65, every 5 years if using co-testing (pap and HPV) and both are negative

c. Abnormal results should be treated in accordance with professional standards of care (for example, http://www.asccp.org/guidelines)

3. The Pelvic examination (including vulvar evaluation and bimanual exam) should be performed with routine pap testing and should be provided if medically indicated.

E. Clinics **must** stress the importance of:
1. The National Comprehensive Cancer Network recommends annual screening mammograms starting at age 40.
2. ACOG recommends offering average-risk women beginning at age 40 years and to initiate mammography by no later than 50. Screenings may be every 1 or 2 years. Biennial screenings after age 55. Mammography screenings should continue until at least age 75.
3. ACS recommends offering mammogram screenings annually at age 40 and biennially at 55 years. Screening should continue as long as the woman is in good health and is expected to live at least 10 more years.
4. USPSTF recommends starting biennial mammography screening at age 50.

F. Clinics should conduct a genital examination for adolescent males and document:
1. Skin and hair distribution (observation)
2. Hydrocele, varicocele, (observation and palpation)
3. Signs of STI (observation and/or palpation)

## QUALITY MANAGEMENT

### A. Referrals and Follow-up

Title X projects should offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site to promote holistic health and provide seamless care.

Written protocols and operating procedures for referrals and follow-up **must** be in place for the following:
- referrals that are made as a result of abnormal physical exams or laboratory findings,
- referrals for required services, and
- referrals for services determined to be necessary but beyond the scope of family planning.

6. Referral procedures **must** be sensitive to clients' concerns for confidentiality and privacy.

7. Client consent for release of information to providers **must** be obtained, except as may be necessary to provide care or as required by law.

8. Protocols and operating procedures for referrals and follow-up made because of abnormal physical examination or laboratory test findings within the scope of Title X that impact contraceptive management **must** include the following:
   a. A system to document referrals and follow-up procedures **must** be in place.
   b. Follow-up procedures **must** include the following:

1) A method to identify clients needing follow-up.
2) A method to track follow-up results on necessary referrals (such as, Pap and breast follow-up).
3) Documentation in the client record of contact and follow-up.
4) Documentation of reasons, actions, and follow-up where recommendations were not followed and/or protocols not acted upon.

c. Referral procedures should include that the client be given an explanation of the referral and need for follow-up including:
   1) Reason and importance of the referral
   2) Services to be received from the referral agency
   3) Address of the referral provider/agency
   4) Any instructions needed to follow through with the referral
   5) When to return to the family planning clinic Sub-recipient agencies **must** provide all Quality Family Planning Service components either on-site or by referral. When required services are provided by referral, the agency **must** have in place formal arrangements with a referral provider that includes a description of the services provided and includes cost reimbursement information.

9. For services determined to be necessary but which are beyond the scope of the project (such as thyroid abnormalities), clients **must** be referred to other providers for care. When a client is referred for non-family planning or emergency clinical care, agencies **must**:
   a. Document that the client was advised of the referral and the importance of follow-up.
   b. Document that the client was advised of their responsibility to comply with the referral.

10. Sub-recipients **must** maintain a current referral list that includes healthcare providers, local health and human service departments, hospitals, voluntary agencies, and health service projects supported by other federal programs.
    a. Referral lists **must** be current and updated annually.
    b. When possible, clients should be given a choice of providers.

## Pharmaceuticals

Agencies **must** operate in accordance with federal and state laws relating to security and record keeping for drugs and devices. The inventory, supply, and provision of pharmaceuticals **must** be conducted in accordance with state pharmacy laws and professional practice regulations.

It is essential that each facility maintain an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients. Projects should also ensure access to other drugs or devices that are necessary for the provision of other medical services included within the scope of the Title X project. Agencies can write prescriptions for Title X clients who choose and can conveniently obtain their contraceptives and medications from a pharmacy. Prescriptions may be written for contraceptives/medications on the clinic formulary or on the client's insurance plan formulary.

According to the OAC § 4723-9-09, a dispensing prescriber, except as authorized for expedited partner therapy (EPT), shall only dispense drugs to his/her clients with a valid prescriber-patient relationship.

Written protocols and operating procedures for the distribution, security and record keeping of pharmaceuticals and supplies **must** meet the following required standards:

8. The medical director is responsible for all policies and procedures pertaining to the general handling of pharmaceuticals.

9. Prescription of pharmaceuticals is done under the direction of a physician (who **must** have a drug control license for each location in which the storage and the dispensing of prescription drugs occur). The physician may dispense indirectly under his/her delegated authority to a R.N. or certified mid-level clinician. Pre-labeled, pre-packaged oral contraceptives may be distributed if delegated by a dispensing prescriber.
    a. All medications dispensed in Title X clinics **must** be pre-packaged.
    b. Prescription medications dispensed (including samples) **must** be labeled and labels **must** contain the following information:
        1) Name and address of location from which the prescription drug is dispensed
        2) Name of the client, unless prescription is authorized for EPT
        3) Date the prescription drug is dispensed
        4) Name, strength, and quantity of drug dispensed
        5) Directions for use, including frequency of use
        6) Prescriber's name (medical director/prescribing practitioner)
        7) Expiration date of prescription drug
        8) Record number of client
    c. All clients **must** receive verbal and written instructions for each drug. Medication education sheets should be kept current annually reviewed and revised as needed. The nature of drug education should be documented in medical records.
    d. There **must** be documentation that in-service training pertaining to the nature and safety aspects of pharmaceuticals is provided at least every two years to staff involved in the provision of medications to clients (i.e., new staff orientation, staff meeting, and quiz).

10. The inventory, supply and provision of pharmaceuticals may be delegated to appropriately qualified health professionals.
    a. Family planning health professionals delegated to deliver prescriptions drugs **must** be trained in all aspects of pharmaceutical and supply distribution.
    b. Delegate agencies **must** have proper segregation between requisition, procuring, receiving and payment functions for pharmaceuticals and supplies.
    c. Delegate agencies **must** have an inventory system to control purchase, use, reordering of pharmaceuticals and supplies.
    d. Delegate agencies **must** have adequate controls over access to medications and supplies including:
        1) Contraceptive and therapeutic pharmaceuticals **must** be kept in a secure place, either under direct observation or locked.
        2) Access to pharmaceuticals **must** be limited to health care professionals responsible for distributing these items.
        3) Safeguards **must** be in place to ensure that supplies purchased through the 340 B program are provided only to clients of the Converge Title X network.

e. A system **must** be in place to monitor the expiration date on drugs and ensure disposal of all expired drugs.
f. A system for silent notification in case of drug recall **must** be in place.
g. Inventory levels should not exceed a six-month supply.

11. A current formulary, listing all drugs available for Title X clients, **must** be maintained, and reviewed at least annually. Formularies should be retained for three years.

12. An adequate supply and variety of drugs and devices **must** be available to meet their client's contraceptive needs.
    a. Purchase and use of generic drugs based on therapeutic equivalence as published by the FDA or in the Formularies of Therapeutic Equivalence accepted by the State Board of Pharmacy is acceptable.
    b. Sub-recipient agencies may elect to identify certain supplies on the formulary, such as more expensive or infrequently used methods, that will be ordered upon client request and be available within two weeks of the request.

13. At a minimum, each site that provides medical services **must** have the following:
    a. Emergency drugs and supplies for treatment of vaso-vagal reaction.
    b. Emergency drugs and supplies for treatment of anaphylactic shock.

14. Prescriptive Methods for Transfer Clients
    a. An informed (general) consent form **must** be obtained, and a client history **must** be completed/reviewed. A BP **must** be taken if the client desires to continue a combined hormonal contraceptive. The provider will review the transfer records and decide if current prescription can be continued. The provider **must** document the prescription in the client's record.

## Medical Emergencies

Emergency situations involving clients and/or staff may occur at any time; therefore, all agencies **must** have written plans and protocols/ operating procedures for the management of on-site medical and non-medical emergencies.

5. At a minimum, written protocols **must** address:
    a. Vaso-vagal reactions/Syncope (fainting)
    b. Anaphylaxis
    c. Cardiac arrest
    d. Shock
    e. Hemorrhage
    f. Respiratory difficulties

6. Protocols **must** also be in place for emergencies requiring EMS transport, after-hours management of contraceptive emergencies and clinic emergencies.

7. All staff **must** be trained in emergency procedures and **must** be familiar with the plans. Licensed medical staff providing direct patient care services **must** be trained in CPR and hold current certification.

8. There **must** be a procedure in place for maintenance of emergency resuscitative drugs, supplies, and equipment.

## Medical Records

4. General Policy
   a. A medical record **must** be established for each client who receives clinical services, including pregnancy testing/counseling clients and emergency contraception clients.
   b. Title X requires the use of an electronic health record.
   **c.** Medical records are maintained in accordance with the accepted medical standards and state laws regarding record retention. Records **must** be**:**
      1) Complete, legible, and accurate
      2) Signed and dated by the clinician/health professional making each entry
         a) Each entry includes date, name, and title of the clinician/health professional
         b) Each entry is a permanent part of the record
      3) Readily accessible
      4) Confidential
      5) Safeguarded against loss or use by unauthorized persons
      6) Available upon request to the client
   d. HIPAA regulations regarding personal health information **must** be followed.

5. Record Contents
   The client's medical record **must** contain sufficient information to identify the client, indicate where and how the client can be contacted, justify the clinical diagnosis, and warrant the treatment and end results. Records **must** include the following:
   a. Personal data:
      1) Name
      2) Address, phone number(s), and how to contact
      3) Age
      4) Sex
      5) Marital status
      6) Income Assessment
      7) Unique client number
      8) Race and ethnicity (as required for FPAR)
      9) Medical history
      10) Allergies recorded in a prominent, consistent location
   b. Physical exam
   c. Documentation of clinical findings, diagnostic/therapeutic orders
      1) Laboratory test results and follow-up done for abnormal results
      2) Treatments and special instructions
      3) Documentation of continuing care, referral, and follow-up

4) Documentation of scheduled revisits

d. Contraceptive method chosen by the client
e. Informed consents
f. Documentation of all counseling, education, and social services given
g. Documentation of deferrals, reason for deferral, and refusal of services
h. Date and signature of clinician or health professional for each entry, including documentation of telephone encounters of a clinical nature.
    1) Signature includes name and title of provider
    2) A signature log if full name and title are not used in medical record
i. A confidentiality assurance statement in the client's record.
j. A list of identified problems should be maintained to facilitate continuing management and follow- up.

6. Confidentiality and Release of Records

A system **must** be in place to maintain confidentiality of client records.

a. A confidentiality assurance statement **must** appear in the client's record.
b. HIV, mental health, and substance use information **must** be handled according to state law.
c. The written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality.
    1) Consent form for release of information, signed by the client, specifies to whom information may be disclosed.
    2) Only the specific information requested may be released.
d. Information collected for reporting purposes **must** be disclosed only in summary, statistical, or other form which does not identify individuals.
e. Upon request, clients transferring to other providers **must** be provided with a copy or summary of their record to expedite continuity of care.
f. Upon request, clients **must** be given access to their medical record

## Quality Improvement

Sub-recipient agencies **must** have a system in place that provides for the ongoing evaluation for conducting quality improvement.

5. The quality improvement system should include the selection and measurement of activities of at least one quality measure such as suggested measures on Table 4 in the QFP on page 24.

6. The quality improvement system **must** include the following elements:
   a. A tracking system that identifies clients in need of follow-up and/or continuing care **must** be in place. (Referrals and Follow-up)
   b. A system to assure that professional licenses and CPR certifications are current **must** be in place. (Personnel & Emergencies)
   c. Medical Audits to determine conformity with agency protocols, current standards, and acceptable medical practices **must** be conducted quarterly by the medical director.
      1) Minimum of two to three charts per clinician **must** be reviewed by the medical director biannually.
   d. Chart Audits/ Record Monitoring to determine completeness and accuracy of the medical record **must** be conducted at least biannually by the quality assurance committee or identified personnel.
      1) Chart audits **must** represent a minimum of three percent (3%) of the agency's *quarterly* caseload, or a minimum of 10 charts, whichever is more, randomly selected and reviewed by staff.
      2) All clinical sites should be represented in the sampling.
   e. Clinical protocols and procedures **must** be reviewed and signed annually by the medical director.
   f. Infection control policies and procedures reflecting current CDC recommendations and OSHA regulations **must** be in place.
   g. Laboratory audits to ensure quality and CLIA compliance **must** be in place.
   h. Equipment maintenance and calibration **must** be documented. (Equipment and Supplies)
   i. A process to implement corrective actions when deficiencies are noted **must** be in place.

7. Sub-recipient agency quality improvement systems should include:
   a. Annual peer review of all clinician/providers should be conducted. (Personnel)
   b. Regularly scheduled staff meetings to update and/or review medical or service delivery topics. Minutes should be kept of these meetings.
   c. Routine check of emergency drugs and supplies.
   d. A process to elicit consumer feedback should be in place.
   e. Periodic review of forms used by the agency for completeness and applicability.
   f. Routine monitoring of critical incident/occurrence reports.
   g. Periodic review of credentials of contracted laboratories.
   h. Periodic patient flow analysis.
   i. Periodic review of provider liability insurance coverage.
   j. Periodic monitoring for reliability and accuracy of the client data system to assure program performance, reporting, quality care, and generation of revenues. The following components should be monitored:
      1) Missing user data

2) Coding errors
3) Data outcome

8. A Quality Improvement Committee should be in place. This committee should meet quarterly, or as deemed necessary by the Project Director, to discuss quality assurance issues and to make recommendations for corrective action when deficiencies have been noted.
   a. If a formal Quality Improvement Committee is in place, minutes should be kept of all committee meetings.
   b. The function of the Quality Improvement Committee may be assumed by an in-house nursing or medical advisory committee with ongoing documentation of quality improvement activities.

## Reference

Centers for Disease Control and Prevention (CDC). (2014). Providing quality family planning services: Recommendations of the CDC and the U.S. Office of Population Affairs. *MMWR, 63*(4). https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

## SECTION 2
## Program Monitoring

### PROGRAM REVIEWS

The following resources are consistent in these program expectations: The Federal Register Title X [42 CFR Part 59, Subpart A], the Family Planning Statute which defines the legislative requirements for the program. The OPA Title X Program Guidelines, consisting of The Title X Handbook and Providing Quality Family Planning Services 2014 (QFP) is the guidance issued to grantees to assist with implementation of these requirements. These are available on the OPA website and in the federal resource section of this document.

### Reviews for Converge Subrecipients

All Title X subrecipients undergo a comprehensive program review conducted by the clinical services team every three years. The program site review is conducted to assure that Converge supported family planning service sites are managed effectively and are in compliance with federal Title X regulations. All program areas are reviewed: administration, finance, clinical services and community outreach and education.

### Methods

At least four weeks prior to the review, Converges staff will work with subrecipients to schedule the comprehensive site review (on site or virtually). If requested, subrecipients submit their required pre- materials directly to the Clinical Services team at least four weeks prior to the site review.

The clinical reviewer is responsible for reviewing the clinic service portion of the program including clinic protocols, contraceptive supplies, clinic observation and medical review. The administrative reviewer examines administrative portions of the program including policy review, observation, community outreach and education, and staff training. The financial reviewer analyzes billing, collections, collection processes and financial records.

## Process

The following are steps in the site review process:

7. Converge Clinical services teams work with subrecipients to identify review date/s and provide needed documentation lists.
8. Pre-Materials are to be submitted to the Medical Direct at least four weeks prior to the scheduled review. The materials should be submitted electronically.
9. Unless otherwise requested by the program, the family planning lead serves as the contact for the review process.
10. Subrecipients have the option to request a pre-review conference call or meeting to ask questions as they prepare for the site review.
11. Programs **must** have at least one clinic session scheduled during the visit to facilitate the evaluation of administrative and clinical components of the program. If review is conducted virtually, calls will be scheduled to access through role play.
    a. Upon request, an **entrance pre-conference** can be scheduled. The pre-conference occurs immediately at the beginning of the review to enable reviewers and program staff to meet prior to beginning the review. The program may include any staff person who will be able to provide information regarding clinical, administrative, education or financial aspects of the program. This is an opportunity for the reviewers to meet program personnel and get acquainted with the building, schedules, etc. It is a time for program staff to make reviewers aware of individual characteristics of the program and organization, as well as clarify the review process.
    b. The **exit conference** is an opportunity for discussion between the reviewers and the program staff regarding the general findings of the review.
    c. Completed **program review reports** are sent to the sub recipient within 30 days of the review. Any requirement that was not met is identified in the report with recommendations for correction. The report may also include recommendations for program improvement. Corrective plans of action **must** be submitted and accepted for all unmet requirements.
12. A **corrective plan of action (CPA)** must be submitted after the receipt of the program review report.
    a. CPAs are due within sixty days of the final day of the review.
    b. Plan may be approved with no further action needed, with conditions such as subsequent site visit or submission of support materials or may be rejected with revisions required.
    c. Implementation of CPA **must** be completed within one year of the review to continue accreditation.

## TECHNICAL ASSISTANCE AND MONITORING VISITS

Subrecipient agencies are visited in person or through a technical assistance call at least once every grant year. These visits are to provide technical assistance and to monitor progress in areas needing improvement identified during the previous site review, grant review or other means. This is done to ensure that those areas have been corrected to confirm Title X and Converge compliance.

In addition, program issues and changes are discussed at these visits and any technical assistance requested by the agency is provided.

## FINANCIAL PROGRAM AUDITS

An audit is a systematic review or appraisal to determine whether internal accounting and other control systems assure the following:

6. Financial operations are properly conducted.
7. Financial reports are timely, fair, and accurate.
8. The subrecipient has complied with applicable laws, regulations, and the terms and conditions of the award.
9. Resources are managed efficiently.
10. Desired results and objectives are being achieved.

Subrecipients are subject to the audit requirements of Uniform Grants Guidance A-133, as implemented by 45 CFR 74.26 and 92.26, or the audit requirements stated in 45 CFR 74.26(d), and this manual. The Uniform Grants Guidance A-133 requires state government, local government, or non-profit organizations, including institutions of higher education, that expend $750,000 or more per year under federal grants, cooperative agreements and/or procurement contracts to have an annual audit by a public accountant or a federal, state or a local governmental audit organization. The audit must meet the standards specified in generally accepted government auditing standards (GAGAS).

## SECTION 4
## Clinical Protocol Review by Clinicians

The following clinical protocols provide a consistent approach to the provision of quality family planning services. A clinical protocol is a written plan of clinical management for an identified health condition. It is used to guide the clinician in the provision of health care to a client in an ambulatory healthcare setting. Clinical protocols incorporate standards of healthcare and reflect compliance with appropriate laws and regulations.
Clinicians include nurse practitioners, certified nurse midwives, physician's assistants, and physicians.

All clinicians must review each clinical protocol during orientation to the agency and prior to the provision of family planning medical services. Acceptance and agreement to use the clinical protocols in their entirety as practice guidelines is documented by clinician signature below. Each clinician must repeat this procedure annually. Knowledge, skills and legal scope of practice of each clinician must be assessed by the medical director prior to use of a clinical protocol that includes medically delegated responsibility to the clinician. In the event that a clinician cannot accept medically delegated responsibilities as included in all the medically delegated clinical protocols, the clinician and medical director must document which clinical protocols that the clinician is permitted to use. This may happen if the clinician is new to the agency or during clinician preceptorship. One approach is for both to sign or initial the individual clinical protocols that by mutual agreement the clinician is permitted to use.

On an appropriate line below, each clinician must: print name, sign name, sign initials and date signature. This information also provides a legal record of clinician signatures. Additional lines will be added as necessary.

| | |
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| Medical Director | Date |
| Physician | Date |
| Physician | Date |
| Nurse Practitioner | Date |
| Nurse Practitioner | Date |
| Certified Nurse Midwife | Date |
| Physician's Assistant | Date |

## SECTION 5
## General

### What are clinical lab services?

This policy is to provide guidance for staff providing clients with accurate, efficient, and confidential laboratory testing through compliance with the CLIA, Federal and State rules and regulations, HIPAA regulations regarding confidentiality, and ongoing development, implementation, and evaluation of quality control methods.

A clinical laboratory is defined by CLIA as any facility which performs laboratory testing on specimens obtained from humans for providing information for health assessment and for the diagnosis, prevention, or treatment of disease.

There are four types of CLIA certifications for laboratories which include:

- Certification of Waiver;
- Certification for Provider-Performed Microscopy Procedures (PPMP);
- Certification of Compliance; and
- Certification of Accreditation.

Reproductive Health clinic laboratories performing *only* "waived" tests must apply for a Certificate of Waiver.

Reproductive Health clinics performing *only* tests indicated as "waived" and "provider-performed microscopy procedures" (PPM) must apply for a Certification of PPM.

Reproductive Health clinics laboratories that perform a higher level of complexity testing must adapt this protocol to reflect their certification.

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| **Protocol** | All staff performing any laboratory test will be provided an orientation when hired, as well as ongoing competency assessment on laboratory policies, and procedures at least annually, and additional training when laboratory tests are added or changed.<br><br>Certification:<br>• A CLIA certificate is required in order to operate a clinical laboratory.<br>  ○ Applications and renewals are submitted to ODH Office of Health Assurance and Licensing CLIA Program.<br>  ○ The fee is determined by CMS according to the complexity level of testing.<br>  ○ The CLIA certificate will be displayed in a prominent place in view of the public.<br><br>CLIA Laboratories: Waived and PPM<br>• Are subjected to inspections only: |

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| | ○ If a complaint is made;<br>○ To validate that:<br>▪ Only waived categorized tests are performed under a waived lab certificate; and<br>▪ Only waived and PPM tests are performed under a PPM certificate; or<br>○ If there is a risk of harm to client due to inaccurate testing.<br>• Waived laboratories may perform only those tests categorized as waived.<br>• PPM laboratories may perform only tests classified as waived and PPM.<br>• Written Orders:<br>○ Waived tests may be performed at the written request of a:<br>▪ Medical Doctor;<br>▪ Doctor of Osteopathy;<br>▪ Naturopathic Doctor;<br>▪ Physician Assistant;<br>▪ Certified Nurse Practitioner; or<br>▪ Certified Nurse Midwife.<br>○ Written protocols, policies, and procedures cover the use of standing orders when specific guidance is provided.<br>• Waived tests may be performed by any individual following appropriate training and documentation.<br>• PPM testing may be performed only by a:<br>○ Medical Doctor;<br>○ Doctor of Osteopathy;<br>○ Physician's Assistant;<br>○ Certified Nurse Practitioner; or<br>○ Certified Nurse Midwife.<br>• Written procedures will be developed and maintained for all tests performed in the waived and PPM laboratory and will be approved by the laboratory director and/or health officer.<br>• A PPM laboratory must have a lab director who is legally liable and responsible for all aspects of testing and must be a:<br>○ Physician (MD or DO) licensed to practice in Mississippi;<br>○ Nurse practitioner or nurse midwife licensed and certified by the Mississippi Board of Nursing; or<br>○ Physician's assistant licensed by Mississippi Board of Medical Examiners.<br>• Maintain:<br>○ Complete records on each test kit/device per manufacturer's recommendations, for 2 years, including:<br>▪ Quality control;<br>▪ Calibration; and<br>▪ Instrument maintenance. |

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| | ○ Records on all testing personnel indicating laboratory training and competency assessment.<br>○ Meet department standards for safety, disposal of hazardous and infectious waste.<br>○ Refer specimens only to laboratories operating in compliance with CLIA.<br>▪ To determine if a referred lab is CLIA compliant staff may access information at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Laboratory_Demographic_Information.html.<br>▪ Staff may call the laboratory directly to ask about their CLIA status.<br>▪ Laboratory staff will reevaluate the CLIA status when the referred labs certificate expiration date is due.<br><br>• Laboratory will not revise results or information directly related to interpretation of results provided by the testing laboratory.<br>• Inform Laboratory Compliance Section of changes in laboratory name, owner, director, or address within 30 days after a change occurs. |
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| **Procedure** | Test Preparation:<br><br>• Tests will be performed in an area with adequate space while maintaining client privacy.<br><br>• Testing and storage must meet specific environmental requirements per manufacturer's instructions.<br><br>• Clinical equipment will be maintained, and calibration checks performed as directed in manufacturer's instructions. Points to consider:<br><br>○ Clean work area before and after testing;<br>○ Perform testing in well-lit area;<br>○ Check and record temperatures of the testing and reagent storage areas;<br>○ Check and record expiration dates of reagents/kits, discard when expired;<br>○ Do not mix reagents;<br>○ Inspect reagents for damage, discoloration, or contamination and discard if found;<br>○ Prepare reagents according to manufacturer's instructions; and<br>○ Allow time for refrigerated reagents/samples to come to room temperature.<br>• External quality control (QC) per manufacturer's instructions.<br>○ Will be performed at a minimum:<br>▪ With each new shipment of kits/reagents;<br>▪ With a change in lot numbers; and<br>▪ By each new testing staff before conducting testing. |

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| | o Results will be recorded on the lab's results log; and records kept for 2 years.<br><br>Performing Tests:<br>• Staff will:<br>o Confirm test order;<br>o Confirm client's identification;<br>o Confirm client is aware of what test(s) is/are being done;<br>o Confirm client has followed pretest instructions, if indicated;<br>o Wear appropriate personal protective equipment;<br>o Use the proper specimen collection device;<br>o Follow the testing steps in the exact order per manufacturer's instructions;<br>o Use a timer to follow the required timing intervals;<br>o Interpret test results according to the manufacturer's instructions;<br>o In-house test results will be given to the client at the time of testing;<br>o If test results are invalid, compromised, or disagree with client's clinical information, the test will be repeated; and<br>o Record test results in client's chart and on the lab's results log.<br><br>• Any test not performed in this laboratory will be referred to a licensed reference laboratory.<br>o Specimens sent out will be documented on a specimen tracking log.<br>o The original report form from the reference laboratory will be filed in the client's chart.<br>o Abnormal cervical cytology results will be entered into a client management tracking system. (see *Management of Abnormal Cervical Cytology Policies and Procedures*)<br><br>Critical Values:<br>o Establish critical values which require immediate treatment or evaluation from an ordering provider;<br>o Define which tests have critical values;<br>o Ensure staff are aware of the critical values;<br>o Provide staff directions in how to alert the provider in a timely manner; and<br>o Document when and to whom the critical values are reported.<br><br>Notification of Lab Test Result(s):<br>o All clients will be notified of test results.<br>o Clients with special requests will be notified per client preference. |

- Clinics providing confidential services will designate a code name or code word (e.g., "Annie") that can be used when calling or leaving a message for clients who need confidential services (e.g., "Hi, this is Annie, please call me back").
- Client will be notified of normal test results by mail within 7 days.
  - Inform the client to call the clinic for results if they have not received any notification within 10-14 days.
- Client with abnormal test results will be contacted by:
  - Phone:
    - First attempt shall occur when lab results are received.
    - Second attempt will be done within 1 week of the first attempt.
  - If unable to contact by phone, a letter will be sent.
  - If no response is received within 1 month, a registered letter will be sent.
  - If no response is received, the client will be assumed to be lost to follow-up.
- Client notification process will be documented in client's chart.

Quality Assurance (QA) Requirements:

- All laboratories will have a mechanism in place to monitor, assess, and when indicated, correct problems identified in the pre-analytic phase of testing.
- The pre-analytic phase begins from the time a test is ordered by the provider until the sample is ready for analysis. Type of errors include:
  - Client identification and preparation;
  - Test collection procedures;
  - Specimen handling and processing; and
  - Specimen transport.

- PPM labs must monitor and evaluate the total testing process (pre-analytic, analytic, and post-analytic).
  - Pre-analytic phase - see above.
  - Analytic phase consists of two procedures:
    - Confirmation of specimen and corresponding procedure to be done; and
    - The process in which the specimen sample is analyzed.
      - Error types consist of equipment malfunction and sample mix- up.
  - Post-analytic phase is the process of declaring the outcome of the tests performed.
    - Error types consist of erroneous validation of analytical data, failure in reporting/addressing the report, excessive turn-around time, improper data entry, and failure/delay in reporting critical values.

- Staff will assure the accurate, reliable, and prompt reporting of test results.

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| | • All QA activities and corrective action will be documented and discussed with the staff.<br><br>Microscope Maintenance for PPM Lab:<br>• Clean objective lenses, eyepieces, and condenser daily, or after use;<br>• Use a high-quality lens paper dampened with approved lens cleaner;<br>• Keep the 10X and 40X objectives oil-free;<br>• Cover microscope when not in use; and<br>• Ensure annual service is performed by a trained technician. |
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| **Training** | Competency Assessment Requirements:<br>• Will be done semiannually during the first year of employment and annually thereafter.<br>• Can be done throughout the entire year by coordinating it with routine practices and procedures to minimize impact on workload.<br>• Consists of six elements:<br>o Direct observations of routine client test performance, including client preparation, if applicable, specimen handling, processing, and testing;<br>o Monitoring the recording and reporting of test results;<br>o Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records;<br>o Direct observation of performance of instrument maintenance and function checks;<br>o Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and<br>o Assessment of problem-solving skills.<br><br>PPM Test Performance:<br>o Perform either proficiency testing or quality assurance (split sampling or an external quality assurance program) bi-annually. |
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Centers for Medicare & Medicaid Services. (2012). *What do I need to do to assess personnel competency?* http://www.cms.gov/Regulations-and Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf

**Resources**

5. CLIA application for certification: http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf
6. Centers for Disease Control and Prevention. 2011. Ready? Set? Test! Patient Testing is Important booklet: http://wwwn.cdc.gov/clia/Resources/WaivedTests/pdf/ReadySetTestBooklet.pdf
7. Tests granted waived status under CLIA: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/waivetbl.pdf
8. Centers for Medicare & Medicaid Services– list of PPM (Provider Performed Microscopy Procedures): http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ppmplist.pdf

## What is autoclave pre-sterilization, operation, and maintenance?

This policy provides guidance on the sterilization process to ensure client safety and best practice in the sterilization of equipment and use of the autoclave as well as preventative and scheduled maintenance procedures.

Autoclaving is a process used to destroy microorganisms and decontaminate biohazardous waste from instruments by using high pressure and high temperature steam for sterilization. There are potential risks to the operators which include:

- Heat burns from hot materials and autoclave chamber walls and door;
- Steam burns from residual steam coming from autoclave and materials on completion of cycle;
- Hand and arm injuries when closing the door; and
- Body injury if there is an explosion.

To ensure the health and safety of staff using the autoclave, it is important for each department to maintain their autoclave per manufacturer's instructions and to train staff in their proper use.

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| **Protocol** | Clinical staff will be trained in the operation of the autoclave and follow the manufacturer's recommendations for proper maintenance to ensure not only their safety, but also to ensure that equipment is correctly sterilized. |
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| **Procedure** | Safety Practices of the Autoclave:<br>• Follow manufacturer's instructions for loading, operating, maintaining, cleaning, and performing quality assurance checks.<br>• Before using the autoclave, check inside the autoclave for any items left by the previous user that could pose a hazard.<br>• Clean the drain strainer before loading the autoclave.<br>• Load the autoclave properly as per the manufacturer's instructions(do not overload).<br>• Make sure the door of the autoclave is fully closed and latched when in use.<br>• Make sure the correct cycle for the material is selected.<br>• When the cycle is complete, open the door slowly. Keep your head, face, and hands away from the opening.<br>• ***Do not*** autoclave items containing corrosives, solvents or volatiles, or radioactive materials.<br><br>Prepare and Package Items Needing Sterilization:<br>• Thoroughly clean instruments first by rinsing with water. |

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| | o Use of personal protective equipment (PPE) shall be worn for handling and cleaning contaminated instruments.<br><br>• Pre-clean with appropriate cleaning product.<br>o If detergent based, ensure that it is mixed to the correct in-use dilution.<br>o Avoid prolonged soaking; soak for the amount of time recommended by the cleaning agent's manufacturer.<br><br>• Clean.<br>o Completely submerge items during the cleaning process to minimize aerosolizing of microorganisms and assist in cleaning.<br>o Remove gross soil using tools such as brushes and cloths.<br>o Inspect brushes and other cleaning equipment for damage after each use, and discard if necessary.<br>o Clean, disinfect, dry, and store tools used to assist in cleaning after each use, or else discard.<br><br>• Rinse.<br>o Rinse all equipment thoroughly with water after cleaning to remove residues which may react with the disinfectant/sterilant.<br><br>• Dry.<br>o Follow manufacturer's instructions for drying of the device.<br>o Instruments may be air-dried or dried by hand with a clean, lint- free towel.<br>o Dry stainless-steel instruments immediately after rinsing to prevent spotting.<br><br>• Post cleaning.<br>o Visually inspect instruments to ensure cleanliness and integrity of the device.<br>o Repeat cleaning on any item that is not clean.<br>o Follow the manufacturer's guidelines for lubrication.<br>o Those instruments requiring lubrication shall be lubricated prior to sterilization.<br><br>• Package in autoclave wrap or pouches.<br>o Use of heat-sensitive tape on the autoclave wrap provides monitoring which indicates the load has undergone an effective steam sterilization process and indicates the proper temperature has been reached.<br>o If the heat-sensitive tape does not turn brown (indicating the load did not undergo proper sterilization process) the load must be reprocessed.<br>o Autoclave pouches have a color sensor strip on the outside of the pouch which also must turn brown to indicate the package was effectively sterilized. |

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| | o Write the date, batch number that day, employee initials, and label contents on the wrap or pouches to be sterilized.<br><br>Loading the Autoclave:<br>• Do not mix unwrapped and wrapped items or sterilized and non-sterilized items.<br>• Do not overload.<br>• Close and latch door firmly.<br><br>Operating the Autoclave:<br>• Follow individual autoclave manufacturer's operating instructions.<br>• Press ON/Standby button.<br>• Refer to Standard Cycle Parameters to select the proper sterilization program time and temperature.<br>• Select and press the appropriate sterilization program button.<br>• Press the START button.<br>• If the autoclave is not working properly discontinue using immediately.<br>o Post sign alerting others not to use the autoclave.<br>o Contact the service company responsible for maintenance of the autoclave.<br>• Address any error messages; make corrections and reprocess the instruments.<br><br>Unloading the Autoclave:<br>• Allow the load to cool down to room temperature.<br>• Examine the load items for:<br>o Any signs of compromised packaging integrity; and<br>o Change to brown color of the heat-sensitive tape or pouch color strip.<br><br>Recordkeeping:<br>• Entries must be placed on the log form each time the autoclave is used.<br>• Entries should include operator's name, date, and time.<br>• Log forms should be kept by the autoclave for easy access.<br>• Log maintenance and repairs into log forms.<br><br>Monitoring:<br>• Monitoring of the autoclave should be performed routinely using:<br>o Mechanical indicators;<br>▪ Assessment of cycle time and temperature after each load.<br>o Chemical indicators; and<br>▪ Affixed to the outside of each pack; changes color when sterilization parameters are present for each package. |

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| | ○ Biological indicators (e.g., Attest™ biological indicators, spore-strip biological indicators).<br>▪ Sterilizer should be monitored at least weekly.<br>▪ If sterilizer is used frequently (several loads per day) daily use of biological indicators may be indicated.<br>▪ Consider sending a processed pack or pouch to a laboratory for culture to verify sterility.<br><br>Contingency Plans:<br>• If autoclave does not operate as expected, do not attempt to fix the problem.<br>○ Record the problem on the log form.<br>○ Notify **(insert name)** to report the problem.<br>• Burn emergency.<br>○ If you are burned, seek medical treatment as soon as possible.<br>○ Burns to the face, third degree burns, or burns over large area should be treated as emergencies.<br>○ Minor burns should be treated using first aid procedures.<br>○ Regardless of the degree of severity, report the burn to (**insert name**) as an occupational injury.<br>Maintenance:<br>• Preventative and scheduled.<br>○ Follow the manufacturer's recommendations for routine maintenance and cleaning.<br>○ Daily: clean door gasket with a soft cloth.<br>○ Weekly:<br>▪ Clean the tray holder and trays with a cleaning agent and water and a soft sponge.<br>▪ Clean and descale the chamber and reservoir with a descaling agent.<br>○ Clean the outer parts of the autoclave with a soft cloth. |
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| **Training** | • All users must become familiar with the manufacturer's operation manual prior to the use of the autoclave.<br>• All users must be trained before operating an autoclave.<br>• All training should be documented, and records should be maintained in the lab with other safety training records. |
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BC Ministry of Health. (2013). *Best practices for cleaning, disinfection and sterilization of medical equipment/devices in all health care settings*. http://www.publichealthontario.ca/en/eRepository/PIDAC_Cleaning_Disinfection_and_Sterilization_2013.pdf

## What is cleaning and disinfection for healthcare settings?

This policy provides guidance for Reproductive Health clinic staff in reducing the risk of infection through cleaning and disinfection of environmental surfaces in patient-care areas and common-use areas.

All healthcare settings, regardless of the level of care provided, must make infection prevention a priority and must be equipped to observe Standard Precautions. Outpatient facilities have been identified as vectors for transmission of infectious agents among patients. Vulnerable patient populations rely on frequent and intensive use of ambulatory care to maintain or improve their health. It is critical that all this care be provided under conditions that minimize or eliminate risks of healthcare-associated infections.

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| **Protocol** | All staff will follow the Standard Precautions for disinfection and sterilization of patient-care areas and common-use areas. |
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| **Procedure** | Those surfaces in proximity to the patient and those that are touched frequently in the exam room will be cleaned between each patient and disinfected daily.<br>These include surfaces such as:<br>• Exam tables;<br>• Countertops;<br>• Mayo stand;<br>• Chairs;<br>• Stools; and<br>• Tabletops.<br><br>Select EPA-registered disinfectants or detergents/disinfectants with label claims for use in healthcare.<br><br>Follow the manufacturer's recommendations for use of cleaners and EPA-registered disinfectants (this includes):<br>• Amount;<br>• Dilution;<br>• Contact time;<br>• Safe use; and<br>• Disposal.<br><br>Use appropriate personal protective equipment (PPE), as indicated.<br><br>Change the paper covering the exam table between patient use. |

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| | Place any used linens (e.g., exam gowns, sheets) in a designated container located in each exam room after each patient use.<br><br>Clean personal and diagnostic equipment regularly; disinfect if equipment becomes contaminated with blood or body fluids.<br><br>Proper Hand Hygiene:<br>• Use of alcohol-based hand rub with emollient is the preferred method.<br>• Use soap and water when hands are visibly soiled or in contact with suspected infectious material.<br>• Decontaminate hands with alcohol-based hand rub before and after each patient encounter.<br>• Decontaminate hands with alcohol-based hand rub after contact with body fluids or excretions, mucous membranes, and nonintact skin if hands not visibly soiled.<br>• Decontaminate hands with alcohol-based hand rub after removing gloves.<br>• Wash hands with soap and water before eating and after using a restroom.<br><br>Clean floors in exam rooms, lab, and bathrooms daily.<br><br>Promptly clean and decontaminate spills of blood and other potentially infectious materials.<br><br>If reusable cleaning cloths or mops are used, they should be decontaminated regularly to prevent surface contamination.<br><br>Cleaning Common Areas:<br>• Floors in common areas shall be cleaned daily.<br>• Common area surfaces (e.g., counters, doorknobs, telephones) will be disinfected daily or more frequently, using an EPA-registered disinfectant. |
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| **Training** | • Job- or task-specific infection prevention education and training will be provided to all healthcare providers.<br>• Training will focus on both healthcare staff safety and patient safety.<br>• Training on Bloodborne Pathogens will be provided upon orientation and repeated at least annually for all staff whose assigned tasks may lead to occupational exposure. |

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| | • Competencies will be documented upon orientation to clinic, should be repeated annually, and any time policies or procedures are updated or revised.<br>• Assessments of current infection prevention measures and update as needed will be performed annually. |
| | |

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Centers for Disease Control and Prevention. (2016). *Guide to infection prevention for outpatient settings: Minimum expectations for safe care.* https://www.cdc.gov/infectioncontrol/pdf/outpatient/guide.pdf

American Academy of Family Physicians. (2001). *AAP issues recommendations on infection control in physicians' offices.* http://www.aafp.org/afp/2001/0215/p787.html

## What is a reproductive life plan?

The CDC recommends all people of reproductive age should have a reproductive health plan as part of providing quality family planning services. A reproductive life plan is a set of personal goals and subsequent plans about having or not having children. All clients need to make a reproductive life plan based on their own values, goals, and resources. Clients need to think about when and under what conditions they want to become pregnant. If pregnancy is not desired, contraceptive options should be discussed.

The provider should avoid making assumptions about the client's needs based on his or her characteristics, such as sexual orientation or disabilities. For clients whose initial reason for coming to the service site was not related to preventing or achieving pregnancy, asking questions about his or her reproductive life plan might help identify unmet reproductive health-care needs. Identifying a need for contraceptive services might be particularly important given the high rate of unintended pregnancy in the United States.

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| **Subjective Data** | History must include:<br>• All clients of reproductive age must be assessed at least annually as to their reproductive plans<br>• Discussing a reproductive life plan enhances the family planning aspects of the visit. |
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| **Clinical Pathway of family planning services for men and women of reproductive age (*See* Figure 2)** | Client encounters with women and men of reproductive age may require different service needs (i.e., contraceptive services, pregnancy testing and counseling, achieving pregnancy, STI services and related preventive health services). The following questions will determine what family planning services are most appropriate for a given visit and must be asked and documented:<br><br>• What is the client's reason for the visit?<br>• Does the client have another source of primary healthcare?<br>• What is the client's reproductive life plan? |
| | |
| **Reproductive Life Plan** | **Providers should assess the client's reproductive life plan by asking the client questions such as:**<br>• Do you have any children?<br>• Do you want to have (more) children?<br>• How many (more) children would you like to have and when?<br>*Or*<br>• Would you or your partner like to become pregnant in the next 12 months?<br>*And*<br>• Do you want to prevent a pregnancy now? |
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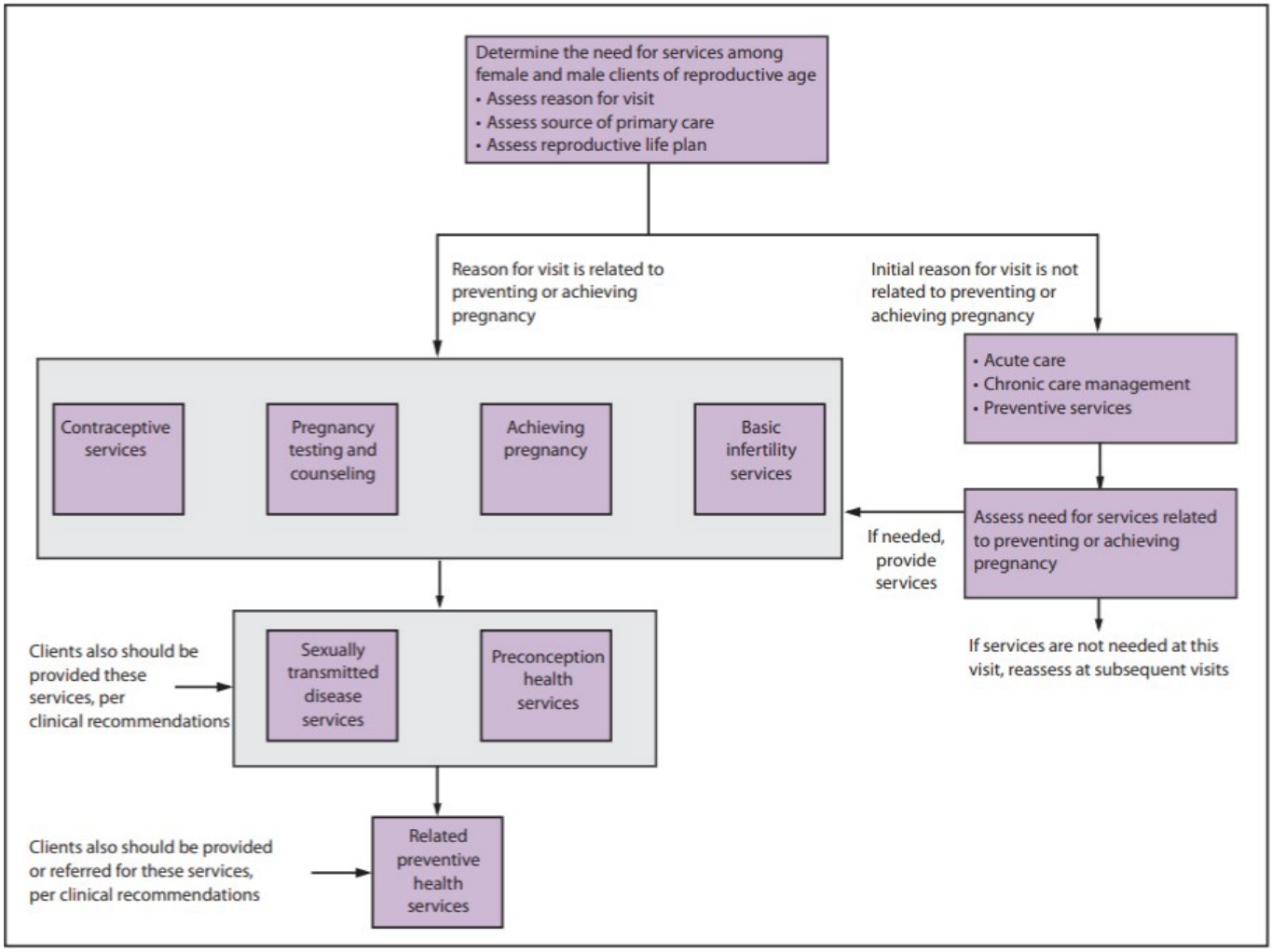
| **Plan**<br>**(*See* Figure 2)** | • If the client does not want a child currently and is sexually active, then offer **Contraceptive Services**<br>• If the client desires pregnancy testing, then provide **Pregnancy Testing and Counseling Services**<br>• If the client wants to have a child within the next twelve months, then provide **Achieving Pregnancy Services**<br>• If the client wants to have a child and is experiencing difficulty conceiving, then provide **Basic Infertility Services**<br>• If the female client of reproductive potential is not pregnant but at risk of becoming pregnant, or the male client is at risk for impregnating his female partner, then provide **Preconception Health Services**<br>• If the client is at risk for STI exposure, provide **STI Services** |
| | |
| **Patient Education/Counseling** | • Nearly half of pregnancies are unintended.<br>• Risks associated with unintended pregnancies<br>  o Late entry to prenatal care<br>  o Maternal depression<br>  o Increased rates of abortion<br>  o Exposure to potentially harmful substances during pregnancy<br>  o Poor pre-pregnancy disease control<br>  o Reduced school completion and lower income attainment (for an unmarried woman)<br>• Preconception, contraception, STI prevention counseling etc.<br>• Importance of planning and goal setting.<br>• Importance of birth spacing. Women with interpregnancy intervals of less than 18 months are more likely to have premature infants and low birthweight babies<br>• Reproductive life plans are fluid and are never right or wrong.<br>• If the client does not have a plan to prevent pregnancy, the client has a plan to get pregnant.<br>• Benefits of a reproductive life plan<br>  o Choose contraceptive methods that best fit the plan<br>  o Decrease risks for unintended and short interval pregnancies<br>  o Increase likelihood of achieving life goals (e.g., graduating school or college, obtaining a certain job) |
| | |
| **Consultation/Referral** | • Based upon client's need. |
| | |

**FIGURE 2. Clinical pathway of family planning services for women and men of reproductive age**

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Moos, M.K., & Johnson, F. (2015). *Reproductive life planning: From concept to practice* [PowerPoint Slides]. http://www.healthystartepic.org/wpcontent/uploads/2015/08/MoosReproductiveLifePlanningSlides.pdf

## Clinic Emergencies

6. Syncope
    a. Symptoms (sudden onset of one or more of the following):
        i. Nausea and/or vomiting
        ii. Diaphoresis
        iii. Weakness
        iv. Dizziness
        v. Pallor
    b. Clinical Signs
        i. Weakness, sweaty, possible decreased level of consciousness
        ii. Pulse < 60/min. or >110
        iii. BP < 80 systolic
    c. Laboratory
        i. Consider checking a Hgb/HCT
        ii. Consider finger stick glucose
    d. Plan
        i. Check vital signs and perform physical examination
        ii. Lie client flat with legs elevated
        iii. Treat symptomatically; supportive care only
            1.) Aromatic spirits of ammonia may be helpful (Do not use if patient is asthmatic) 2.) Offer juice or cola with sugar for clients with hypoglycemic episode
        iv. If cardiovascular collapse is suggested by examination activate EMS system and begin basic life support

7. Anaphylactic Shock
    a. Symptoms (Sudden onset of one or more of the following):
        i. Hives
        ii. Pruritus
        iii. Swelling
        iv. Red, watery eyes
        v. Rhinorrhea
        vi. Dizziness or syncope
        vii. Change of voice
        viii. Coughing or wheezing
        ix. Throat tightness or closing
        x. Difficulty with breathing or swallowing
        xi. Sense of doom
        xii. Change of color

    b. Plan
        i. If cardiovascular collapse, respiratory distress, or facial/oral swelling is suggested by examination, activate EMS system and begin basic life support if needed

ii. Monitor vital signs frequently (every 2 to 5 minutes)
iii. Medications (below), as available:
    i. If available, give Aqueous Epinephrine 1:1,000, 0.5 ml subcutaneously, with a dose for adults of 0.01 mL/kg up to a maximum dose of 0.2 to 0.5 mL. Repeat q 10-15 min. as needed if available
    ii. Administer oxygen by facial mask at 8-10 liters/min if available
    iii. Give Benadryl (diphenhydramine) 25-50 mg I.M.
    iv. If anaphylaxis is due to an injection, give aqueous epinephrine, 0.15-0.3 ml, into injection site to inhibit further absorption

8. Cardio-Pulmonary Arrest (Basic Life Support for Health Care Providers)
    a. Establish unresponsiveness
        i. Activate Emergency Medical System (EMS) or appropriate resuscitation team.
        ii. Get AED and emergency equipment or send someone to do so. (All clinics and facilities should have an AED on the premises.)
    b. Evaluate the airway and check for breathing
        i. Look, listen and feel
        ii. If unresponsive and not breathing, open the airway (person needs to be in a supine position)
        iii. Head tilt-chin lift or jaw thrust
        iv. If victim is breathing or resumes effective breathing, place in the recovery position
        v. If victim is not breathing, give 2 slow breaths (1 second each) while using pocket mask or bag-mask. Allow for exhalation between breaths.
    e. Check for signs of circulation (breathing, coughing, movement), including pulse. (Carotid)
        i. If signs of circulation/pulse present but breathing is absent, provide rescue breathing (1 breath every 5 seconds for adult, 10-12 breaths per minute)
        ii. If signs of circulation/pulse absent, begin chest compressions interposed with breaths
            1) Compression depth of at least 2 inches in adults and at least 1/3 the AP dimension of the chest in infants and children
            2) Compression rate: 100-120/min
            3) Compression/Breath Ratio (1 Person): 30:2 – 5 cycles (about 2 minutes)
            4) Compression/Breath Ratio (2 people): 30:2 – 5 cycles (check pulse and switch roles every 2 minutes)
    3. Defibrillation
        i. If CPR is in progress, continue CPR until the AED is turned on, the AED pads are applied, and the AED is ready to analyze the heart rhythm.
        ii. If you are alone and an AED is available, you should use it once you have determined the person in in cardiac arrest.

    4. For an AED to be effective, you MUST use it properly by doing the following:
        i. Turn it on first.
        ii. Make sure the patient's chest is clearly exposed and dry.
            1) Remove any medication patches with a gloved hand.
            2) If necessary, remove or cut any undergarments that may be in the way. The pads need to be adhered to the skin for the shock to be delivered to the heart.

iii. Apply the appropriate-sized pads for the patient's age in the proper location on the bare chest.
    1) Use adult pads for adults and children over the age of 8 years or over 55 pounds.
    2) Place one pad on the upper right chest below the right clavicle to the right of the sternum; place the other pad on the left side of the chest on the mid-axillary line a few inches below the left armpit.
iv. Plug in the connector, and push the analyze button, if necessary. (Most AEDs available today have their pads pre-connected and will automatically analyze once the pads are applied to the chest. Make sure you understand how the AED within your organization operates.)
v. Tell everyone to "clear" while the AED is analyzing to ensure accurate analysis. Ensure no one is touching the patient during the analysis or shock.
vi. When "clear" is announced, have the rescuer performing the compressions stop compressions and hover a few inches above the chest, but remain in position to resume compressions immediately after a shock is delivered or the AED advises that a shock is not indicated.
vii. Observe the AED analysis and prepare for a shock to be delivered if advised.
    1) Ensure that everyone is clear of the patient before the shock is delivered.
    2) Remember that the AED delivers an electrical current that could injure anyone in contact with the patient.
    3) Have the rescuer in the hover position ready to resume compressions immediately after a shock is delivered or the AED advises that a shock is not indicated.
viii. Deliver the shock by pressing the shock button, if indicated.
ix. After the shock is delivered, immediately start compressions and perform about 2 minutes of CPR (about 5 cycles of 30:2) until the AED prompts that it is reanalyzing, the patient shows signs of return of spontaneous circulation, or you are instructed by the team leader or more advanced personnel to stoop.
x. Do not wait for the AED to prompt to begin CPR after a shock or no shock advised message.

CPR information taken from:
American Red Cross. (2015). *Basic life support for healthcare providers*. https://www.redcross.org/content/dam/redcross/atg/Landing_Pages/BLS/BLS_Handbook Final_.pdf

American Heart Association. (2019). *CPR & ECC guidelines*. https://eccguidelines.heart.org/circulation/cpr-ecc-guidelines/

9. Shock/Hemorrhage
    a. Symptoms (sudden onset of one or more of the following):
        i. Uncontrolled, profuse bleeding
        ii. Pallor, weakness, diaphoresis, fainting
    b. Clinical Signs
        i. Client may appear weak and may exhibit disorientation

ii. Pulse may be weak, shallow, rapid, or slow
iii. Blood pressure may be decreased (hypotension)
iv. Skin may appear pale and cold

c. Plan
i. Place client in Trendelenburg position
ii. Activate EMS system
iii. Monitor vitals as indicated
iv. If able, start intravenous line and infusion
v. If etiology identified, attempt to control bleeding

10. General Emergency Information
a. Staff should be trained in emergency procedures and must be familiar with the emergency plans. All licensed medical staff should be trained in CPR and hold current certification.
i. All client medical emergencies requiring referral to another provider should have referral results documented in client's record.
ii. If appropriate, copy pertinent records to send with emergency personnel.
iii. Staff should engage in periodic drills; if multiple use facility, coordinate drills with other personnel.

b. After Hours Emergencies (all facilities must have in place at least one of the following for the management of afterhours contraceptive emergencies):
i. Answering service that can direct a client to either an on-call staff nurse or the nearest ED.
ii. Message left on clinic phone with clear instructions to the nearest ED.
iii. Call-forwarding to the on-call staff nurse.
iv. In addition to the above, written instructions must be provided to every client during the initial and subsequent visits detailing the facilities after-hour policies or be posted on the clinic website.

c. Emergency situations (fire, natural disaster, vandalism, power failure, harassment, bomb/terrorism, earthquake, and tornado) may occur at any time. All projects must therefore have written plans and procedures for the management of emergencies.
i. Disaster plans must be developed and made available to all staff.
ii. Staff must understand all assigned emergency escape routes.
iii. Staff must complete training and understand their role in an emergency or natural disaster.
iv. All exits must be recognizable and free from barriers.

## Latex

Latex allergy is caused by a reaction to certain proteins found in natural rubber latex. A latex allergy may cause minor symptoms, such as itchy skin, to hives or anaphylaxis.

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| **Subjective Data/Symptoms** | *History may include:*<br>• Rash with latex exposure<br>• Swollen lips with blowing up a latex balloon<br><br>*Symptoms may include:*<br>• Itchy, stuffy, or runny nose<br>• Watery eyes<br>• Scratchy throat<br>• Hives or swelling<br>• Nausea or vomiting<br>• Dizziness, confusion<br>• Wheezing, cough, chest tightness, and difficulty breathing |
| | |
| **Objective Data** | *Physical Findings:*<br>• Rash or redness<br>• Hives or swelling<br>• Hypotension<br>• Confusion, loss of consciousness<br>• Weak or rapid pulse<br>• Cough<br>• Wheezing |
| | |
| **Plan / Pharmacologic Treatment** | *Medication:*<br><br>• If person is having an anaphylactic reaction, the person needs an immediate injection of epinephrine. See Section 3, Anaphylactic Shock<br>• For less severe reactions, antihistamines or corticosteroids should control the reaction and relieve discomfort |
| | |
| **Latex Allergy Precautions** | Latex allergy precautions include:<br>• Remove all latex gloves from the area and replace with:<br>o Nonsterile latex free gloves, powder free, low protein, or vinyl gloves for non-sterile procedures. |

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| | ○ Sterile latex free gloves for sterile procedures.<br>• Remove all items containing latex.<br>• A facility-wide strategy to manage latex allergies in the health care environment should be in place.<br>• Latex free materials should be readily available for those patients with allergies. |
| | |

**References**


Centers for Disease Control and Prevention. (2012). *Home healthcare workers: How to prevent latex allergies.* https://www.cdc.gov/niosh/docs/2012-119/pdfs/2012-119.pdf

Premier. (2020). *Latex: Allergy prevention.* https://www.premiersafetyinstitute.org/safety-topics-az/latex-allergies/latex-allergy-prevention-control-strategies-healthcare/

Tang, M. (2013). *Latex management of a patient at risk of or with a known latex allergy.* https://www.rch.org.au/rchcpg/hospital_clinical_guideline_index/Latex_management_of_a_patient_at_risk_of_or_with_a_known_latex_allergy/

## What are medical records, personal health information, and confidentiality?

Agencies must maintain complete medical records for every client, in accordance with accepted professional standards. The medical records must be completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information. Each entry must be signed.

A record must be maintained of every client encounter with the staff. All staff, including non-medical workers, should record every encounter (including telephone calls), reason for encounter, and any action taken.

Concern with respect to confidentiality of information may not be used as a rationale for noncompliance with state laws regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws.

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| **Custody of Records** | The agency is the legal custodian of client records. It is responsible for the provision of a safe place for storage of client records to prevent disclosure to unauthorized persons.<br><br>Client records should be kept in locked files when not in use and must not be left where individuals other than authorized persons have access to them. EMRs must be password protected and should have an automatic time out when not in use. Users should lock the EMR when not in use to ensure against unauthorized access. Also, consider that portable laptops should not be left in a room with a client. An additional layer of security can be provided with the use of biometrics. |
| | |
| **Confidentiality and HIPAA** | Agencies must be compliant with HIPAA regulations. HIPAA covered entities are expected to have adequate administrative, technical, and physical safeguards in place to protect personal health information under its control.<br><br>A summary of the HIPAA privacy rule is available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html<br><br>A summary of the HIPAA security rule is available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html<br><br>In January 2013, HHS announced a final rule that implements a number of provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act to strengthen the privacy and security protections for health information established under HIPAA. See http://www.hhs.gov/ocr/privacy/hipaa/administrative/omnibus/index.html for the press release and a link to the final rule. |

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| | Clients must be informed of agency privacy practices and a signed acknowledgment of receipt of the notice must be part of the medical record. Model notices of privacy practices that reflect 2013 regulatory changes are available at http://www.hhs.gov/ocr/privacy/hipaa/modelnotices.html |
| | |
| **Some Considerations in Maintaining Confidentiality** | All staff must be oriented to the importance of safeguarding the confidential nature of the record and any other client information.<br><br>Privacy and confidentiality in gathering client information by interview or any other means is essential.<br><br>Office and clinic facilities should be such that client information is not inadvertently revealed to persons in the waiting room or any place else.<br><br>Use discretion in engaging a client in discussion in his home or on the street while neighbors, relatives, or other persons are present.<br><br>Electronic email exchanges with clients should be encrypted. |
| | |
| **Accessibility of Medical Records** | The records must be systematically organized to facilitate retrieval and compiling of information.<br><br>Funding agencies, such as the U.S. Department of Health and Human Services, have the right to review charts of those individuals whose care is supported by their funds.<br><br>The original medical record is the property of the clinic. However, the client or her/his attorney, upon presentation of appropriate documentation, is entitled to copies of the record. |
| | |
| **Retention of Records** | Each agency should have an established written policy regarding the length of time for retention of records and the method of disposing of client records. This is usually done by obtaining a ruling from the agency or county attorney.<br><br>It is recommended that all client records be retained for a minimum of 7 years plus current year after discharge; or, in the case of a minor, 7 years after their 18th birthday. |
| | |
| **Destruction of Records** | When materials no longer need to be retained, in order to ensure the confidentiality of records, they should be destroyed. Agencies that use EMRs should establish a business plan that addresses how and when records will be deleted or moved to a secure network drive. |
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| **Content of Client Record** | The medical record must contain sufficient information to identify the client, justify the diagnosis or clinical impression, and warrant the treatment and end results.<br><br>The record should contain the following:<br><br>• Personal Data<br>  o Client identification.<br>  o Name, address, and telephone number.<br>  o Name of someone who may be contacted to reach client.<br>  o Name, address, telephone number, and relationship to client of a person who may be contacted in the event of a medical emergency. For the client under 18, the parent or guardian should be listed.<br>  o Dates of visits.<br>  o Identification of other sources of medical care.<br><br>• Clinical data<br>  o Medical history, which must be updated at least annually or more often as indicated.<br>  o Documentation of physical examination.<br>  o Documentation of laboratory tests ordered, results, and follow-up.<br><br>• Diagnostic and therapeutic orders, observations, clinical findings, and action taken<br>  o Indication of treatments and/or medications given, observations, and action taken.<br>  o Progress notes.<br>  o Special instructions.<br>  o Follow-up contact when applicable.<br>  o Any telephone calls to or from a client regarding medical problems.<br>  o Referral forms.<br>  o Follow-up of referrals.<br>  o Whenever possible, a summary of relevant health-related encounters in other health facilities should be included in the client's family planning medical record. |
| | |
| **Record Audit** | Internal record audits should be performed at least monthly, to determine completeness of records, e.g., blanks filled in, releases and consent signed appropriately, physician and staff signatures, etc.<br><br>Chart audits for the Title X funding should be completed twice a year. |
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## SECTION 6
## Psychosocial

### Human Trafficking

## Mandated Reporting

**Policy:**

Title X projects shall comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking (collectively, "State notification laws") (Legislative mandate and OPA's Notice of Funding Opportunity)

F. Must have in place and implement a plan to comply with State notification laws. Such plan shall include, at a minimum, policies and procedures that include:
   a. A summary of obligations of the project or organizations and individuals carrying out the project under State notification laws, including any obligation to inquire about or determine the age of a minor client or of a minor client's sexual partner(s)
   b. Timely and adequate annual training of all individuals (whether or not they are employees) serving clients for, or on behalf of, the project regarding State notification laws; policies and procedures of the Title X project and/or provider with respect to notification and reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence and human trafficking; appropriate interventions, strategies, and referrals to improve the safety and current situation of the patient; and compliance with State notification laws."

G. Ensure that every minor who presents for treatment is provided counseling on how to resist attempts to coerce them into engaging in sexual activities.

H. Projects may conduct a preliminary screening of any minor who presents with a sexually transmitted disease (STI), pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor. Projects are permitted to diagnose, test for, and treat STIs.

I. Projects should maintain records to demonstrate compliance with each of the requirements, including which:
   a. Indicate the age of minor clients.
   b. Indicate the age of the minor client's sexual partners if such age is an element of a State notification law under which a report is required.
   c. Document each notification or report made pursuant to such State notification laws.

J. Refer to *Minor Consent, Confidentiality, and Reporting Child Sexual Abuse: A Guide for Title XFamily Planning Providers* in Mississippi for full details and procedures.

**What is mandated reporting?**
Agencies must be compliant with all applicable state laws regarding the mandatory reporting of child abuse, child molestation, sexual abuse, rape, incest, or domestic violence. Agencies must have written procedures in place demonstrating compliance.

Program Directors must assure that all staff members are trained annually and familiar with Mississippi law regarding mandatory reporting / human trafficking. Documentation must be kept.

Family Planning agencies must develop written internal procedures for staff on how to address mandatory reporting incidents**.** It is expected that the Project Director will solicit input from local agencies involved in the issue before writing up a local procedure. Local agencies include law enforcement, child protective services, etc. Your clinic's procedure must detail how you will respond to any reportable or potentially reportable situation as outlined in this policy. All Family Planning Program staff must be familiar with the policy and procedures outlined in this section.

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| **Who are mandated reporters?** | Mississippi law specifies the persons or professions that are required to report child abuse or neglect. Mississippi mandatory reporters are listed in Section 43-21-353 of the Mississippi Code of 1972.<br>Mandatory reporters include:<br>• Attorney<br>• Physician (including interns and residents)<br>• Dentist<br>• Nurse<br>• Psychologist<br>• Social worker<br>• Family protection worker<br>• Family protection specialist<br>• Child caregiver<br>• Minister<br>• Law enforcement officer<br>• Public or private school employee<br>• Or any other person having reasonable cause to suspect that a child is neglected, abused, or a victim of commercial sexual exploitation or human trafficking. |
| | |
| **How is a report made?** | The person making the report "shall cause an oral report to be made immediately by telephone or otherwise and followed as soon thereafter as possible by a report in writing to the Department of Child Protection Services, and immediately a referral shall be made by the Department of Child Protection Services to the youth court intake unit, which unit shall promptly comply with Section 43-21-357. "<br><br>Mandated reported must immediately report. The report can be made by phone or in person. If requested, the mandated reporter must submit a written report. |
| | |
| **What information should be included** | • The names and addresses of the child and the child's parents or the person or persons having custody of the child, if known. |

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| **in a mandatory report?** | • The child's age and the nature and extent of the child's injuries, abuse or neglect that is known or reasonably suspected or believed, as applicable, to have occurred or of the threat of injury, abuse, or neglect that is known or reasonably suspected or believed, as applicable, to exist, including any evidence of previous injuries, abuse, or neglect.<br>• Any other information that might be helpful in establishing the cause of the injury, abuse, or neglect that is known or reasonably suspected or believed, as applicable, to have occurred or of the threat of injury, abuse, or neglect that is known or reasonably suspected or believed, as applicable, to exist. Mississippi Rev. Code § 2151.421(C). |
| | |
| **When must abuse be reported?** | "A mandated reporter who is acting in an official or professional capacity and knows or suspects that a child under eighteen years of age or a mentally retarded, developmentally disabled, or physically impaired child under twenty- one years of age has suffered or faces a threat of suffering any physical or mental wound, injury, disability, or condition of a nature that reasonably indicates abuse or neglect of the child, shall immediately report that knowledge or suspicion." ORC § 2151.421.<br><br>Confirmation of abuse is not required. Reporters must report whenever they "suspect" that abuse has occurred. |
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| **What sexual activity must be reported?** | Sexual activity that must be reported includes any sexual activity that would constitute any of the following offenses:<br><br>• Rape (defined at 2907.02)<br>• Sexual Battery (defined at 2907.03)<br>• Unlawful Sexual Conduct with a Minor (defined at 2907.04)<br>• Sexual Imposition (defined at 2907.06)<br>• Gross Sexual Imposition (defined at 2907.05)<br><br>ORC § 2151.421.<br><br>**Am I ever required to report a minor's *consensual* sexual activity as child abuse?**<br>Consensual acts that **must** be reported as child abuse include:<br>• Sexual conduct with a minor under 13 years old, irrespective of partner's age. (2907.02)<br>• Sexual contact with a minor under 13 years old, irrespective ofpartner's age. (2907.05) |

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| | • Sexual conduct with a minor 13 years old or older but under 16, if the partner is 18 or older and knew or was reckless about the minor's age. (2907.04)<br>• Causing sexual contact between others, if one of the parties is under 13 years old. (2907.05)<br>• Sexual contact with a minor 13 or older but under 16 if the partner is 18 or older and at least 4 years older than the minor (sexual contact between a 13 or 14 year old and someone 18 or older, or a 15 year old and someone 19 or older).(2907.06)<br>• Causing sexual contact between others if one of the parties is a minor 13 or older but under 16, if the instigator is 18 or older and at least 4 years older than the minor (13 year old/18 or older, 14 year old/at least 18, 15 year old/at least 19).(2907.06)<br>• Sexual conduct with a minor under 18 years old who is a primary, secondary, or higher education school student if the partner is a teacher, administrator, coach, or other person in authority employed by the school. (2907.03)<br>• Sexual conduct with a minor under 18 years old if the partner is a coach, instructor, leader of a scouting troop or a person with temporary or occasional disciplinary control over the minor. (2907.03)<br><br>"'Sexual conduct' means vaginal intercourse between a male and female; anal intercourse, fellatio, and cunnilingus between persons regardless of sex; and without privilege to do so, the insertion, however slight, of any part of the body or any instrument, apparatus, or other object into the vaginal or anal cavity of another. Penetration, however slight, is sufficient to complete vaginal or anal intercourse." ORC § 2907.01<br><br>"'Sexual contact' means any touching of an erogenous zone of another, including without limitation the thigh, genitals, buttock, pubic region, or if the person is a female, a breast, for the purpose of sexually arousing or gratifying either person." ORC § 2907.01.<br><br>**In general, the following consensual acts do not require reporting:**<br>• Sexual conduct or contact when both partners are 13 years old or older and under 18 years old.<br>• Sexual contact with a minor 15 or older if the partner is under 19 years old.<br>• Sexual contact or conduct with a minor 16 or older, irrespective of partner age, (unless partner is a teacher, coach or other specially identified category as described above). |
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| **What is abuse or neglect?** | Mississippi law defines an "abused child" to include any child who: |

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| | "(A) Is the victim of "sexual activity" as defined under Chapter 2907 of the Revised Code, where such activity would constitute an offense under that chapter;<br>(F) Is endangered;<br>(G) Exhibits evidence of any physical or mental injury or death, inflicted other than by accidental means, or an injury or death which is at variance with the history given of it. Except as provided in division (D) of this section, a child exhibiting evidence of corporal punishment or other physical disciplinary measure by a parent, guardian, custodian, person having custody or control, or person in loco parentis of a child is not an abused child under this division if the measure is not prohibited under section 2919.22 of the Revised Code.<br>(H) Because of the acts of his parents, guardian, or custodian, suffers physical or mental injury that harms or threatens to harm the child's health or welfare.<br>(I) Is subjected to out-of-home care child abuse." ORC § 2151.031.<br><br>Mississippi defines a "neglected child" as any child:<br><br>"(1) Who is abandoned by the child's parents, guardian, or custodian;<br>(8) Who lacks adequate parental care because of the faults or habits of the child's parents, guardian, or custodian;<br>(9) Whose parents, guardian, or custodian neglects the child or refuses to provide proper or necessary subsistence, education, medical or surgical care or treatment, or other care necessary for the child's health, morals, or well-being;<br>(10) Whose parents, guardian, or custodian neglects the child or refuses to provide the special care made necessary by the child's mental condition;<br>(11) Whose parents, legal guardian, or custodian have placed or attempted to place the child in violation of sections 5103.16 and 5103.17 of the Revised Code;<br>(12) Who, because of the omission of the child's parents, guardian, or custodian, suffers physical or mental injury that harms or threatens to harm the child's health or welfare;<br>(13) Who is subjected to out-of-home care child neglect."<br>ORC § 2151.03. |
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| **When mandated reporters in Mississippi must report consentual sexual activity as child abuse** | If a minor engages in consentual sexual conduct* with an older (or younger) partner, is a report mandated?** |

| Age of Partner⇒ | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Age of Patient ⇓ | | | | | | | | | | | |
| 11 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 12 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 13 | Y | N | N | N | N | N | Y | Y | Y | Y | Y |
| 14 | Y | N | N | N | N | N | Y | Y | Y | Y | Y |
| 15 | Y | N | N | N | N | N | Y | Y | Y | Y | Y |
| 16 | Y | N | N | N | N | N | N | N | N | N | N |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 17 | Y | N | N | **N** | N | N | N | N | N | N | N |
| 18 | Y | Y | Y | Y | N | N | N | N | N | N | N |

If a minor engages in sexual contact,* is a report required?**

| Age of Partner⇒ | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Age of Patient ⇓ | | | | | | | | | | | |
| 11 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 12 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 13 | Y | N | N | N | N | N | Y | Y | Y | Y | Y |
| 14 | Y | N | N | N | N | N | Y | Y | Y | Y | Y |
| 15 | Y | N | N | N | N | N | N | Y | Y | Y | Y |
| 16 | Y | N | N | N | N | N | N | N | N | N | N |
| 17 | Y | N | N | **N** | N | N | N | N | N | N | N |
| 18 | Y | Y | Y | N | N | N | N | N | N | N | N |

Is sexual activity when both partners are 16 or older ever reportable?

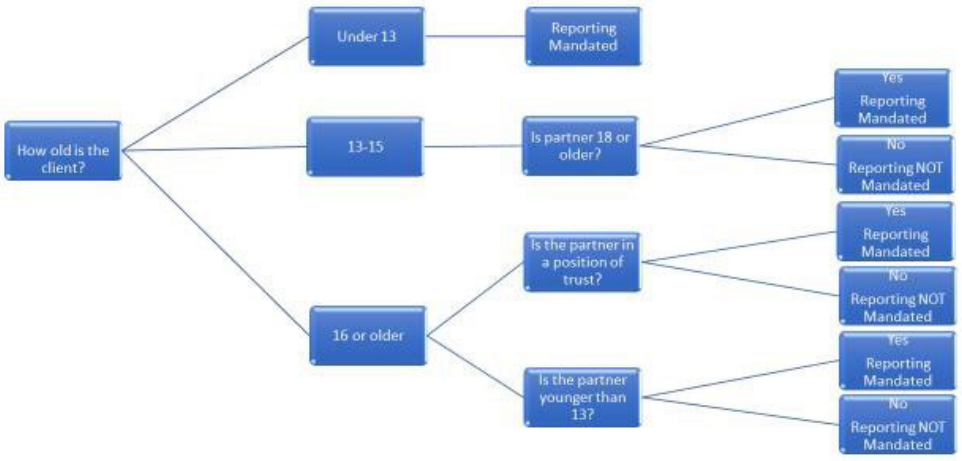
Mandated reporters must report sexual conduct with a minor under 18 years old who is a primary, secondary, or higher education school student if the partner is a teacher, administrator, coach, or other person in authority employed by the school. They also must report sexual conduct with a minor under 18 years old if the partner is a coach, instructor, leader of a scouting troop or a person with temporary or occasional disciplinary control over the minor.

*In addition, mandated reporters must report any sexual activity that appears coerced, exploitative, based on intimidation, or in any other way resembles abuse -- regardless of claimed consent by the minor and regardless of partner age.*

**References**

Gudeman, R. (2011). *Minor Consent, Confidentiality, and Child Abuse Reporting in Title X Funded Family Planning Settings in Ohio*. (3rd ed.). National Center for Youth Law. Oakland: CA.

# Mandated Reporting Algorithm




Source: http://codes.ohio.gov/orc/2907
ORC 2907.02, 2907.03, 2907.04

Ohio Department of Health, Reproductive Health and Wellness Program
July, 2017

## What is family and intimate partner violence?

Intimate partner violence (IPV) is a serious, preventable public health problem that affects millions of Americans. The term "intimate partner violence" describes physical violence, sexual violence, stalking, or psychological harm by a current or former partner or spouse. This type of violence can occur among heterosexual or same-sex couples and does not require sexual intimacy.

IPV is abuse or aggression that occurs in a close relationship. "Intimate partner" refers to both current and former spouses and dating partners. IPV can vary in how often it happens and how severe it is. It can range from one episode of violence that could have lasting impact to chronic and severe episodes over multiple years. IPV includes four types of behavior:

- **Physical violence** is when a person hurts or tries to hurt a partner by hitting, kicking, or using another type of physical force.
- **Sexual violence** is forcing or attempting to force a partner to take part in a sex act, sexual touching, or a non-physical sexual event (e.g., sexting) when the partner does not or cannot consent.
- **Stalking** is a pattern of repeated, unwanted attention and contact by a partner that causes fear or concern for one's own safety or the safety of someone close to the victim.
- **Psychological aggression** is the use of verbal and non-verbal communication with the intent to harm another person mentally or emotionally and/or to exert control over another person.

Several types of IPV behaviors can occur together. IPV is connected to other forms of violence and causes serious health issues and economic consequences. By using a public health approach that addresses risk and protective factors for multiple types of violence, IPV and other forms of violence can be prevented.

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| **Screening** | ACOG recommends that physicians screen ALL patients for intimate partner violence. Be sure to inform patients of any legal reporting requirements prior to screening. For women who are not pregnant, screening should occur:<br>• At routine OB-GYN visits<br>• At family planning visits<br>• At pre-pregnancy visits<br><br>Domestic violence screening can be conducted by making the following statement and asking these three simple questions:<br>• Within the past year — or since you have been pregnant — have you been hit, slapped, kicked or otherwise physically hurt by someone?<br>• Are you in a relationship with a person who threatens or physically hurts you?<br>• Has anyone forced you to have sexual activities that made you feel uncomfortable?" |
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| **If Abuse is Denied** | If abuse is denied and no indicators of abuse are present, document the findings in the medical record and offer referral information for future reference. |

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| | What to do if a patient says "no":<br>• Respect her/his response;<br>• Let the patient know that you are available should the situation ever change;<br>• Assess again at regular intervals as an indication that it is safe to disclose to you;<br>• Display information and resources in exam and waiting rooms, or bathrooms;<br>• If patient says "no" but you believe she/he may be at risk, discuss the specific risk factors and offer information and resources;<br>• Let patient know that experts and help are available. Offer a crisis card/safety card. Tell them that even if they don't need it that they can give it to a friend or family member who might use it. Discuss possible repercussions if their partner finds the card.<br>• Do not write any domestic violence referral on discharge papers that will be taken home with the patient.<br><br>If patient has obvious or suspected abuse but cannot communicate to acknowledge abuse (i.e. unconscious or impaired), schedule a follow-up appointment or initiate appropriate social work consult to ensure follow up. |
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| **If Abuse is Identified** | If a patient discloses that they are currently being abused, at a minimum their immediate safety should be assessed. This could include asking:<br><br>• Are you in immediate danger?<br>• Is your partner in the facility now?<br>• Has the violence escalated or gotten worse over the past year?<br>• Has your partner threatened to kill you or your children?<br>• Does your partner have access to guns or other deadly weapons?<br><br>If the patient answers yes to any of these, encourage her/him to speak with a domestic violence advocate to develop a safety plan even if the patient does not intend to leave her/his abuser.<br><br>Provide a phone and a safe place for her/him to contact an advocate. Offer to make the call for them if they would prefer that. Be mindful that your phone may be the only link a survivor has to a domestic violence advocate since cell phones and land lines are easily traceable. |
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| **Resources** | • National Domestic Violence Hotline<br>o Call 1-800-799-7233 and TTY 1-800-787-3224<br><br>• Love is Respect National Teen Dating Abuse Helpline<br>o Call 1-866-331-9474 or TTY 1-866-331-8453 |

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| | • Rape, Abuse & Incest National Network's (RAINN) National Sexual Assault Hotline<br>  ○ Call 800-656-HOPE (4673) to be connected with a trained staff member from a sexual assault service provider in your area.<br>• National Resource Center on Domestic Violence<br>• Mississippi Coaltition Against Domestic Violence<br>  ○ Has created a publication with protocols for healthcare providers |
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| **Indicators** | General signs and symptoms of family and intimate partner violence<br>• Conditions such as chronic fatigue or headaches, abdominal and/or pelvic pain, frequent use of pain medication, sexual dysfunction, frequent vague complaints of physical discomfort, or gastrointestinal problems<br>• Drug and alcohol abuse by the patient or her partner<br>• History or signs of depression or anxiety, or use of sedatives and/or tranquilizers<br>• Attempts or thoughts of suicide<br>• Self-injury<br>• Signs of post-traumatic stress disorder<br>• Suspicious injuries that are explained in ways that are inconsistent with the type or severity of the injury<br>• Multiple sites of injury and/or a pattern of repeated injury<br>• Delay in seeking medical care including delayed prenatal care<br>• Description of a partner as jealous, controlling or domineering, prone to anger, and/or frustrated with the patient and/or children |
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| **Sample Safety Planning Guide for a Patient** | We are concerned about your safety and strongly encourage you to talk to an advocate who can help you devise a safety plan. In the meantime, here are some steps you can take to prepare for emergencies and reduce your risk of injury.<br><br>2. Prepare an emergency kit containing items you will need if you must leave suddenly. You may wish to include:<br>• Identification for you and your children<br>• Money, credit cards, checkbook, and bankbook<br>• Green card, custody papers, restraining orders, car registration, health insurance card, and any other important papers<br>• Keys, medications, address book, and a change of clothes. It may be helpful to keep a packed bag at a friend's house |

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| | 8. Let neighbors know you want them to call 911 when they hear an argument. Set a code phrase you can use with a friend to signal that you are asking for help.<br><br>9. Teach your children what to do if you and your partner are fighting. You should tell your children to stay out of the argument and arrange for them to have a safe, nearby place where they can go in an emergency.<br><br>10.Plan for a place where you can stay if you must leave home.<br><br>11.Design and practice escape routes from the house with your children in case of an emergency.<br><br>12.Make sure weapons are not easily accessible. Knives should be removed from the kitchen counter and guns should be kept in a locked box separate from ammunition.<br><br>13.During an argument, you should stay in an area where you can quickly exit. Stay away from the kitchen (where there are knives) and the bathroom (where you can hit your head easily).<br><br>Additional steps if separating from a potentially violent partner:<br><br>6. Put a safety plan in place before discussing your desire to separate. Discuss your plan with your children.<br><br>7. Change the locks on your doors and install locks on windows.<br><br>8. Get the police and court system involved. If possible, obtain a protective order (e.g. restraining order). Always keep a copy with you and give a copy to someone that you trust. Call the police immediately if your partner violates the protective order.<br><br>9. Inform others—your neighbors, especially—that you have a restraining order in effect and encourage them to call the police for you if your partner violates it. Provide a picture of your partner if necessary.<br><br>10.Make sure that your children's caregivers know who has permission to pick them up. |
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## References

Centers for Disease Control and Prevention. (2018). *Intimate partner violence*. https://www.cdc.gov/violenceprevention/intimatepartnerviolence/index.html

## What is Substance Abuse?

The U.S. Department of Health & Human Services reports providing the tools necessary for the inclusion of substance abuse disorder screening into family planning services offered by Title X applicants as a key issue.

Substance use, including alcohol, tobacco, marijuana, illicit drugs, and misuse of prescription drugs, has significant negative health effects on women, especially during the reproductive years.

Screening, brief intervention, and referral to treatment (SBIRT) decreases substance use, health care services, and costs to society. Screening using a validated screening tool quickly gauges a patient's level of substance use risk.

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| **General Screening** | General Screening<br>• Clinic staff should utilize face to face time with proven screening instruments<br>• Agencies need to have policies and procedures in place to assist the client when further assessment is indicated<br>• Agencies should consult their legal counsel for processes when a minor warrants referral for a professional substance abuse assessment |
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| **Drug Abuse** | To screen patients, first use a statement like the following:<br><br>"Substance use is so common in our society that I now ask all my patients, what, if any substances they are using?"<br><br>Then, ask questions from a tool or provide them with a tool. |
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| **Assessment Tools examples** | • The Short Michigan Alcohol Screening Test (SMAST) may be administered in less than 5 Minutes<br><br>• CRAFFT Screening Instrument for Adolescents<br>  ○ Have you ever ridden in a car driven by someone (including yourself) who was high or had been using alcohol or drugs?<br>  ○ Do you ever use alcohol or drugs to relax, feel better about yourself, or fit in?<br>  ○ Do you ever use alcohol or drugs while you are by yourself or alone?<br>  ○ Do you ever forget things you did while using alcohol or drugs?<br>  ○ Do your family or friends ever tell you that you should cut down on your drinking or drug use?<br>  ○ Have you ever gotten into trouble while you were using drugs or alcohol?<br><br>• CAGE AID – 5-question tool to screen for drug and alcohol use |

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| | ○ Have you ever felt you ought to cut down on your drinking or drug use?<br>○ Have people annoyed you by criticizing your drinking or drug use?<br>○ Have you ever felt bad or guilty about your drinking or drug use?<br>○ Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover?<br><br>• AUDIT-C is a 3-question screen for harmful drinking.<br>○ How often do you have a drink containing alcohol?<br>○ How many standard drinks containing alcohol do you have on a typical day?<br>○ How often do you have six or more drinks on one occasion? |
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| **SBIRT** | Screening, **brief intervention**, and referral to treatment<br><br>• With a positive screening, the provider should provide a brief intervention and be prepaid to make a referral<br>• Brief interventions are evidence-based practices design to motivate individuals at risk of substance abuse and related health problems to change their behavior by helping them understand how their substance use puts them at risk and to reduce or give up their substance use.<br>• Healthcare providers can also use brief interventions to encourage those with more serious dependence to accept more intensive treatment within the primary care setting or a referral to a specialized alcohol and drug treatment agency.<br>• Brief interventions last from 5 minutes of brief advice to 15-30 minutes of brief counseling.<br>• The two most common behavioral therapies used in SBIRT programs are brief versions of cognitive behavioral therapy and motivational interviewing, or some combination of the two. |
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| **Create Resource Area** | • Ideal location in each program's waiting room and screening room<br>• Feature publications on substance abuse and family violence<br>• Post names of local counseling centers: mental health, drug-specific, alcohol-specific. Include pamphlets/magnets for the general public from these agencies<br>• Post meeting schedules from Alcoholics Anonymous and Narcotics Anonymous<br>• Post directory of domestic violence shelters and related local resources |
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| **Tobacco Use** | The Five A's for Brief Tobacco Intervention |

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| | Successful intervention begins with identifying users and is based on the patient's willingness to quit. A brief cessation message of 5-15 minutes should be delivered by a trained provider.<br><br>The five major steps to intervention are the "5 A's": Ask, Advise, Assess, Assist, and Arrange.<br><br>6. Ask all patients about their smoking status at every visit; place a sticker on the patient chart indicating tobacco use (current, former, or never)<br>7. Advise to quit in a clear, strong, personalized manner<br>8. Assess willingness to make a quit attempt<br>9. Assist in quit attempt (counseling and pharmacotherapy as appropriate)<br>10. Arrange follow-up (preferably within the first week after the quit date)<br><br>The same treatments benefit both men and women, but some are less efficacious in women, such as nicotine replacement therapies. Women may face different stresses and barriers to quitting such as depression, weight control concerns, and hormonal cycles.<br><br>Reference:<br><br>U.S. Department of Health & Human Services, Office of the Surgeon General (www.surgeongeneral.gov/tobacco/default.htm) |
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| **National Resource** | Substance Abuse and Mental Health Services Administration<br><br>• SAMHSA's National Helpline, 1-800-662-HELP (4357), (also known as the Treatment Referral Routing Service) or TTY: 1-800-487-4889 is a confidential, free, 24-hour-a-day, 365-day-a-year, information service, in English and Spanish, for individuals and family members facing mental and/or substance use disorders.<br>• This service provides referrals to local treatment facilities, support groups, and community-based organizations. Callers can also order free publications and other information. |
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## References

Gotham. H., Wilson, K., Carlson, K., Rodriguez, G., Kuofie, A., & Witt, J. (2019). Implementing substance abuse screening in family planning. *The Journal for Nurse Practitioners, 15.* Retrieved from https://www.npjournal.org/article/S1555-4155(18)31140-1/pdf

SAMHSA-HRSA Center for Integrated Health Solutions. (2020). *Screening tools*. https://www.integration.samhsa.gov/

## SECTION 7
## Contraception

### What is abstinence or sexual risk avoidance?

This policy provides direction for reproductive health clinics to assist clients in the use of abstinence or sexual risk avoidance as a method of birth control.

Abstinence is defined as refraining or not participating in all forms of sexual activity, including vaginal, oral, or anal intercourse. It is recommendation that adolescents postpone consensual sexual activity until they are fully ready for the emotional, physical, and financial consequences of sex. The promotion of healthy and responsible sexual decision-making is one of the goals of counseling adolescents about contraception.

If abstinence is the method chosen, the client must be advised regarding the risks and benefits of the method and instructed on effectiveness. It is the only 100% effective way to prevent pregnancy and reduce risk of STIs, including HIV. Adolescents who choose to abstain from sexual intercourse should be encouraged and supported to do so. Adolescents may also need information about other contraceptive methods before (or if) they decide to have intercourse.

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| **Protocol** | (MDs, NPs, PAs, DOs, and RNs may provide abstinence counseling and education for adolescents (18 and younger) who request birth control at their first visit. Education and information on abstinence may also be provided to any client who requests this method. There are no U.S. Medical Eligibility Criteria (MEC) risk conditions for using abstinence as a birth control method. |
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| **Procedure** | Provide client-centered care through quality counseling and education using the 5 key principles:<br>• Establish and maintain rapport with the client;<br>• Assess the client's needs and personalize discussions accordingly;<br>• Work with the client interactively to establish a plan;<br>• Provide information that can be understood and retained by the client; and<br>• Confirm the client's understanding using a technique such as the teach- back method.<br><br>Review medical history:<br>• Significant illness;<br>• Allergies;<br>• Current medications - prescriptive and over-the-counter (OTC);<br>• Use of tobacco, alcohol, and other drugs;<br>• Immunization and Rubella status; |

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| | • Contraceptive use;<br>• Menstrual history;<br>• Sexual history including risk for STIs;<br>• Obstetrical history;<br>• Gynecological and Pap test history;<br>• Surgical history;<br>• Hospitalizations;<br>• Family History;<br>• In utero exposure to diethylstilbestrol (DES); and<br>• Reproductive life plan.<br><br>Review last menstrual period (LMP) and compliance with contraceptive method (if applicable). Assess for risk of current pregnancy. Offer pregnancy test if indicated.<br><br>• A health care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets the following:<br>o Is ≤7 days after the start of normal menses;<br>o Has not had sexual intercourse since the start of last normal menses;<br>o Has been correctly and consistently using a reliable method of contraception;<br>o Is ≤7 days after spontaneous or induced abortion;<br>o Is within 4 weeks postpartum;<br>o Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrhoeic, and < 6 months postpartum.<br><br>Assess for recent sexual activity where intercourse was unprotected and offer emergency contraception (EC) for immediate use if indicated.<br><br>• Note that if Ella® is the EC formulation administered, a reliable barrier method of contraception should be used with subsequent acts of intercourse that occur within the next 14 days. Because Ella® and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effect. After using Ella® if a woman wishes to use hormonal contraception, she should do so no sooner than 5 days after the intake of Ella®.<br><br>Blood Pressure: normal <140/90; refer clients with blood pressure reading ≥ 140 systolic or ≥ 90 diastolic to a primary care provider for further evaluation<br><br>Weight/Height: obtain body mass index (BMI) |

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| | Screen for STIs (if the client has not been screened) according to STI screening guidelines (see *STI Screening Policies and Procedures*).<br><br>Discuss client's reproductive life plan about becoming pregnant by asking:<br>• Do you have children now?<br>• Do you want to have (more) children?<br>• How many (more) children would you like to have and when?<br>  o If the client does not want a child now and is sexually active, then offer contraceptive services.<br>  o If the client desires pregnancy testing, the provide pregnancy testing and preconception counseling.<br>  o If the client wants to have a child now, then provide services to help the client achieve pregnancy and provide preconception counseling.<br>  o If the client wants to have a child and is having trouble conceiving, then provide basic infertility services.<br><br>Present all birth control method options for which the client has no U.S. MEC category 4 risk conditions.<br><br>Each client will receive client instructions regarding warning signs, common side effects, risks, use of method, alternative methods, use of secondary method and clinic follow-up schedule. Document the client's education and understanding of the method of choice. |
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| **Plan** | • Abstinence can be initiated at any time in the menstrual cycle and at any time in the client's life.<br>• Abstinence requires the cooperation of both partners and staff will encourage partner involvement if indicated.<br>• Have a backup plan and supplies in case the method fails (e.g., condoms, EC).<br>• Review the client's history and access of recommended health screenings.<br>• Offer and schedule a Reproductive Health Well Visit if the client has not been screened appropriately within the past 12 months or if an earlier assessment is clinically indicated.<br>• Offer and provide condoms for use as a back-up method and for STI protection.<br>• The decision to offer and dispense future-use EC should be made on an individualized basis and should include shared decision making between the provider and the client. Clients *requesting* (those that self-identify that they need or want) EC for future use and those using less reliable |

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| | methods of birth control (tier 3 methods) might benefit most from having future-use EC made available.<br>o Instruct client to wait 5 days after the administration of Ella® before initiating hormonal contraceptives. Recommend the use of a barrier method of contraception with all subsequent acts of intercourse that occur within the next 14 days. |
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| **Routine Follow-up** | The recommendations listed below address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women and men. Although routine follow-up is not necessary for the use of abstinence as a birth control method, recommendations for follow-up might vary for different users and different situations.<br>Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple conditions may benefit from more frequent follow-up visits.<br>• Advise the client to return at any time to discuss their birth control method, or if the client wants to change the method being used.<br>• At other routine visits, healthcare providers should do the following:<br>o Assess the client's satisfaction with the contraceptive method and whether the client has any concerns about method use; and<br>o Assess any changes in health status that would change the appropriateness of the birth control method. |
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| **Client Education** | • All women who are planning or capable of pregnancy should be counseled to take a daily supplement containing 0.4 to 0.8 milligrams (400 to 800 µg) of folic acid.<br>• Advise the client that abstinence is always an option and can be initiated at any time even if she/he has already had sex.<br>• Provide information to the client on all birth control methods; it is important that the client understands all options available if/when they decide to have sexual intercourse.<br>• Advise the client that abstinence does not prevent HIV/AIDS, hepatitis B and hepatitis C, provide risk reduction counseling.<br>• Encourage the client to determine in advance what sexual activities are okay and discuss these with their partner.<br>• Provide the client with information on how to resist sexual coercion.<br>• Encourage family involvement for clients 17 and younger. |

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## What are combined oral contraceptives?

Combined oral contraceptives (COCs) contain both estrogen and a form of progestin. Approximately 9 out of 100 women become pregnant in the first year of use with typical use. COCs are generally used for 21-24 consecutive days, followed by 4-7 hormone-free days. These methods are sometimes used for an extended period with infrequent or no hormone-free days. COCs do not protect against sexually transmitted infections (STIs).

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| **Protocol** | MDs, NPs, PAs, and DOs, may provide COCs to any client who requests this method and has no U.S. MEC category 4 risk conditions.<br>• Category 4 risk conditions (risk of use outweighs the benefits of pregnancy prevention):<br>o Current breast cancer;<br>o Severe cirrhosis: (decompensated);<br>o Deep venous thrombosis/pulmonary embolism (DVT/PE): History of DVT/PE, not on anticoagulant therapy: higher risk for recurrent DVT/PE;<br>o Acute DVT/PE;<br>o DVT/PE and established on anticoagulant therapy for at least 3 months with higher risk for recurrent DVT/PE;<br>o Major surgery with prolonged immobilization;<br>o Diabetes mellitus with nephropathy/retinopathy/neuropathy;<br>o Diabetes mellitus: other vascular disease or diabetes of >20 years' duration;<br>o Migraines with aura, any age;<br>o Hypertension: systolic ≥160 or diastolic ≥100;<br>o Hypertension with vascular disease;<br>o Ischemic heart disease: current and history;<br>o Benign liver tumors: hepatocellular adenoma;<br>o Malignant liver tumors;<br>o Multiple risk factors for arterial cardiovascular disease (such as older age [> 35 years of age], smoking, diabetes, and hypertension);<br>o Peripartum cardiomyopathy: normal or mildly impaired cardiac function < 6 months;<br>o Peripartum cardiomyopathy: moderately or severely impaired cardiac function;<br>o Postpartum < 21 days;<br>o Smoking: age ≥35, ≥15 cigarettes/day;<br>o Solid organ transplantation: complicated;<br>o Stroke: history of cerebrovascular accident;<br>o Systemic lupus erythematosus: positive (or unknown) antiphospholipid antibodies; |

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| | ○ Thrombogenic mutations;<br>○ Valvular heart disease: complicated;<br>○ Viral hepatitis: acute or flare *for initiation of method*.<br>• (MDs, NPs, PAs, and DOs, may consider providing COCs to any client who requests this method and with U.S. MEC Category 3 risk conditions but other methods should be strongly considered because the theoretical or proven risk may outweigh the advantages of using the method):<br><br>○ Breast cancer: past and no evidence of current disease for 5 years;<br>○ Breastfeeding 21 to <30 days postpartum with and without other factors for VTE;<br>○ Breastfeeding 30-42 days postpartum with other risk factors for VTE<br>○ Non-breastfeeding 21-42 days postpartum with other risk factors for VTE<br>○ Deep venous thrombosis/pulmonary embolism: History of DVT/PE, not on anticoagulant therapy with lower risk for recurrent DVT/PE;<br>○ DVT/PE and established on anticoagulant therapy for at least 3 months with lower risk for recurrent DVT/PE;<br>○ Superficial venous thrombosis (acute or history)<br>○ Diabetes mellitus: nephropathy/retinopathy/neuropathy;<br>○ Diabetes mellitus: other vascular disease or diabetes of >20 years duration;<br>○ Gallbladder disease: medically treated;<br>○ Gallbladder disease: current;<br>○ History of cholestasis with past combined oral contraceptives related;<br>○ Hypertension: adequately controlled;<br>○ Hypertension: elevated blood pressure levels with systolic 140-159 or diastolic 90-99;<br>○ Inflammatory bowel disease: ulcerative colitis, Crohn's disease;<br>○ Multiple risk factors for arterial cardiovascular disease *for initiation of method*;<br>○ Multiple Sclerosis with prolonged immobility<br>○ Peripartum cardiomyopathy ≥ 6 months;<br>○ Smoking: age ≥ 35, < 15 cigarettes/day;<br>○ Viral hepatitis: acute or flare *for initiation of method*;<br>○ Antiretroviral therapy protease inhibitors without ritonavir - Fosamprenavir<br>○ Anticonvulsant medications – phenytoin, carbamazepine, barbiturates, primidone, topiramate, and oxcarbazepine<br>○ Lamotrigine;<br>○ Antimicrobial therapy -Rifampicin or rifabutin therapy.<br>• Clients with a category 1 & 2 risk condition are candidates for using this method. |
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| **Procedure** | Provide client-centered care through quality counseling and education using the 5 key principles:<br>• Establish and maintain rapport with the client;<br>• Assess the client's needs and personalize discussions accordingly;<br>• Work with the client interactively to establish a plan;<br>• Provide information that can be understood and retained by the client; and<br>• Confirm the client's understanding using a technique such as the teach-back method.<br><br>Review medical history:<br><br>• Significant illness;<br>• Allergies;<br>• Current medications - prescriptive and over-the-counter (OTC);<br>• Use of tobacco, alcohol, and other drugs;<br>• Immunization and Rubella status;<br>• Contraceptive use;<br>• Menstrual history;<br>• Sexual history including risk for STIs;<br>• Obstetrical history;<br>• Gynecological and Pap test history;<br>• Surgical history;<br>• Hospitalizations;<br>• Family History;<br>• In utero exposure to diethylstilbestrol (DES); and<br>• Reproductive life plan.<br><br>Review last menstrual period (LMP) and compliance with contraceptive method (if applicable). Assess for risk of current pregnancy. Offer pregnancy test if indicated.<br><br>• A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets the following:<br>o Is ≤7 days after the start of normal menses;<br>o Has not had sexual intercourse since the start of last normal menses;<br>o Has been correctly and consistently using a reliable method of contraception;<br>o Is ≤7 days after spontaneous or induced abortion;<br>o Is within 4 weeks postpartum;<br>o Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrhoeic, and < 6 months postpartum.<br><br>• Assess for recent sexual activity where intercourse was unprotected and offer emergency contraception (EC) for immediate use if indicated. |

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| | o Note that if Ella® is the EC formulation administered, a reliable barrier method of contraception should be used with subsequent acts of intercourse that occur within the next 14 days. Because Ella® and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effect. After using Ella® if a woman wishes to use hormonal contraception, she should do so no sooner than 5 days after the intake of Ella®.<br><br>• Blood Pressure: normal <140/90; refer clients with blood pressure reading ≥ 140 systolic or ≥ 90 diastolic to a primary care provider for further evaluation.<br><br>• Weight/Height: obtain body mass index (BMI)<br><br>• Screen for STIs (if the client has not been screened) according to STI screening guidelines (see *STI Screening Policies and Procedures*).<br><br>• Discuss the client's reproductive life plan about becoming pregnant by asking:<br><br>o Do you have children now?<br>o Do you want to have (more) children?<br>o How many (more) children would you like to have and when?<br><br>▪ If the client does not want a child at this time and is sexually active, then offer contraceptive services.<br>▪ If the client desires pregnancy testing, then provide pregnancy testing and preconception counseling.<br>▪ If the client wants to have a child now, then provide services to help the client achieve pregnancy and provide preconception counseling.<br>▪ If the client wants to have a child and is experiencing difficulty conceiving, then provide basic infertility services.<br><br>• Present all birth control method options for which the client has no U.S. MEC category 3 or 4 risk conditions.<br><br>• Selection of contraceptive type based on U.S. MEC:<br><br>o Prescribing providers, after having a discussion with the client regarding risk versus benefit of a method, may initiate a method for which the client has a category 3 risk condition only if the benefit of pregnancy prevention outweighs the risks and the client finds other lower risk methods unacceptable. |

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| | o Clients requesting a method for which they have a category 4 risk condition will be offered lower risk methods and referred to an OB/GYN or specialist provider.<br><br>• Each client will receive client instructions regarding warning signs, common side effects, risks, method of use, alternative methods, use of secondary method, and clinic follow-up schedule. Document client education and understanding of the method of choice. |
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| **Plan** | Initiating combined oral contraceptives:<br>• COCs can be initiated at any time if it is reasonably certain that the client is not pregnant.<br>o If started within the first 5 days since menstrual bleeding started, no additional contraceptive protection is needed.<br>o If COCs are started > 5 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br>When the initial start of the method occurs within a visit with NP, PA, or MD the provider will write a prescription for up to 1-year supply and may dispense this amount depending on the client's preference and anticipated use.<br>• If the initial start of the method occurred within a visit with the RN, the RN **must** obtain an order from the provider for the COCs.<br>• A Method Revisit appointment may be scheduled with the prescribing provider in 3 months. The purpose of this visit is for the prescribing provider to review the client's health history, discuss the method, and address any concerns or issues.<br>o Pill pick-ups do not count as client visits.<br>o Schedule the client for a Reproductive Health Well Visit if the client has not been screened appropriately within the past 12 months or if an earlier assessment is clinically indicated. |
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| **Special Considerations** | **Amenorrhea (not postpartum):**<br>• COCs can be started at any time if it is reasonably certain the client is not pregnant.<br>• The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br>**Postpartum (breastfeeding):**<br>• COCs can be started when the client is medically eligible to use the method and if it is reasonably certain that she is not pregnant. |

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| | ○ Postpartum clients who are breastfeeding should not use COCs during the first 3 weeks after delivery (category 4) because of concerns of increased risk for venous thromboembolism and generally should not use COCs during the fourth week postpartum (category 3) because of concerns about potential effects on breastfeeding.<br>• If the client is < 6 months postpartum, amenorrhoeic, and fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥ 85 %] of feeds are breastfeeds), no additional contraceptive protection is needed.<br>• A client who is < 21 days postpartum, no additional contraceptive protection is needed.<br>• A client who is ≥ 21 days postpartum and has not experienced a return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br>• If a client's menstrual cycle has returned and it has been > 5 days since menstrual bleeding started, the client will need to abstain from intercourse or use additional contraceptive protection for the next 7 days.<br>**Postpartum (not breastfeeding):**<br>• COCs can be started when the client is medically eligible and if it is reasonably certain that the client is not pregnant.<br>○ Postpartum clients should not use COCs during the first 3 weeks after delivery (Category 4) because of concerns of increased risk for venous thromboembolism.<br>○ Postpartum clients with other risk factors for venous thromboembolism generally should not use COCs 3-6 weeks after delivery (category 3).<br>• A client who is ≥ 21 days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br>• If a client's menstrual cycle has returned, and it has been > 5 days since the menstrual bleeding began, the client will need to abstain from sexual intercourse or use additional contraceptive protection for next 7 days.<br>**Post abortion (spontaneous or induced):**<br>• COCs can be started within the first 7 days after first or second trimester abortion, including immediately post-abortion (category 1).<br>• The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days unless COCs are started at the time of the surgical abortion. |
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| **Switching from Another Contraceptive Method** | COCs can be started immediately if it is reasonably certain that the client is not pregnant. Waiting for the next menstrual period is not necessary.<br>• If it has been > 5 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. |

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| | **Switching from an IUD/IUS:**<br>• If the client has had sexual intercourse since the start of her current menstrual cycle and it has been > 5 days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract. A healthcare provider may consider any of the following options:<br>o Advise the client to retain the IUD/IUS for at least 7 days after combined hormonal contraceptives are initiated and return for IUD/IUS removal;<br>o Advise the client to abstain from sexual intercourse or use barrier contraceptive for 7 days before removing the IUD/IUS and switching to the new method; advise the client to use ECPs at the time of IUD removal.<br>o Combined hormonal contraceptive can be started immediately after use of ECPs (with the exception of Ella®)<br>o Combined hormonal contraceptives can be started no sooner than 5 days after use of Ella®)<br>• If uncertain whether the client might be pregnant, the benefits of starting COCs likely exceed any risk; therefore, starting COCs should be considered at any time, with a follow-up pregnancy test in 2-4 weeks.<br>• Offer and provide condoms for use as a back-up method and for STI protection.<br>• The decision to offer and dispense future-use EC should be made on an individualized basis and should include shared decision making between the provider and the client.<br>o Clients requesting (those that self-identify that they need or want) EC for future use and those using less reliable methods of birth control (tier 3 methods) might benefit most from having future-use EC made available.<br>o Instruct the client to wait 5 days after the administration of Ella® before initiating combined oral contraceptives. Recommend the use of a barrier method of contraception with all subsequent acts of intercourse that occur within the next 14 days. |
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| **Routine Follow-up** | The recommendations listed below address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women and men.<br>Although routine follow-up is not necessary for the use of COCs, recommendations might vary for different users and different situations. Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple conditions may benefit from more frequent follow-up visits.<br>• Advise the client to return at any time to discuss side effects or other problems or if the client wants to change the method being used. |

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| | • At other routine visits, healthcare providers should do the following:<br>o Assess the client's satisfaction with the contraceptive method and whether the client has any concerns about method use;<br>o Assess any changes in health status, including medications that would change the appropriateness of combined hormonal methods' safe and effective use based on U.S. MEC;<br>o Assess blood pressure;<br>o Consider assessing weight changes and counsel clients who are concerned with any weight changes perceived to be due to contraceptive method; and<br>o Provide up to the maximum number of refills of the birth control method under a current prescription from prescribing provider. |
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| **Patient Education** | • All women who are planning or capable of pregnancy should be counseled to take a daily supplement containing 0.4 to 0.8 milligrams (400 to 800 µg) of folic acid.<br>• Advise the client that combined hormonal contraceptive may change their periods; the client may have spotting or irregular bleeding for the first few months.<br>• Advise the client of common side effects. If the client has nausea from the COCs, suggest taking the pill with the evening meal or with food at bedtime. May consider if lower dose estrogen pill, progestin only pill, or nonoral method.<br>• Advise the client to call the clinic if she has any questions or concerns regarding the birth control method.<br>• Advise the client to use condoms for protection against STIs.<br>• Inform the client that any signs or symptoms of complications should be reported to the clinic; if the clinic is not open, clients should call 911 or go to the emergency room.<br>• Advise the client the warning signs of **ACHES** (client should be informed to seek immediate care if any warning signs are noted):<br>o Abdominal pain;<br>o Chest pain;<br>o Headaches;<br>o Eye problems; and/or<br>o Severe leg pain. |
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| **Late or Missed Dose** | Recommendations for late or missed Combined Oral Contraceptives: |

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| | • If one hormonal pill is late (<24 hours since a pill should have been taken), or if one hormonal pill has been missed (24 to <48 hours since a pill should have been taken):<br>o Take the late or missed pill as soon as possible;<br>o Continue taking the remaining pills at the usual time (even if it means taking 2 pills on the same day);<br>o No additional contraceptive protection is needed; and<br>o EC is not usually needed but can be considered (with the exception of Ella®) if hormonal pills were missed earlier in the cycle or in the last week of the previous cycle.<br>• If two or more consecutive hormonal pills have been missed (>48 hours since a pill should have been taken):<br>o Take the most recent missed pill as soon as possible (any other missed pills should be discarded);<br>o Continue taking the remaining pills at the usual time (even if it means taking 2 pills on the same day; and<br>o Use back-up contraception or avoid sexual intercourse until hormonal pills have been taken for 7 consecutive days.<br>o If pills were missed in the last week of hormonal pills (days 15-21 for 28-day pill pack):<br>▪ Omit the hormone-free interval by finishing the hormonal pills in the current pack and starting a new pack the next day.<br>▪ If unable to start a new pack immediately, use back-up contraception or avoid sexual intercourse until hormonal pills from a new pack have taken for 7 consecutive days.<br>o EC should be considered (except for Ella®) if hormonal pills were missed during the first week and unprotected sexual intercourse occurred in the previous 5 days.<br>o EC may also be considered (except for Ella®) at other times as appropriate. |
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| **Vomiting or Severe Diarrhea** | Recommendations for vomiting or diarrhea (for any reason, for any duration) that occurs within 24 hours after taking a hormonal pill, or vomiting or diarrhea, for any reason, continuing for 24 to < 48 hours after taking any hormonal pill:<br>• Taking another hormonal pill (re-dose) is unnecessary.<br>• Continue taking pills daily at the usual time (if possible, despite discomfort).<br>• No additional contraceptive protection is needed.<br>• EC is not usually needed but can be considered (except for Ella®) as appropriate.<br><br>Recommendations for vomiting or diarrhea, for any reason, continuing for ≥ 48 hours after taking any hormonal pill: |

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| | • Continue taking pills daily at the usual time (if possible, despite discomfort).<br>• Use back-up contraception or avoid sexual intercourse until hormonal pills have been taken for 7 consecutive days after vomiting or diarrhea has resolved.<br>• If vomiting or diarrhea occurred in the last week of hormonal pills (days 15-21 for 28-day pill packs):<br>  o Omit the hormone-free interval by finishing the hormonal pills in the current pack and starting a new pack the next day.<br>  o If unable to start a new pack immediately, use back-up contraception or avoid sexual intercourse until hormonal pills from a new pack have been taken for 7 consecutive days.<br>• EC should be considered (except for Ella®) if vomiting or diarrhea occurred within the first week of a new pill pack and unprotected sexual intercourse occurred in the previous 5 days.<br>• EC may also be considered (except for Ella®) at other times as appropriate. |
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| **Extended / Continuous Use of COCs** | Unscheduled Bleeding<br><br>• Extended contraceptive use is defined as a planned hormone-free interval after at least two contiguous cycles.<br>• Continuous contraceptive use is defined as uninterrupted use of hormonal contraception without a hormone-free interval.<br>• Before initiation of combined oral contraceptives, provide counseling about potential changes in bleeding patterns during extended or continuous use.<br>  o Unscheduled spotting or bleeding is common during the first 3-6 months of extended or continuous combined hormonal use. It is not harmful and typically decreases with continued use.<br>  o If clinically indicated, consider an underlying gynecological problem (e.g., STI, pregnancy or new pathologic uterine conditions). Refer to the prescribing provider/primary care provider for evaluation.<br>  o If an underlying gynecological problem is not found and the client wants treatment, the following treatment option can be considered:<br>  ▪ Advise the client to discontinue combined hormonal contraceptive use for 3-4 consecutive days. A hormone-free interval is not recommended during the first 21 days of using the continuous or extended combined hormonal contraceptive method. A hormone-free interval also is not recommended more than once per month because contraceptive effectiveness might be reduced.<br>  ▪ If unscheduled spotting or bleeding persists and the client finds it unacceptable, counsel client on alternative contraceptive methods, and offer another method if it is desired. |
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| **Discontinuing the COCs** | • Combined hormonal contraceptives may be stopped at any time.<br>• Fertility will return rapidly.<br>• If client does not want to be pregnant, advise the client to begin a new contraceptive method immediately.<br>• If client desires to be pregnant:<br>  ○ Provide the client with preconception counseling; and<br>  ○ Advise client to begin taking a daily prenatal vitamin with 0.4 to 0.8 milligrams of folic acid at least 30 days before trying to become pregnant. |
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## What is emergency contraception?

This policy provides direction for reproductive health clinics to assist clients in the use of emergency contraception.

Emergency contraception (EC**)** consists of several different formulations which can be used by women to prevent pregnancy after unprotected sexual intercourse, or a known or suspected contraceptive failure. Emergency contraceptive pills (ECPs) prevents pregnancy primarily by delaying or inhibiting ovulation and inhibiting fertilization. Best available evidence indicates that the ability of Levonorgestrel and Ulipristal acetate ECPs to prevent pregnancy can be fully accounted for by mechanisms that do not involve interference with post-fertilization events.

The copper intrauterine device (Cu-IUD) may be used as an emergency method of contraception and acts primarily to prevent fertilization. The release of copper causes an inflammatory reaction within the intrauterine environment that is toxic to sperm and ova. This impairs sperm function and prevents fertilization.

EC does not cause abortion or harm an established pregnancy. ECPs should be used as soon as possible and within 120 hours of unprotected sexual intercourse. Cu-IUD may be inserted up to 5 days after unprotected sexual intercourse. EC may be provided for immediate use or provided in advance for future use. Additional guidance is provided in the "Plan" section for the pill formulations of EC.

Formulations: There are four options of EC available in the United States, including:

- Cu-IUD for immediate use.
- Levonorgestrel formulations for immediate and future use–is available in a 1.5 mg single dose tablet.
- Ulipristal acetate (Ella®) for both immediate and future use–is available in a 30-mg single dose tablet.
- Combined estrogen and progestin or the Yuzpe formulation (for immediate use) is available in a two- dose regimen. (Yuzpe regimen includes one dose of 100 µg of ethinyl estradiol plus 0.5 mg of levonorgestrel followed by a second dose of 100 µg of ethinyl estradiol plus 0.5 mg of levonorgestrel 12 hours later.)

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| **Protocol** | MDs, NPs, PAs, and DOs may write a prescription or provide EC to any client who requests this method and has no U.S. MEC category 4 risk conditions. RNs may provide the EC if there is a prescription. Only prescribing providers trained in the insertion of the Cu-IUD may perform the insertion of this method of EC.<br><br>**Cu-IUD**: Intrauterine contraceptives are among the safest and most effective methods of contraception available today. The Cu-IUD can be inserted for use as EC within 5 days of unprotected sexual intercourse; if the day of ovulation can be estimated, the Cu-IUD can be inserted beyond 5 days after sexual intercourse if insertion does not occur > 5 days after ovulation.<br>• Effectiveness of the Cu-IUD is not affected by weight or body mass index (BMI). |

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| | • Category 4 risk conditions (risk of use outweighs the benefits of pregnancy prevention):<br>  o Anatomic abnormalities: distorted uterine cavity;<br>  o Cervical cancer: awaiting treatment *for initiation of method*;<br>  o Endometrial cancer *for initiation of method*;<br>  o Gestational trophoblastic disease: persistently elevated ß-hCG levels;<br>  o Current pelvic inflammatory disease *for initiation of method*;<br>  o Post abortion: immediately post-septic abortion;<br>  o Postpartum: puerperal sepsis;<br>  o Current pregnancy;<br>  o STIs: current purulent cervicitis or CT/GC infection *for initiation of method*;<br>  o Pelvic Tuberculosis *for initiation of method*; or<br>  o Unexplained vaginal bleeding with suspicion for serious condition (before evaluation) *for initiation of method.*<br>• Category 3 risk conditions (must consult with prescribing provider prior to initiation as the theoretical or proven risk may outweigh the advantages of using the method:<br>  o Solid organ transplantation: complicated *for initiation of method*;<br>  o Systemic lupus erythematosus: severe thrombocytopenia *for initiation of method*;<br>  o Pelvic Tuberculosis *for continuation of method*.<br><br>**Levonorgestrel EC**: Progestin-only ECPs (Plan B one step and its generic forms Take Action, Next Choice one dose and My Way) are available OTC for males and females of any age. It is recommended that women take levonorgestrel EC as soon as possible but within 72 hours of unprotected intercourse (UPS).<br>Levonorgestrel may be taken up to 120 hours after UPI, however, recent evidence suggests that it is ineffective if taken more than 96 hours after UPI. Women weighing more than 154 pounds should be informed that the effectiveness of levonorgestrel may be decreased.<br>• According to the U.S. MEC, there are no category 3 or 4 risk conditions for the use of progestin-only EC given that the duration of use is less than that of regular use and would be expected to have less clinical impact. Recurrent EC use is an indication that the woman requires further counseling about other contraceptive options. Recurrent use may be harmful for women with U.S. MEC conditions classified as 2, 3, or 4 for progestin-only pills.<br>• Contraindications (There are no U.S. MEC category 3 or 4 risks conditions): |

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| | o Pregnancy: Use of levonorgestrel EC once a pregnancy has been established is not harmful to the pregnancy but simply provides no benefit.<br><br>**Ulipristal acetate (Ella®)**: Ulipristal acetate (Ella®), a selective progesterone receptor modulator, is a more recently approved option for EC. Ella® should not be taken if pregnancy is suspected or known. A pregnancy test should be performed to rule out pregnancy. Ella® does not interrupt an existing pregnancy. It is not recommended to use Ella® for breastfeeding women as it is not known if any active metabolites are excrete3d into the breast milk. Breastfeeding women should be informed not to breastfeed for one week, rather they should express and discard the breast milk to maintain lactation. Ella® is available by prescription only. Ella® should be administered as soon as possible and within 120 hours of UPI. Studies have shown no significant reduction in effectiveness with increasing time between UPI and taking Ella® (up to 120 hours). Some limited data suggest Ella® could be less effective for women with a BMI over 35.<br>Recent studies looking at repeated use of Ella® within the same menstrual cycle showed no safety concerns, indicating Ella® can safely be used more than once per cycle.<br>Ella® is an anti-progestin, With the progestin component of hormonal contraceptives and Ella® both binding to the progesterone receptor, using them together may decrease the ability of Ella® to delay ovulation. After using Ella® a woman should use a reliable barrier of contraception for the next 14 days. If a woman wishes to start using a hormonal contraception after using Ella®, she should delay starting for at least 5 days and use a reliable barrier method for the next 14 days.<br><br>• Contraindications (There are no U.S. MEC category 3 or 4 conditions):<br>o Pregnancy;<br>o Ella® is not recommended for use by breastfeeding women.<br><br>• Warnings and Precautions<br>o After use of Ella®, a reliable barrier method of contraception should be used with subsequent acts of intercourse that occur within the next 14 days.<br>o Because Ella® and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effect. After using Ella®, if a woman wishes to use hormonal contraception, she should do so no sooner than 5 days after the intake of Ella®.<br><br>**Yuzpe – ECP containing ethinyl estradiol and levonorgestrel**: The Yuzpe method for EC has been in place since the mid 1970's but has been rarely used since the advent of levonorgestrel and ulipristal formulations. The standard dosage consists of ethinyl estradiol, 100 mg, and levonorgestrel, 0.5 mg, to be taken within 72 hours of UPI and repeated 12 hours later. The Yuzpe method of<br>EC has been shown to be about 75% effective and requires a prescription. At this |

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| | point, there are no documented studies that evaluate the impact of weight or BMI on the effectiveness of this method.<br>• According to the U.S. MEC, there are no category 3 or 4 risk conditions for the use of combined oral contraceptives as EC given that the duration of use is less than that of regular use and would be expected to have less clinical impact. Recurrent EC use is an indication that the woman requires further counseling about other contraceptive options. Recurrent use may be harmful for women with U.S. MEC conditions classified as 2, 3, or 4 for COCP.<br>o Contraindications:<br>▪ Pregnancy: Use of COCP once a pregnancy has been established is not harmful to the pregnancy but simply provides no benefit.<br>o No one should be denied or discouraged from using ECPs based on weight. Clients with higher body weights should be provided with information on the most effective form of EC for them. |
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| **Procedure** | Provide client-centered care through quality counseling and education using the 5 key principles:<br>• Establish and maintain rapport with the client;<br>• Assess the client's needs and personalize discussions accordingly;<br>• Work with the client interactively to establish a plan;<br>• Provide information that can be understood and retained by the client; and<br>• Confirm the client's understanding using a technique such as the teach-back method.<br><br>Screen client for appropriateness to receive EC:<br>• Last normal menstrual period;<br>• Date and time of unprotected intercourse;<br>• Current contraceptive method;<br>• Ensure that client is not wanting to be pregnant;<br>• Assess need for future-use EC;<br>• Rule out contraindications per U.S. MEC category 3 and 4 risk conditions; and<br>• Obtain weight/BMI to offer the most effective EC formulation.<br><br>Review medical history:<br>• Significant illness;<br>• Allergies; |

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| | • Current medications - prescriptive and OTC;<br>• Use of tobacco, alcohol, and other drugs;<br>• Immunization and Rubella status;<br>• Contraceptive use;<br>• Menstrual history;<br>• Sexual history including risk for STIs;<br>• Obstetrical history;<br>• Gynecological and Pap test history;<br>• Surgical history;<br>• Hospitalizations;<br>• Family History;<br>• In utero exposure to diethylstilbestrol (DES); and<br>• Reproductive life plan.<br><br>Review last menstrual period (LMP) and compliance with contraceptive method (if applicable). Assess for risk of current pregnancy. Offer pregnancy test if indicated.<br><br>• A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets the following:<br>o Is ≤7 days after the start of normal menses;<br>o Has not had sexual intercourse since the start of last normal menses;<br>o Has been correctly and consistently using a reliable method of contraception;<br>o Is ≤7 days after spontaneous or induced abortion;<br>o Is within 4 weeks postpartum;<br>o Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds),amenorrhoeic, and < 6 months postpartum.<br><br>Blood Pressure: normal <140/90; refer clients with blood pressure reading ≥ 140 systolic or ≥ 90 diastolic to a primary care provider for further evaluation<br><br>Weight/Height: obtain body mass index (BMI)<br><br>Screen for STIs (if the client has not been screened) according to STI screening guidelines (see *STI Screening Policies and Procedures*).<br><br>Discuss client's reproductive life plan about becoming pregnant by asking:<br>• Do you have children now?<br>• Do you want to have (more) children? |

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| | • How many (more) children would you like to have and when?<br>  o If the client does not want a child at this time and is sexually active, then offer contraceptive services.<br>  o If the client desires pregnancy testing, then provide pregnancy testing and preconception counseling.<br>  o If the client wants to have a child now, then provide services to help the client achieve pregnancy and provide preconception counseling.<br>  o If the client wants to have a child and is experiencing difficulty conceiving, then provide basic infertility services.<br><br>Discuss EC options available for the individual client incorporating information regarding effects of weight/BMI on efficacy of EC of formulation. |
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| **Plan** | Administer/provide selected EC formulation (see below).<br>• **Cu-IUD:**<br>  o Scheduling:<br>  ▪ RN will schedule client with NP/PA/MD/DO for insertion the same day if possible, and within 120 hours of unprotected intercourse.<br>  o Insertion:<br>  ▪ NP/PA/MD/DO will follow the IUD policy and procedure for insertion of the device.<br>  o Client education:<br>  ▪ Follow the client education steps outlined in the *Intrauterine Contraception - IUD/IUS Policies and Procedures*.<br>  ▪ Instruct the client to return to the clinic for a pregnancy test if no menses occurs within the next 3 weeks.<br>• **Levonorgestrel EC:**<br>  o Administration:<br>  ▪ Administer levonorgestrel EC tablet as soon as possible (ASAP) while the client is in the office; otherwise instruct the client to take the pill ASAP within 120 hours after UPI.<br>  ▪ If a two-pill formulation of levonorgestrel is used, administer both pills together as a single dose.<br>  ▪ Advise the client to eat or drink something, if possible, prior to administration to prevent nausea.<br>  ▪ If vomiting occurs within one hour of taking the dose, the client should repeat the dose. May use over-the-counter anti-nausea drugs: |

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| | • Dramamine 50 mg 1-2 tablets by mouth every 4-6 hours;<br>• Benadryl 25 mg 1-2 tablets by mouth every 4-6 hours.<br>o Dispensing for future use:<br>▪ The decision to offer and dispense future-use EC should be made on an individualized basis and should include shared decision making between the provider and the client. The practice of offering and dispensing future-use EC to all clients has had no impact on unplanned pregnancy rates. Data shows that clients who had EC available at the time of unprotected intercourse either didn't take it at all or took it incorrectly, and the practice of providing EC to all clients represents a significant cost to the agency with no measurable impact. Clients requesting (those that self-identify that they need or want) EC for future-use and those using less reliable methods of birth control (tier 3 methods) might benefit most from having future-use EC made available.<br>o Client education:<br>▪ Give client copy of EC information/fact sheet.<br>▪ When a two-pill formulation is used, instruct the client to take both pills together as a single dose.<br>▪ Counsel the client on the effects of weight on efficacy of EC.<br>▪ Levonorgestrel EC is not contraindicated for those weighing over 154 pounds or with a BMI over 25; it just might not be effective.<br>▪ Instruct the client to abstain or to use a barrier or hormonal contraception until their next menses, as this EC formulation will not provide pregnancy protection for future acts of UPI.<br>▪ Any contraceptive method may be started immediately after the use of levonorgestrel EC.<br>▪ Discuss and facilitate plans for future contraception, beginning with the most effective methods.<br>▪ Recommend the use of condoms for protection from STIs/HIV – offer/dispense condoms.<br>▪ Provide counseling on the contraceptive method currently used or initiated at this visit.<br>▪ Offer and schedule all clients for a Prescription Visit with the clinic's prescribing provider to obtain a written prescription for continuation of the birth control method.<br>▪ Schedule the client for a Reproductive Health Well Visit if the client has not been screened appropriately within the |

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| | past 12 months or if an earlier assessment is clinically indicated.<br>▪ Advise the client to call the clinic if she has any questions or concerns regarding this contraceptive method.<br>▪ Inform the client that any signs or symptoms of complications should be reported to the clinic; if the clinic is not open, the client should call 911 or go to the emergency room.<br>▪ Over-the-counter EC formulations may be made available to clients as a supply pick-up when the client previously received complete counseling and written information on the particular EC formulation.<br><br>• **Ulipristal acetate (Ella®)**<br>o Administration:<br>▪ Administer Ella® tablet ASAP while client is in the office; otherwise instruct the client to take the pill ASAP within 120 hours after UPI.<br>▪ The prescription may be called into a local pharmacy for an established client.<br>▪ Advise the client to eat or drink something, if possible, prior to administration to prevent nausea.<br>▪ If vomiting occurs within one hour of taking the dose, the client should repeat the dose. May use over-the-counter anti-nausea drugs:<br>• Dramamine 50 mg 1-2 tablets by mouth every 4-6 hours;<br>• Benadryl 25 mg 1-2 tablets by mouth every 4-6 hours.<br>▪ Because Ella® and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effect. After using Ella®, if a woman wishes to use hormonal contraception, she should do so no sooner than 5 days after the intake of Ella®, and she should use a reliable barrier method for the next 14 days.<br>o Dispensing for future use:<br>▪ The decision to offer and dispense future use EC should be made on an individualized basis and should include shared decision making between the provider and the |

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| | client. The practice of offering and dispensing future use EC to all clients has had no impact on unplanned pregnancy rates. Data shows that clients who had EC available at the time of unprotected intercourse either didn't take it at all or took it incorrectly, and the practice of providing EC to all clients represents a significant cost to the agency with no measurable impact. Clients requesting (those that self-identify that they need or want) EC for future use and those using less reliable methods of birth control (tier 3 methods) might benefit most from having future use EC made available.<br><br>o Client education:<br>▪ Give the client a copy of EC information/fact sheet.<br>▪ Counsel the client on the effects of weight on efficacy of EC.<br>▪ Ella® is not contraindicated for those weighing over 193 pounds or with a BMI over 35; it just might not be effective.<br>▪ Instruct the client to abstain, use a barrier method, or hormonal contraception to prevent pregnancy. If she is currently using a hormonal method (pill, patch, or ring), or plans on using a hormonal method, the client should suspend use of the method until at least 5 days after taking Ella®. Instruct the client to use condoms as a back-up method for the next 14 days.<br>▪ Discuss and facilitate plans for future contraception, beginning with the most effective method.<br>▪ Advise the client to use condoms for protection from STIs/HIV—offer/dispense condoms.<br>▪ Provide counseling on contraceptive method currently used or initiated at this visit.<br>▪ Offer and schedule all clients for a Prescription Visit with the clinic's prescribing provider in order to obtain a written prescription for continuation of the birth control method.<br>▪ Schedule the client for a Reproductive Health Well Visit if the client has not been screened appropriately within the past 12 months or if an earlier assessment is clinically indicated.<br>▪ Advise the client to call the clinic if she has any questions or concerns regarding this contraceptive method.<br>▪ Inform the client that any signs and symptoms of complications should be reported to the clinic, if the clinic is not open, the client should call 911 or go to the emergency room. |

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| | • **Yuzpe**<br>o Administration:<br>▪ When administering EC to clients presenting to the clinic for care, other formulations are preferable to the Yuzpe method, simply because they are better tolerated by the client. Therefore, most often the Yuzpe method will be utilized by clients in need of EC who have no future-use EC at hand or are unable to obtain EC from a pharmacy, are unable to return to the clinic, and have combined oral contraceptive pills (COCP) on hand.<br>▪ Determine the type of COCP on hand by referring to the Yuzpe chart for the number and color of pills needed for each dose. (*See* Emergency Contraceptive Dosages)<br>▪ Consult with the prescribing provider for written or verbal orders for EC dosage.<br>▪ Advise the client to eat or drink something, if possible, prior to administration to prevent nausea.<br>▪ May use over-the-counter anti-nausea drugs:<br>• Dramamine 50 mg 1-2 tabs by mouth every 4-6 hours;<br>• Benadryl 25 mg 1-2 tabs by mouth every 4-6 hours.<br>o Client education:<br>▪ Give the client a copy of EC information/fact sheet.<br>▪ Instruct the client to abstain or use barrier or hormonal contraception to prevent pregnancy. If already using a hormonal method but incorrectly or inconsistently, instruct the client to use condoms as a back-up method until their next menses.<br>▪ Discuss and facilitate plans for future contraception, beginning with the most effective methods.<br>▪ Provide counseling on contraceptive method currently used or initiated at this visit.<br>▪ Offer and schedule all clients for a Prescription Visit, if indicated, with the clinic's prescribing provider in order to obtain a written prescription for continuation of the birth control method.<br>▪ Schedule the client for a Reproductive Health Well Visit if the client has not been screened appropriately within the past 12 months or if an earlier assessment is clinically indicated.<br>▪ Advise the client to call the clinic if she has any questions or concerns regarding this contraceptive method.<br>▪ Inform the client that any signs and symptoms of complications should be reported to the clinic, if the clinic is |

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| | not open the client should call 911 or go to the emergency room. |
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## ATTACHMENT 1: Emergency Contraceptive Dosages

| Brand | Manufacturer | Pills per Dose | Ethinyl Estradiol per Dose (mcg) | Levonorgestrel per Dose (mg) |
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| **Dedicated emergency contraception (take one dose)** | | | | |
| Plan B One-Step™ | Teva | 1 white pill | 0 | 1.5 |
| Next Choice® | Watson | 2 peach pills | 0 | 1.5 |
| ella® | Watson | 1 white pill | 0 | 0 |
| **Combined progestin and estrogen pills (take two does 12 hours apart)** | | | | |
| Aviane™ | Teva | 5 orange pills | 100 | 0.50 |
| Cryselle™ | Teva | 4 white pills | 120 | 0.60 |
| Enpresse™ | Teva | 4 orange pills | 120 | 0.50 |
| Jolessa™ | Teva | 4 pink pills | 120 | 0.60 |
| Lessina® | Teva | 5 pink pills | 100 | 0.50 |
| Levora™ | Watson | 4 white pills | 120 | 0.60 |
| Lo/Ovral® | Akrimax | 4 white pills | 120 | 0.60 |
| LoSeasonique® | Teva | 5 orange pills | 100 | 0.50 |
| Low-Ogestrel® | Watson | 4 white pills | 120 | 0.60 |
| Lutera™ | Watson | 5 white pills | 100 | 0.50 |
| Lybrel® | Wyeth | 6 yellow pills | 120 | 0.54 |
| Nordette® | Teva | 4 light-orange pills | 120 | 0.60 |
| Ogestrel® | Watcon | 2 white pills | 100 | 0.50 |
| Portia® | Teva | 4 pink pills | 120 | 0.60 |
| Quasense® | Watson | 4 white pills | 120 | 0.60 |
| Seasonale® | Teva | 4 pink pills | 120 | 0.60 |
| Seasonique® | Teva | 4 light-blue-green pills | 120 | 0.60 |
| Sronyx™ | Watson | 5 white pills | 100 | 0.50 |
| Trivora® | Watson | 4 pink pills | 120 | 0.50 |

## What is Depo Medroxyprogesterone Acetate (DMPA)?

This policy provides direction for reproductive health clinics to assist clients in the use of DMPA as a method of birth control.

DMPA is an injectable progestin, similar to the naturally occurring hormone progesterone, which can be used to provide long-acting contraception. It is a microcrystalline suspension made for slow release.

DMPA has a direct effect upon the reproductive organs and other cells with hormone receptors. DMPA inhibits ovulation by suppression of the pituitary release of follicle stimulating hormone (FSH) and luteinizing hormone (LH). Cervical mucus is changed to inhibit sperm capacitation and penetration. The endometrium becomes thin and atrophic due to decreased estrogen.

With typical use, approximately 4 out of 100 women will become pregnant in the first year of use. DMPA injections must be given every 3 months. There are two formulations, depo-subQ provera 104 and Depo- Provera CI (intramuscular injection).

DMPA does not protect against sexually transmitted infections (STIs).

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| **Protocol** | MDs, NPs, PAs, and DOs, may provide DMPA to any client who requests this method and has no U.S. MEC category 4 risk conditions.<br>• Category 4 risk conditions (risk of use outweighs the benefits of pregnancy prevention):<br>o Current breast cancer.<br>• Category 3 risk conditions (must consult with prescribing provider prior to initiation as the theoretical or proven risk may outweigh the advantages of using the method):<br>o Breast cancer; past and no evidence of current disease for 5 years;<br>o Cirrhosis; severe (decompensated);<br>o Diabetes mellitus: nephropathy/retinopathy/neuropathy;<br>o Diabetes mellitus: other vascular disease or diabetes of > 20 years' duration;<br>o Hypertension: systolic ≥ 160 or diastolic ≥ 100;<br>o Hypertension with vascular disease;<br>o Ischemic heart disease: current and history of;<br>o Benign liver tumors: hepatocellular adenoma;<br>o Malignant liver tumors;<br>o Multiple risk factors for arterial cardiovascular disease: (old age, smoking, diabetes, and hypertension);<br>o Rheumatoid arthritis: receiving long-term corticosteroid therapy with a history of, or risk factors for, non-traumatic fractures.<br>o Stroke: history of cerebrovascular accident; |

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| | ○ Systemic lupus erythematosus: positive (or unknown) antiphospholipid antibodies;<br>○ Systemic lupus erythematosus: severe thrombocytopenia *for initiation of method*;<br>○ Unexplained vaginal bleeding (suspicious for serious condition) before evaluation.<br>• Clients with a category 1 & 2 risk condition are candidates for DMPA.<br>○ RNs must have a prescription in order to provide DMPA to clients. |
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| **Procedure** | Provide client-centered care through quality counseling and education using the 5 key principles:<br>• Establish and maintain rapport with the client;<br>• Assess the client's needs and personalize discussions accordingly;<br>• Work with the client interactively to establish a plan;<br>• Provide information that can be understood and retained by the client; and<br>• Confirm the client's understanding using a technique such as the teach- back method.<br>Review medical history:<br>• Significant illness;<br>• Allergies;<br>• Current medications - prescriptive and OTC;<br>• Use of tobacco, alcohol, and other drugs;<br>• Immunization and Rubella status;<br>• Contraceptive use;<br>• Menstrual history;<br>• Sexual history including risk for STIs;<br>• Obstetrical history;<br>• Gynecological and Pap test history;<br>• Surgical history;<br>• Hospitalizations;<br>• Family History;<br>• In utero exposure to diethylstilbestrol (DES); and<br>• Reproductive life plan.<br><br>Review last menstrual period (LMP) and compliance with contraceptive method (if applicable). Assess for risk of current pregnancy. Offer pregnancy test if indicated.<br>• A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets the following: |

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| | ○ Is ≤7 days after the start of normal menses;<br>○ Has not had sexual intercourse since the start of last normal menses;<br>○ Has been correctly and consistently using a reliable method of contraception;<br>○ Is ≤7 days after spontaneous or induced abortion;<br>○ Is within 4 weeks postpartum;<br>○ Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrhoeic, and < 6 months postpartum.<br><br>Assess for recent sexual activity where intercourse was unprotected and offer emergency contraception (EC) for immediate use if indicated.<br><br>• Note that if Ella® is the EC formulation administered, a reliable barrier method of contraception should be used with subsequent acts of intercourse that occur within the next 14 days. Because Ella® and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effect. After using Ella® if a woman wishes to use hormonal contraception, she should do so no sooner than 5 days after the intake of Ella®.<br><br>Blood Pressure: normal <140/90; refer clients with blood pressure reading ≥ 140 systolic or ≥ 90 diastolic to a primary care provider for further.<br><br>Weight/Height: obtain body mass index (BMI).<br><br>Screen for STIs (if the client has not been screened) according to STI screening guidelines.<br><br>Discuss the client's reproductive life plan about becoming pregnant by asking:<br>• Do you have children now?<br>• Do you want to have (more) children?<br>• How many (more) children would you like to have and when?<br>○ If the client does not want a child now and is sexually active, then offer contraceptive services.<br>○ If the client desires pregnancy testing, then provide pregnancy testing and preconception counseling.<br>○ If the client wants to have a child now, then provide services to help the client achieve pregnancy and provide preconception counseling.<br>○ If the client wants to have a child and is having trouble conceiving, then provide basic infertility services. |

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| | Present all birth control method options for which the client has no U.S. MEC category 3 or 4 risk conditions.<br><br>Selection of contraceptive type based on U.S. MEC:<br>• Prescribing providers, after having a discussion with the client regarding risk versus benefit of a method, may initiate a method for which the client has a category 3 risk condition only if the benefit of pregnancy prevention outweighs the risks and the client finds other lower risk methods unacceptable.<br>• Clients requesting a method for which they have a category 4 risk condition will be offered lower risk methods and referred to an OB/GYN or specialist provider.<br><br>Each client will receive client instructions regarding warning signs, common side effects, risks, use of method, alternative methods, use of secondary method, and clinic follow-up schedule. Document the client's education and understanding of the method of choice.<br><br>Administration<br>• Depo-Provera CI injection dose is 150 mg (shake vial vigorously prior to use). Administer it as a deep IM injection using a 21-23-gauge needle in the deltoid (using at least a 1-inch needle) or upper outer quadrant of the gluteal muscle (use a 1.5 inch or longer needle at this site). Do not massage the area.<br>or<br>• Depo-subQ Provera 104 dose is 104mg/0.65 mL (shake the prefilled syringe vigorously) and is stored at room temperature. It is given by subcutaneous injection to the anterior thigh or abdomen, using a 26- gauge needle, once every 12 to 14 weeks.<br><br>Provide the client with a reminder card for when next injection appointment is due. |
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| **Plan** | Initiating DMPA:<br>• The first DMPA injection can be given at any time if it is reasonably certain that the client is not pregnant.<br>• If DMPA is started within 7 days since menstrual bleeding started, no additional contraceptive protection is needed. |

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| | • If DMPA is started > 7 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br><br>When the initial start of the method occurs within a visit with NP, PA, or MD the provider will write a prescription for up to 1-year supply.<br>• If the initial start of the method occurred within a visit with the RN, the RN **must** obtain an order from the provider for the DMPA.<br>• A Method Revisit appointment may be scheduled with the prescribing provider in 3 months. The purpose of this visit is for the prescribing provider to review the client's health history, discuss the method, and address any concerns or issues.<br>o DMPA injections do count as client visits.<br>o Schedule the client for a Reproductive Health Well Visit if the client has not been screened appropriately within the past 12 months or if an earlier assessment is clinically indicated.<br><br>Special considerations:<br>• Use of Ella®:<br>o The administration of DMPA should be delayed for 5 days after use of Ella® to prevent the reduction of contraceptive effects of either.<br>o A reliable barrier method of contraception should be used with subsequent acts of intercourse for the next 14 days.<br><br>• Amenorrhea (not postpartum):<br>o The first DMPA injection can be given at any time if it reasonably certain that the client is not pregnant.<br>o The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br><br>• Postpartum (breastfeeding):<br>o The first DMPA injection can be given at any time, including immediately postpartum (U.S. MEC 2 if < 1 month postpartum and U.S. MEC 1 if ≥ 1 month postpartum) if it is reasonably certain that the client is not pregnant.<br>o If the client is < 6 months postpartum, amenorrhoeic, and fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [85%] of feeds are breastfeeding), no additional contraceptive protection is needed.<br>o A client who is ≥ 21 days postpartum and has not experienced the return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. |

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| | o If the client's menstrual cycles have returned and it has been > 7 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br><br>• Postpartum (not breastfeeding):<br>o The first DMPA injection can be given at any time, including immediately postpartum (U.S. MEC 1), if it reasonably certain the client is not pregnant.<br>o A client who is < 21 days postpartum, no additional contraceptive protection is needed,<br>o A client who is ≥ 21 days postpartum and has not experienced the return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br>o If a client's menstrual cycles have returned and it has been > 7 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br><br>• Post abortion:<br>o The first DMPA injection can be given within the first 7 days, including immediately post-abortion.<br>o The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days unless the injection is given at the time of a surgical abortion.<br><br>Switching from another method:<br><br>• The first DMPA injection can be given immediately if it is reasonably certain that the client is not pregnant. Waiting for the next menstrual cycle is unnecessary.<br>o If it has been > 7 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br><br>• Switching from an IUD/IUS:<br>o If the client is switching from an IUD/IUS and has had sexual intercourse since the start of the current menstrual cycle and it has been > 5 days since menstrual bleeding started, residual sperm might be in the genital tract, a healthcare provider may consider any of the following options:<br>▪ Advise client to retain the IUD/IUS for at least 7 days after the injection and return for IUD removal;<br>▪ Advise the client to abstain from sexual intercourse or use barrier contraception for 7 days before removing the |

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| | IUD/IUS and switching to the new method; advise the client to use ECPS at the time of IUD removal.<br>▪ Combined hormonal contraceptives can be started immediately after use of ECPs (except for Ella®).<br>▪ Combined hormonal contraceptives can be started no sooner than 5 days after use of Ella®.<br>• If uncertain whether the client might be pregnant, the benefits of starting DMPA likely exceed any risk; therefore, starting DMPA should be considered at any time, with a follow-up pregnancy test in 2-4 weeks.<br>• If a client needs to use additional contraceptive protection when switching to DMPA from another contraceptive method, consider continuing her previous method for 7 days after DMPA injection.<br><br>Offer and provide condoms for use as a back-up method and for STI protection.<br><br>The decision to offer and dispense future-use EC should be made on an individualized basis and should include shared decision making between the provider and the client. Clients *requesting* (those that self-identify that they need or want) EC for future use and those using less reliable methods of birth control (tier 3 methods) might benefit most from having future-use EC made available.<br><br>Continuing DMPA:<br>• Repeat Depo-Provera CI IM injections every 3 months (11-13 weeks):<br>o The repeat DMPA injection can be given early when necessary (there are no time limits on early injections).<br>o The repeat DMPA injection can be given up to 2 weeks late (15 weeks from the last injection) without requiring additional contraceptive protection.<br>o If the client is > 2 weeks late (>15 weeks from the last injection) for a repeat DMPA injection, the client can have the injection if it is reasonably certain that the client is not pregnant. The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. Consider the use of EC (except for Ella®), if appropriate.<br>• Repeat Depo-subQ Provera 104 injections every 12 to 14 weeks:<br>o If more than 14 weeks elapse between injections, confirm the patient is not pregnant before the next injection.<br>o If the patient does not receive the next injections within 12-14 weeks, another contraceptive method should be used until the next depo-subQ provera 104 injection. |
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| **Routine Follow-Up** | The recommendations listed below address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women and men.<br><br>Although routine follow-up is not necessary for the use of DMPA, recommendations might vary for different users and different situations. Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple conditions may benefit from more frequent follow-up visits.<br><br>• Advise the client to return at any time to discuss side effects or other problems, if the client wants to change the method being used, and when it is time for reinjection.<br><br>• At other routine visits healthcare providers, should do the following:<br>o Assess the client's satisfaction with the contraceptive method and whether the client has any concerns about the method use;<br>o Assess any changes in health status, including medications that would change the appropriateness of the injectable for safe and effective continued use based on U.S. MEC;<br>o Consider assessing weight changes and counsel clients who are concerned about weight changes perceived to be associated with their contraceptive method; and<br>o Consider continuing to administer DMPA every 3 months with a current prescription from prescribing provider. |
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| **Management of DMPA Side Effects** | Prior to initiation provide counseling about potential changes in bleeding patterns:<br>• Amenorrhea;<br>• Unscheduled spotting;<br>• Light bleeding; and<br>• Heavy or prolonged bleeding.<br>• These irregularities are not harmful and may decrease with continued use.<br><br>Unscheduled Spotting or Light Bleeding:<br>• If clinically indicated, consider an underlying gynecological problem (e.g., STI, pregnancy or new pathologic uterine conditions). Schedule with prescribing provider/primary care provider for evaluation.<br>• If an underlying condition is not found, consider nonsteroidal anti-inflammatory drugs (NSAIDs) for short term treatment (5-7 days) during the days of bleeding. |

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| | • If unscheduled spotting or light bleeding persists and the client finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if desired.<br><br>Heavy or Prolonged Bleeding:<br>• If clinically indicated, consider an underlying gynecological problem (e.g. STI, pregnancy or new pathologic uterine conditions). Refer to the prescribing provider/ primary care provider for evaluation<br>• If an underlying condition is not found, consider the following treatment option during the days of bleeding:<br>o NSAIDs for short term treatment (5-7 days); or<br>o Hormonal treatment (if medically eligible) with low dose combined oral contraceptives or estrogen for short-term treatment (10-20 days).<br>• If heavy or prolonged bleeding persists and the client finds it unacceptable, counsel the client on alternative contraceptive methods, and offer another method if it is desired. |
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| **Stopping DMPA** | DMPA may be stopped at any time.<br><br>If the client does not want to become pregnant, advise the client to start using new contraceptive 13 weeks after her last injection. The client may start birth control pills, have a contraceptive implant or IUD placed, or use another contraceptive *before* it is time for the next injection.<br><br>If the client desires to be pregnant:<br>• Advise client that pregnancy may not occur for up to 6-12 months after stopping DMPA;<br>• Provide the client with preconception counseling; and<br>• Advise the client to begin taking a daily prenatal vitamin with 0.4 to 0.8 milligrams of folic acid at least 30 days before trying to become pregnant. |
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| **Client Education** | All women who are planning or capable of pregnancy should be counseled to take a daily supplement containing 0.4 to 0.8 milligrams (400 to 800 µg) of folic acid.<br><br>Advise the client there may be changes in periods (e.g., irregular bleeding, spotting, heavy bleeding, or no periods).<br><br>Advise the client that prolonged use of DMPA may put her at risk for osteoporosis and decreased bone mass. According to manufacturer information, DMPA should |

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| | not be used for more than two years unless a client cannot use other methods of birth control.<br><br>Advise the client using DMPA to have adequate intake of calcium and vitamin D, engage in regular exercise, and avoid cigarette smoking and excessive alcohol consumption in order to maximize bone health.<br><br>Advise client that there may be a delay in the return to ovulation and fertility is likely to be delayed after having several doses of DMPA.<br><br>Advise the client to use condoms for protection against STIs.<br><br>Inform the client to call the clinic if she has any questions or concerns regarding the birth control method.<br><br>Inform the clients that any signs or symptoms of complications should be reported to the clinic; if the clinic is not open, clients should call 911 or go to the emergency room.<br><br>Discuss DMPA warning signs that indicate the need for medical evaluation (client should be informed to seek immediate care if any warning signs are noted):<br>• Repeated, very painful headaches;<br>• Heavy bleeding;<br>• Depression;<br>• Severe, lower abdominal pain (may be sign of pregnancy); and/or<br>• Pus, prolonged pain, redness, itching or bleeding at injection site (may be sign of infection). |
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## What is a subdermal implant (Nexplanon)?

This policy provides direction for reproductive health clinics to assist clients in the use of the subdermal implant as a method of birth control.

Implants are controlled contraceptive release systems, implanted into subcutaneous tissue to deliver synthetic progestin hormones directly to the circulation. Nexplanon™ is a single rod implant containing 68 mg of etonogestrel (ENG) which is released slowly and is effective for at least 3 years. The Nexplanon™ rod is polymer, 4 cm long with a 2-mm diameter. It is non-biodegradable, does not contain latex and is radio-opaque. The contraceptive effect is achieved by suppression of ovulation, increased viscosity of the cervical mucus and alterations in the endometrium.

The implant is very effective, with less than 1 woman out of 100 becoming pregnant in the first year of typical use. The implant is long-acting, is reversible, and can be used by women of all ages, including adolescents.

The implant does not protect against sexually transmitted infections (STIs).

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| **Protocol** | MDs, NPs, PAs, and DOs may provide Nexplanon™ to any client who requests this method and has no U.S. MEC, 2010 category 4 risk conditions. RNs may provide counseling and education related to the subdermal implant.<br>• Category 4 risk conditions (risk of use outweighs the benefits of pregnancy prevention):<br>  o Current breast cancer.<br>• Category 3 risk conditions (must consult with prescribing provider prior to initiation as the theoretical or proven risk may outweigh the advantages of using the method):<br>  o Breast cancer: past and no evidence of current disease for 5 years;<br>  o Cirrhosis: severe (decompensated);<br>  o Ischemic heart disease: current and history of *for continuation of method*;<br>  o Benign liver tumors: hepatocellular adenoma;<br>  o Malignant liver tumors;<br>  o Stroke: history of cerebrovascular accident *for continuation of method*;<br>  o Systemic lupus erythematosus: positive (or unknown) antiphospholipid antibodies;<br>  o Unexplained vaginal bleeding (suspicious for serious condition before evaluation).<br>• Clients with Category 1 & 2 risk conditions are candidates for using this method. |

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| **Procedure** | Provide client-centered care through quality counseling and education using the 5 key principles:<br>• Establish and maintain rapport with the client;<br>• Assess the client's needs and personalize discussions accordingly;<br>• Work with the client interactively to establish a plan;<br>• Provide information that can be understood and retained by the client; and<br>• Confirm the client's understanding using a technique such as the teach- back method.<br><br>Review medical history:<br>• Significant illness;<br>• Allergies;<br>• Current medications - prescriptive and OTC;<br>• Use of tobacco, alcohol, and other drugs;<br>• Immunization and Rubella status;<br>• Contraceptive use;<br>• Menstrual history;<br>• Sexual history including risk for STIs;<br>• Obstetrical history;<br>• Gynecological and Pap test history;<br>• Surgical history;<br>• Hospitalizations;<br>• Family History;<br>• In utero exposure to diethylstilbestrol (DES); and<br>• Reproductive life plan.<br><br>Review last menstrual period (LMP) and compliance with contraceptive method (if applicable). Assess for risk of current pregnancy. Offer pregnancy test if indicated.<br>• A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets the following:<br>o Is ≤7 days after the start of normal menses;<br>o Has not had sexual intercourse since the start of last normal menses;<br>o Has been correctly and consistently using a reliable method of contraception;<br>o Is ≤7 days after spontaneous or induced abortion;<br>o Is within 4 weeks postpartum; |

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| | o Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrhoeic, and < 6 months postpartum.<br><br>Assess for recent sexual activity where intercourse was unprotected and offer emergency contraception (EC) for immediate use if indicated.<br><br>• Note that if Ella® is the EC formulation administered, a reliable barrier method of contraception should be used with subsequent acts of intercourse that occur within the next 14 days. Because Ella® and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effect. After using Ella® if a woman wishes to use hormonal contraception, she should do so no sooner than 5 days after the intake of Ella®.<br><br>Blood Pressure: normal <140/90; refer clients with blood pressure reading ≥ 140 systolic or ≥ 90 diastolic to a primary care provider for further.<br><br>Weight/Height: obtain body mass index (BMI).<br><br>Screen for STIs (if the client has not been screened) according to STI screening guidelines.<br><br>Discuss the client's reproductive life plan about becoming pregnant by asking:<br>• Do you have children now?<br>• Do you want to have (more) children?<br>• How many (more) children would you like to have and when?<br>o If the client does not want a child now and is sexually active, then offer contraceptive services.<br>o If the client desires pregnancy testing, then provide pregnancy testing and preconception counseling.<br>o If the client wants to have a child now, then provide services to help the client achieve pregnancy and provide preconception counseling.<br>o If the client wants to have a child and is having trouble conceiving, then provide basic infertility services.<br><br>Selection of contraceptive type based on U.S. MEC:<br><br>• Prescribing providers, after having a discussion with the client regarding risk versus benefit of a method, may initiate a method for which the client has a category 3 risk condition only if the benefit of pregnancy prevention |

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| | outweighs the risks and the client finds other lower risk methods unacceptable.<br>• Clients requesting a method for which they have a category 4 risk condition will be offered lower risk methods and referred to an OB/GYN or specialist provider.<br><br>Each client will receive client instructions regarding warning signs, common side effects, risks, use of method, alternative methods, use of secondary method, and clinic follow-up schedule. Document the client's education and understanding of the method of choice. |
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| **Plan** | Initiation of the implant:<br>• The implant can be inserted at any time if it is reasonably certain that the client is not pregnant:<br>o If the implant is inserted within the first 5 days since menstrual bleeding started, no additional contraceptive protection is needed.<br>• If the implant is inserted >5 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. Instruct the client of the need to wait 5 days after the administration of Ella® before having the implant inserted. Schedule the insertion as soon as possible after the recommended 5-day period and recommend the use of a barrier method of contraception with all subsequent acts of intercourse that occur within the next 14 days.<br><br>Insertion Procedure:<br>• **Only clinicians who have received certification by undergoing approved training by the manufacturer and have demonstrated skill in successful Nexplanon™ insertion and removal, shall insert the implant**.<br>• Obtain consent for the procedure and for use of the devise using the manufacturer's consent form.<br>• Insert the device; the manufacturer's instructions **MUST** be followed.<br>o Provider and client should palpate the arm to check for placement.<br>• Apply a small adhesive bandage over the insertion site.<br>• The clinician and client must be able to palpate the device under the skin immediately after the insertion. If it cannot be palpated, the client must be advised to use a non-hormonal birth control method until placement is verified.<br>• Apply a pressure bandage with sterile gauze to minimize bruising. |

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| | • Instruct the client to remove the pressure bandage in 24 hours and the small adhesive bandage over the insertion site in 3-5 days. Instruct the client to keep the area dry for 48 hours to prevent infection.<br>• Document the procedure in the client's medical record including:<br>  o Date of procedure;<br>  o Site of the procedure;<br>  o The lot number of the implant; and<br>  o The clinician and client confirmed placement by palpating the implant after insertion.<br>• Complete the "User Card" supplied by the manufacturer and give it to the client to keep.<br>• Because the device is inserted and retained, it is recommended that the lot number and expiration date is documented in the client's medical record in addition to the pharmacy dispensing log.<br><br>Implant Removal:<br>• **Only clinicians who have received certification by undergoing a training course approved by the manufacturer and have demonstrated skill in successful Nexplanon™ insertion and removal, shall remove implants**.<br>• Implants must be removed by the end of the third year of use.<br>• Unless pregnancy is desired, an alternative method of contraception should be offered.<br>• Another Nexplanon™ may be inserted immediately after removal through the same incision and in a track parallel to the one removed.<br>• If pregnancy is desired, provide preconception counseling and advise client to begin taking a daily prenatal vitamin with 0.4 milligrams of folic acid at least 30 days before trying to become pregnant.<br>• Obtain consent for the procedure.<br>• Remove the device; the manufacturer's instructions, which **MUST** be followed.<br>• After removal, close the incision with a butterfly closure and apply an adhesive bandage.<br>• Apply a pressure bandage with sterile gauze to minimize bruising.<br><br>Special insertion considerations:<br>• Amenorrhea (Not Postpartum):<br>  o The implant can be inserted at any time if it reasonably certain that the client is not pregnant.<br>  o The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br>• Postpartum (breastfeeding): |

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| | ○ The implant can be inserted at any time (U.S. MEC 2 if < 1 month postpartum and U.S. MEC 1 if ≥ 1 month postpartum), if it is reasonably certain that the client is not pregnant.<br>○ If the client is <6 months postpartum, amenorrhoeic, and fully or nearly fully breastfeeding (exclusively breastfeeding or vast majority [85%] of feeds are breastfeeds) no additional contraceptive protection is needed.<br>○ A client who is ≥21 days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br>○ If a client's menstrual cycles have returned and it has been > 5 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br>• Postpartum (not breastfeeding):<br>○ The implant can be inserted at any time, including immediately postpartum (U.S. MEC 1) if it is reasonably certain that the client is not pregnant.<br>○ A client who is < 21 days postpartum, no additional contraceptive protection is needed.<br>○ A client who is ≥21 days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br>○ If a client's menstrual cycles have returned and it has been > 5 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.<br>• Post abortion (spontaneous or induced):<br>○ The implant can be inserted within the first 7 days, including immediately after the abortion (U.S. MEC 1).<br>○ The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days unless the implant is inserted at the time of a surgical abortion.<br><br>Switching from another contraceptive method<br>• The implant can be inserted immediately if it is reasonably certain that the client is not pregnant. Waiting for her next menstrual period is unnecessary.<br>○ If it has been >5 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days after insertion. |

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| | • Switching from an IUD/IUS:<br>  o If the client has had sexual intercourse since the start of her current menstrual cycle and it has been >5 days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract. A healthcare provider may consider any of the following options:<br>  ▪ Advise the client to retain the IUD/IUS for at least 7 days after the implant is inserted and return for IUD/IUS removal;<br>  ▪ Advise the client to abstain from sexual intercourse or use barrier contraception for 7 days before removing the IUD/IUS and switching to the new method; or<br>  ▪ If the client cannot return for IUD removal and has not abstained from sexual intercourse or used barrier contraception for 7 days, advise the client to use EC pills (with the exception of Ella®) at the time of IUD/IUS removal.<br><br>Offered and provide condoms. |
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| **Routine Follow-up** | The recommendations listed below address when routine follow-up is needed for safe and effective continued use of contraception for healthy women. These recommendations refer to general situations and might vary for different users and different situations. Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions may benefit from more frequent follow-up visits.<br>  o Advise client to return at any time to discuss side effects or other problems, if she wants to change her method, or when it is time to remove or replace the implant. No routine follow-up is required.<br>  o At other routine visits, healthcare providers should do the following:<br>  o Assess a client's satisfaction with the implant and whether she has any concerns about the method use;<br>  o Assess any changes in health status, including medications that would change the appropriateness of the implant for safe and effective continued use based on U.S. MEC (e.g., category 3 or 4 conditions or characteristics); and<br>  o Consider assessing weight changes and counseling women who are concerned about weight changes perceived to be due to contraceptive method. |
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| **Management of Bleeding Irregularities** | Prior to implant insertion, provide counseling about potential changes in bleeding patterns during implant use. Unscheduled spotting or light bleeding is common with implant use, and some women experience amenorrhea. This bleeding is not harmful and may or may not decrease with continued use.<br>• Heavy or unusually prolonged bleeding is uncommon with implant use.<br><br>Irregular bleeding (spotting, light bleeding or heavy or prolonged bleeding):<br>• If clinically indicated, consider underlying gynecological problem; such as interaction with other medications, STIs, pregnancy, or new pathologic uterine conditions.<br>o Refer to the prescribing provider/ PCP for evaluation.<br>• If any underlying condition is not found and the client wants treatment, the following treatment options during days of bleeding can be considered:<br>o NSAIDS for short term treatment (5-7 days); or<br>o Hormonal treatment (if medically eligible) with low dose combined oral contraceptives or estrogen for short-term treatment (10-20 days).<br>• If irregular bleeding persists and the client finds it unacceptable, counsel her on alternative methods, and offer another method if it is desired.<br><br>Amenorrhea:<br>• Amenorrhea does not require any medical treatment. Provide reassurance.<br>o If a client's regular bleeding pattern changes abruptly to amenorrhea, consider ruling out pregnancy if clinically indicated.<br>o If amenorrhea persists and the client finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired. |
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| **Client Education** | All women who are planning or capable of pregnancy should be counseled to take a daily supplement containing 0.4 to 0.8 milligrams (400 to 800 µg) of folic acid (USPSTF, Grade A recommendation; January 2017).<br><br>Ensure that the client is aware of all contraceptive choices and has received information that meets the criteria for informed consent.<br><br>**Review care of insertion or removal site.** |

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| | **Instruct client to return to clinic if a significant Nexplanon™ related problem is suspected and/or if any of the following occur:**<br>• Unable to palpate rod or it feels bent (use back-up birth control until evaluated);<br>• Expulsion (use back-up birth control until she can return to the clinic);<br>• Very heavy vaginal bleeding or bleeding that lasts longer than 14 days;<br>• Delayed menses after a long interval of regular cycles;<br>• Concern about a possible pregnancy;<br>• Arm pain; pus, redness, or bleeding at the insertion site;<br>• Onset or worsening of episodes of migraine, aura, or severe headache; or<br>• Client decides she wants the implant removed.<br><br>Advise the client to use condoms for protection against STIs.<br><br>Advise the client to contact the clinic whenever she has questions about her contraceptive method.<br><br>Client shall be informed that any signs or symptoms of complications should be reported to the clinic; if the clinic is not open, clients should call 911 or go to the emergency room. |
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## What is a diaphragm and cervical cap?

This policy provides direction for reproductive health clinics to assist clients in their use of the diaphragm or cervical cap as a method of birth control.

Diaphragms/cervical caps provide contraception by blocking sperms' entry into the cervix by both a barrier effect and by spermicidal activity from the spermicides used with the diaphragm/cervical cap. These contraceptive devices are used with a spermicidal agent in front of the cervix to kill the sperm. In typical use12 out of 100 women will experience an unintended pregnancy within the first year.

The diaphragm is a reusable dome-shaped rubber cup which covers the cervix and is inserted into the vagina before intercourse. The diaphragm may provide effective contraceptive protection up to 6 hours. If a longer interval has elapsed, insertion of additional doses of spermicides into the vagina with an applicator (without removing the diaphragm) is recommended. After intercourse, the diaphragm should be left in place for at least 6 hours. Wearing it longer than 24 hours is not recommended because of rare risk of toxic shock syndrome.

The cervical cap is a reusable bowl-shaped silicone rubber cap with a brim that flares outward. The concave side covers the cervix completely. Spermicides can be placed on the inside and outside of the cap. The cervical cap can be worn for up to 48 hours.

Diaphragms and cervical caps do not protect against sexually transmitted infections (STIs).

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| **Protocol** | (MDs, NPs, PAs, and DOs may provide a diaphragm or cervical cap to any client who requests this contraceptive method and has no<br>U.S. MEC category 4 risk conditions. RNs may provide counseling and education related to the diaphragm/cervical cap.<br>• Category 4 risk conditions (risk of use outweighs the benefits of pregnancy prevention):<br>o High risk for HIV (related to the association between increased risk for HIV infection and use of nonoxynol-9 (N-9) spermicides);<br>o < 6 weeks postpartum (diaphragm and cap use are unsuitable until uterine involution is complete).<br>• Category 3 risk conditions (must consult with prescribing provider prior to initiation as the theoretical or proven risk may outweigh the advantages of using method):<br>o HIV infections;<br>o AIDS;<br>o History of toxic shock syndrome;<br>o Antiretroviral (ARV) therapy: nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), ritonavir-boosted protease inhibitors;<br>o Allergic to latex (does not apply to plastic diaphragms). |

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| | • Clients with a category 1 & 2 risk condition are candidates for using this method. |
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| **Procedure** | Provide client-centered care through quality counseling and education using the 5 key principles:<br>• Establish and maintain rapport with the client;<br>• Assess the client's needs and personalize discussions accordingly;<br>• Work with the client interactively to establish a plan;<br>• Provide information that can be understood and retained by the client; and<br>• Confirm the client's understanding using a technique such as the teach- back method.<br><br>Review medical history:<br>• Significant illness;<br>• Allergies;<br>• Current medications - prescriptive and OTC;<br>• Use of tobacco, alcohol, and other drugs;<br>• Immunization and Rubella status;<br>• Contraceptive use;<br>• Menstrual history;<br>• Sexual history including risk for STIs;<br>• Obstetrical history;<br>• Gynecological and Pap test history;<br>• Surgical history;<br>• Hospitalizations;<br>• Family History;<br>• In utero exposure to diethylstilbestrol (DES); and<br>• Reproductive life plan.<br><br>Review last menstrual period (LMP) and compliance with contraceptive method (if applicable). Assess for risk of current pregnancy. Offer pregnancy test if indicated.<br>• A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets the following:<br>o Is ≤7 days after the start of normal menses;<br>o Has not had sexual intercourse since the start of last normal menses;<br>o Has been correctly and consistently using a reliable method of contraception;<br>o Is ≤7 days after spontaneous or induced abortion; |

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| | o Is within 4 weeks postpartum;<br>o Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrhoeic, and < 6 months postpartum.<br><br>Assess for recent sexual activity where intercourse was unprotected and offer emergency contraception (EC) for immediate use if indicated.<br><br>• Note that if Ella® is the EC formulation administered, a reliable barrier method of contraception should be used with subsequent acts of intercourse that occur within the next 14 days. Because Ella® and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effect. After using Ella® if a woman wishes to use hormonal contraception, she should do so no sooner than 5 days after the intake of Ella®.<br><br>Blood Pressure: normal <140/90; refer clients with blood pressure reading ≥ 140 systolic or ≥ 90 diastolic to a primary care provider for further.<br><br>Weight/Height: obtain body mass index (BMI).<br><br>Perform pelvic examination and fitting for diaphragm/cervical cap to ensure proper size and placement.<br><br>Screen for STIs (if the client has not been screened) according to STI screening guidelines.<br><br>Discuss the client's reproductive life plan about becoming pregnant by asking:<br>• Do you have children now?<br>• Do you want to have (more) children?<br>• How many (more) children would you like to have and when?<br>o If the client does not want a child now and is sexually active, then offer contraceptive services.<br>o If the client desires pregnancy testing, then provide pregnancy testing and preconception counseling.<br>o If the client wants to have a child now, then provide services to help the client achieve pregnancy and provide preconception counseling.<br>o If the client wants to have a child and is having trouble conceiving, then provide basic infertility services.<br><br>Selection of contraceptive type based on U.S. MEC:<br><br>• Prescribing providers, after having a discussion with the client regarding risk versus benefit of a method, may initiate a method for which the client |

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| | has a category 3 risk condition only if the benefit of pregnancy prevention outweighs the risks and the client finds other lower risk methods unacceptable.<br>• Clients requesting a method for which they have a category 4 risk condition will be offered lower risk methods and referred to an OB/GYN or specialist provider.<br><br>Each client will receive client instructions regarding warning signs, common side effects, risks, use of method, alternative methods, use of secondary method, and clinic follow-up schedule. Document the client's education and understanding of the method of choice. |
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| **Plan** | Diaphragms/Cervical caps may be initiated at any time.<br><br>Allow the client to practice insertion and removal.<br><br>Provide the client with spermicides.<br><br>Review the client's history and access of recommended health screenings. Send a Release of Records for past health screenings, if performed elsewhere.<br><br>Schedule the client for a Reproductive Health Well Visit if the client has not been screened appropriately within the past 12 months or if an earlier assessment is clinically indicated.<br><br>Offer and provide condoms for use as a back-up method and for STI protection.<br><br>The decision to offer and dispense future-use EC should be made on an individualized basis and should include shared decision making between the provider and the client. Clients *requesting* (those that self-identify that they need or want) EC for future use and those using less reliable methods of birth control (tier 3 methods) might benefit most from having future-use EC made available.<br><br>Instruct the client to wait 5 days after the administration of Ella® before initiating hormonal contraceptives. Recommend the use of a barrier method of contraception with all subsequent acts of intercourse that occur within the next 14 days. |
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| **Routine Follow-Up** | These recommendations address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women. Although |

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| | routine follow-up is not necessary for the use of the diaphragm/cervical cap, recommendations might vary for different users and different situations. Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple conditions may benefit from more frequent follow-up visits.<br>• Advise the client to return at any time to discuss side effects or other problems if she wants to change the method being used.<br>• At other routine visits, healthcare providers should do the following:<br>o Assess the client's satisfaction with the contraceptive method and whether the client has any concerns about method use.<br>o Assess any changes in health status that would change the appropriateness of the vaginal barrier for safe and effective continued use on the basis of U.S. MEC.<br>o Assess any significant weight changes (gain or loss of 10 or more pounds) or recent pregnancy which may affect the fitting of the diaphragm.<br>o Diaphragms/cervical caps should be replaced every 2 years or sooner if there is visible deterioration or damage. |
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| **Managing Problems** | Recurrent vaginal or vulvar irritation, without sign of infection, may indicate an allergy or sensitivity to the product; may suggest client try another contraceptive method.<br>• If symptoms persist after discontinuing the method, reevaluate for other etiology (e.g. STI exposure, yeast vaginitis, or bacterial vaginitis).<br>Counsel the client that recurrent urinary tract infections (UTI) may occur—the client should contact the prescribing provider for a possible refitting with smaller diaphragm size or an alternative rim style if needed.<br>Instruct the client using the cervical cap to seek emergency medical care if she develops and signs and symptoms of Toxic Shock Syndrome (TSS). |
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| **Client Education** | All women who are planning or capable of pregnancy should be counseled to take a daily supplement containing 0.4 to 0.8 milligrams (400 to 800 µg) of folic acid.<br>Advise the client to use the diaphragm/cervical cap every time vaginal intercourse occurs; ensure the diaphragm/cervical cap is in proper place before the penis enters the vagina.<br>Advise the client if unsure about the proper fit or placement of the diaphragm/cervical cap, use an alternative method until evaluated by a medical provider. |

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| | Instruct the client on the use of the diaphragm/cervical cap:<br>• Ideally it is inserted into the vagina less than two hours before sexual intercourse.<br>• Place one tablespoon of spermicide into the dome and along rim.<br>• Place an additional applicator of spermicide in the vagina.<br>• If the diaphragm is placed 3 to 6 hours before intercourse, another applicator full of spermicides needs to be inserted into the vagina prior to sexual intercourse.<br>• Each new episode of intercourse while the diaphragm is in place should be preceded by the insertion of fresh spermicide, and the diaphragm should remain in place for at least six hours after the last episode of intercourse to maximize effectiveness.<br>• For the cervical cap, once it is in place, it is not necessary to use more spermicide with each vaginal intercourse.<br><br>Instruct the client to minimize the risk of vaginal irritation, cystitis and, rarely, toxic shock.<br>• The diaphragm should be removed by 24 hours after initial insertion.<br>• The cervical cap must be removed within 48 hours.<br><br>Counsel the client on their individual risk of STI acquisition or transmission; when using N-9 spermicides more than 3 applications per day, the risk of HIV is increased compared to a placebo.<br><br>Instruct the client when using the diaphragm to avoid lubricants such as mineral oil, baby oil, suntan oil, vegetable oil, and butter; and vaginal cream such as Femstat cream, Monistat cream, estrogen cream, and vagisil.<br><br>Inform the client that she may use contraceptive jelly or water-soluble lubricant intended for use with condoms for lubrication, if needed.<br><br>Advise the client that douching after intercourse is not recommended, if the client chooses to douche, she will need to wait at least 6 hours after intercourse.<br><br>Advise the client to store the diaphragm/cervical cap in a location that is clean, cool, and out of the sunlight.<br><br>Instruct the client to wash diaphragm/cervical cap and spermicides inserter after each use with plain soap and water.<br><br>Instruct the client to check diaphragm/cervical cap before each use to make sure there are no holes or tears and that the device is not damaged. |

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| | Advise the client to use condoms for protection against STIs.<br><br>**Inform the client of signs and symptoms of Toxic Shock Syndrome *(clients should be informed to seek immediate care if any warning signs are noted):***<br>• Sudden high fever;<br>• Chills;<br>• Vomiting;<br>• Diarrhea;<br>• Muscle aches; or<br>• Sunburn-like rash. |
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## Explaining How to Use the Diaphragm

**IMPORTANT:** Whenever possible, show the woman the location of the pubic bone and cervix with a model or a picture. Explain that the diaphragm is inserted behind the pubic bone and covers the cervix.

| Explain the 5 Basic Steps to Using a Diaphragm | |
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| **Basic Steps** | **Important Details** |
| **1. Squeeze a spoonful of spermicidal cream, jelly, or foam into the diaphragm and around the rim** | • Wash hands with mild soap and clean water, if possible.<br>• Check the diaphragm for holes, cracks, or tears by holding it up to the light.<br>• Check the expiration date of the spermicide and avoid using any beyond its expiration date. |

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| | • Insert the diaphragm less than 6 hours before having sex. |
| **2. Press the rim together; push into the vagina as far as it goes** | • Choose a position that is comfortable for insertion—squatting, raising one leg, sitting, or lying down. |
| **3. Feel diaphragm to make sure it covers the cervix** | • Through the dome of the diaphragm, the cervix feels like the tip of the nose.<br>• If the diaphragm feels uncomfortable, take it out and insert it again.<br>  |
| **4. Keep in place for at least 6 hours after sex** | • Keep the diaphragm in place at least 6 hours after having sex but no longer than 24 hours.<br>• *Leaving the diaphragm in place for more than one day may increase the risk of toxic shock syndrome.* It can also cause a bad odor and vaginal discharge. (Odor and discharge may go away after the diaphragm is removed.)<br>• For multiple acts of sex, make sure that the diaphragm is in the correct position and insert additional spermicide in front of the diaphragm before each act of sex. |
| **5. To remove, slide a finger under the rim of the diaphragm to pull it down and out** | • Wash hands with mild soap and clean water, if possible.<br>• Insert a finger into the vagina until the rim of the diaphragm is felt.<br>• Gently slide a finger under the rim and pull the diaphragm down and out. Use care not to tear the diaphragm with a fingernail.<br>• Wash the diaphragm with mild soap and clean water and dry it after each use. |

## What is intrauterine contraception?

An intrauterine device (IUD) is a Tier 1, most effective, method of contraception and falls into the long-acting reversible contraceptive (LARC) category.

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| **Objective Data** | History and Physical exam<br><br>Laboratory tests may include:<br><br>• Cervical cancer screening within the normal screening interval for the client. Cervical intraepithelial neoplasia (CIN) is listed as a category 2 (a condition for which the advantages of using the method generally outweigh the theoretical or proven risk) for Mirena and a category 1 (a condition for which there is no restriction for the use of the contraceptive method) for ParaGard. An IUD/IUS should not be initiated for a client who has cervical cancer. Continuing an IUD/IUS for a client diagnosed with cervical cancer is a category 2.<br><br>• GC and Chlamydia tests according to national screening guidelines and within the normal screening interval for the client. Screening may be provided at time of IUC insertion if screening has not previously been done. |
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| **Assessment and Plan** | Client Education/ Informed Consent<br><br>• Have client read the FDA approved client brochure for the particular IUD that she is to have inserted.<br><br>• Provide anticipatory counseling and reinforce the effects of the IUD on the menstrual cycle.<br>• Client must sign an IUD procedure consent and a copy of the consent and IUD package insert must be provided to the client.<br><br>Pre-insertion Management<br>• Prophylactic antibiotics are generally not recommended for IUC insertion.<br>• Sub-bacterial endocarditis (SBE) prophylaxis prior to IUC insertion is not recommended. Routine administration of prophylactic antibiotics solely to prevent endocarditis is not recommended for clients undergoing genitourinary tract procedures. Routine antibiotic prophylaxis to prevent pelvic infection is not recommended before IUD insertion.<br>• For pre-insertion pain management, clients may be given a non-steroidal anti-inflammatory drug (NSAID) one hour prior to insertion. According to US SPR (2016), paracervical block with lidocaine may reduce patient pain during IUD insertion. Misoprostol is not recommended for routine use |

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| | prior to IUD insertion. Misoprostol might be helpful in women with a recent failed insertion.<br>• Local anesthesia at the tenaculum site: options included 1) no anesthesia or 2) apply benzocaine 20% gel first at the tenaculum site then leave a gel-soaked cotton tipped applicator in the cervical canal for 1 minute before proceeding with the IUD insertion, or 3) inject 1 ml of local anesthetic lip into which the tenaculum will be placed.<br><br>Initiation of IUD- follow manufacturer's instructions for insertion of IUD device.<br><br>Insertion<br><br>• Document baseline pulse and blood pressure prior to insertion.<br>• Document pelvic exam done prior to insertion as to uterine position, size, cervix and discharge appearance and any abnormalities.<br>• Document IUD type, depth to which uterus is sounded, string length after insertion and trimming, and lot # and expiration date of the IUD.<br><br>Post-insertion of the IUD - Vasovagal observation<br>• Blood pressure and pulse should be taken and recorded.<br>• If vital signs indicate a vasovagal response, record BP and pulse frequently (every 5-15 minutes).<br>• Client should not be allowed to leave the clinic until stable.<br>• Clients with persistent vasovagal symptoms should be evaluated for perforation, abdominal bleeding, etc.<br><br>Post-IUD/IUS Insertion Education<br><br>• Client should be instructed on the expiration period for the IUD.<br>o ParaGard is approved for 10 years.<br>o Mirena is approved for 8 years.<br>o Skyla is approved for 3 years<br>o Liletta is currently approved for 8 years<br>• Need for back up contraception, if indicated<br>• Reinforce the signs and symptoms of possible IUD complications. Instruct the client to call the clinic for any of the following:<br>o Late or missed period if using ParaGard; abnormal spotting or bleeding; signs or symptoms of pregnancy.<br>o Pelvic or lower abdominal pain; pain with intercourse<br>o Exposure to STIs; abnormal vaginal discharge<br>o Not feeling well – fever or chills<br>o Inability to locate IUD string, changes in string length<br>o Known partial or full expulsion |

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| | • Instruct the client to check for the string before intercourse, during her first menstrual cycle, and then after each menses<br>• Inform the client if she wishes to discontinue the use of her IUD to make an appointment with her provider to have it removed. If she does not wish to become pregnant, she must start a new method on or before the day she has her IUD removed.<br><br>Follow-up Visits<br>• Scheduling of follow up visits is at the provider's discretion. Routine follow up visits after IUD insertion are not required unless the provider feels that the client would benefit (e.g. adolescents, certain medical conditions).<br>o Advise women to return at any time to discuss side effects or other problems or if she wants to change her method<br>o At other routine visits, assess client's satisfaction and any concerns with method, any changes in health status that would change the appropriateness of IUD use (category 3 or 4 US MEC), consider exam for IUD string check<br>o Hemoglobin/ Hematocrit if indicated<br>o Review of IUD danger signs.<br>o Reinforce the importance of an annual visit and cervical cancer screening according to screening guidelines. |
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| **Management of Complications / Side Effects** | Client diagnosed with PID<br><br>• Treat for PID as outlined in the CDC STI Treatment Guidelines. "If an IUD user receives a diagnosis of PID, the IUD does not need to be removed." Close clinical follow up is required.<br>• Inform the client to seek care immediately if her symptoms do not improve or worsen. Reassess in 48 to 72 hours. If no improvement, consider IUD removal. Continue antibiotics and refer for care.<br>• If the IUD is removed, contraceptive counseling is necessary.<br>o If the client is mid-cycle, and has recently had intercourse, inform her of the risk of removing the IUD and a possible subsequent pregnancy. Offer EC. If the client decides she does not want removal, documentation must exist of discussion of need for close clinical follow up.<br>o If IUD is removed, be certain the client leaves the clinic with an alternative method of birth control.<br><br>Actinomyces on Pap test - SYMPTOMATIC OF PID<br>• Client must receive/be referred for intensive antibiotic therapy, along with the removal of the IUD, as this bacterium prefers to grow on foreign bodies. Physician consultation is required. |

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| | • Client must be counseled on the use of a different method of contraception.<br><br>Actinomyces on Pap test - ASYMPTOMATIC OF PID<br><br>• Pelvic actinomycosis is a rare (<.001%) but serious condition. The relationship between actinomyces found on a Pap test in the asymptomatic IUD user and development of a pelvic actinomycosis infection is not clear. Therefore, management of the asymptomatic IUD user with a Pap with actinomyces is not clearly established. With this is mind, each agency's practitioners should discuss the management of actinomyces on Pap test in an asymptomatic IUD user with the medical consultant and determine the approach to be used.<br>o Review the result with the cytologist/pathologist to confirm the diagnosis.<br>o The IUD does not have to be removed, but the client should be informed and questioned about any symptoms suggestive of PID. If she is asymptomatic, nothing more is required.<br>o Treatment of asymptomatic actinomyces on Pap test is not required, as the actinomyces is a normal vaginal organism. Detecting its presence on Pap test represents colonization rather than infection in a client without pelvic tenderness. Review the signs and symptoms of PID with the client.<br>o Since the importance of clearing the actinomyces colonization in the asymptomatic client is not established, there is no basis for recommending a repeat Pap to check for clearing of actinomyces.<br><br>Spotting, Bleeding<br>• Rule out pregnancy, infection or partial expulsion and manage appropriately.<br>• If client complains of excess bleeding within the first three months after insertion,<br>o Reassure that it is likely to get better in subsequent cycles,<br>o Check HCT or HGB and give iron supplement, if indicated,<br>o For Copper IUD: US SPR recommends short term NSAIDs for 5-7 days.<br>o Rule out other pathology related to vaginal bleeding.<br><br>Cramping or Pain – varying degrees of discomfort may be felt at the time of insertion and may be followed by cramping pain over the next 10-15 minutes.<br>• Pain with sounding of the uterus during insertion<br>o Go slowly, consider smaller sound<br>o If severe, check alignment of uterine cavity on bimanual exam, and consider using a paracervical block before proceeding. |

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| | • Pain at the time of insertion persists, with signs of abdominal tenderness<br>  o If the string is present, treat as pelvic infection<br>  o If the string is absent, consider possibility of perforation, migration, expulsion or pregnancy and refer to physician or emergency room.<br>  o If severe: rule out perforation, pregnancy or infection. Check blood pressure and pulse. Consider removing the IUD if indicated.<br>  o If mild: prescribe a mild analgesic such as Ibuprofen.<br><br>Severe post-insertion reaction, such as syncope<br>• If placement is questionable, remove the IUD. An IUD can be re-inserted now or at a later date.<br>• If the IUD is properly placed, and pulse <60 beats/min, consider the use of ammonium capsules (smelling salts). If symptoms persist, consider atropine 0.5 mg IV. IV fluids may be helpful.<br>• Call 911 for emergency services<br>• Remove the IUD if necessary<br><br>Partial expulsion of IUD<br>• Without signs of infection, remove IUD and another IUD may be inserted if reasonably certain woman is not pregnant and urine pregnancy test is negative.<br>• With PID or question of PID, treat with antibiotics and remove the partially expelled IUD. Provide alternative contraception. Another IUD may be inserted after 3 cycles.<br>• Consider EC<br><br>Pregnancy with IUC in situ- A woman pregnant with an IUD in place must be evaluated promptly to confirm an intrauterine pregnancy and to exclude an ectopic pregnancy.<br>• Do highly sensitive pregnancy test and pelvic exam<br>• If the client is pregnant and the IUD string is visible, the IUD should be removed, regardless of plans to continue or terminate the pregnancy.<br>  o Counsel the client that an ectopic pregnancy, SAB, or sepsis is a possibility and review signs and symptoms of each.<br>  o Refer the client for health care services.<br>  o If the client chooses to keep the IUD, advise her to seek care promptly and especially with heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.<br>• If the client is pregnant and the string not visible, explain the risks of ectopic pregnancy, SAB and sepsis with an IUD in situ during pregnancy.<br>  o Review the warning signs of infection, SAB and ectopic pregnancy, including where to seek emergency care. |

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| | o Refer to physician immediately for follow-up.<br>• Ectopic pregnancy<br>o IUD significantly reduces a woman's risk of an ectopic pregnancy, because the IUD prevents all types of pregnancies. Should a pregnancy occur with an IUD in place, the ratio of ectopic to intrauterine pregnancies may be increased.<br><br>Absent IUC Strings<br>• If menses have not been missed and there is no abdominal pain:<br>o After ruling out pregnancy, attempt to determine if the IUD is in the uterus by gently exploring the cervix for the strings.<br>o If the strings are located, bring them to their appropriate place.<br>o If the strings are not found, the clinician may elect to discuss and provide an alternative method of contraception with the client and have her return with the next menses to check again for the string OR obtain a pelvic ultrasound to determine if the IUD is in the uterus.<br>▪ If the IUD is seen on ultrasound, clarify the location to R/O perforation. If the IUD is in the uterus, nothing else needs to be done.<br>▪ If the IUD is not located by pelvic ultrasound, order an abdominal X-ray to differentiate IUD expulsion from translocation into the abdominal cavity. Translocated intraperitoneal IUD should be removed as promptly as possible, as copper-bearing IUDs are known to cause dense adhesions.<br>• If menses have been missed and/or there are signs and symptoms of infection:<br>o Rule out pregnancy<br>o See management of pregnancy with IUD in situ or PID with IUD. |
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| **IUD Removal** | Subjective Data<br>• LMP and previous menstrual period<br>• Medical history update<br>• History of recent intercourse, if client not menstruating<br>• Reason for IUD removal<br><br>Objective Data<br>• Physical exam/pelvic exam as indicated.<br>• Laboratory as indicated.<br><br>Assessment and Plan |

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| | • Client requesting reinsertion of IUD:<br>  ○ Reinsertion may be done at the same visit<br>• Client requesting change in contraceptive method<br>  ○ Counsel regarding other methods of birth control. Hormonal methods may be initiated before the IUD is removed.<br>  ○ Remove IUD. If client is not menstruating, counsel on risks of pregnancy. Consider EP.<br>  ○ Provide interim method of birth control, as indicated.<br>  ○ If pregnancy is desired, preconception counseling, including the benefits of folic acid, should be provided.<br>• Client symptomatic of PID – refer to Item D. above. |
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| **Resources** | The Contraceptive Choice Project for resources regarding counseling, training, troubleshooting and forms:<br>http://www.choiceproject.wustl.edu/<br><br>ACOG LARC resources: http://www.acog.org/more-info/increasinglarc and https://www.acog.org/About-ACOG/ACOG-Departments/Long-Acting-Reversible-Contraception |
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**Introduction / What are progestin-only pills (POP)?**
Progestin only oral contraceptive are a Tier 2 contraceptive and are moderately effective. US MEC Categories of medical eligibility criteria for contraceptive use to use when assessing the safety of a contraceptive method for women with specific medical conditions or characteristics.

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| **Management of Women with Special Conditions Requiring Further Evaluation** | Drug Interactions<br>• Anti-seizure medications: Concurrent use of anti-seizure drugs that induce hepatic enzymes may reduce effective plasma steroid levels in oral contraceptive users. These medications include phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine.<br>• Gabapentin (Neurontin®), vigabatrin, ethosuximide and lamotrigine (Lamictal®) have no effect on this enzyme system and do not interfere with contraceptive effectiveness. Valproate/ Valproic Acid (Depakote®) and felbamate (Felbatol®) do not increase breakdown of hormones and may even increase hormone levels. No drug interactions have been reported among epileptic women taking lamotrigine and using POPs.<br>• Rifampin increases hepatic clearance of estrogen and progestin; it is recommended that clinicians not prescribe hormonal contraceptives for women on this drug.<br>• Use of broad-spectrum antibiotics, antifungals, and antiparisitics with POPs is a Category 1.<br>• The FDA has alerted providers that the use of St. John's Wart may decrease the therapeutic effect of combined hormonal methods.<br>• Antiretroviral (ARV) drugs have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. Limited data suggest potential drug interactions between many ARV drugs (particularly some NNRTIs and ritonavir-boosted protease inhibitors) and hormonal contraceptives. These interactions may alter the safety and effectiveness of both the hormonal contraceptive and the ARV drug. Thus, if a woman on ARV treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms is recommended to both prevent HIV transmission and compensate for any possible reduction in the effectiveness of the hormonal contraceptive.<br>• Most studies suggest no association between use of hormonal contraception and progression of HIV, as measured by CD4+ count <200 cells/mm3, initiation of antiviral therapy, or mortality. |
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| **Client Education / Informed Consent** | • Fact sheet on all contraceptive options available if she is a new client or is undecided as to what method she wishes to use;<br>• Fact sheet on the client's chosen method<br>• A copy of the FDA approved detailed client labeling pamphlet. The importance of reading the FDA pamphlet must be explained to the client; |

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| | • Instructions on correct use of the method;<br>• Information about the effectiveness of her method and that the effectiveness of hormonal contraception may be decreased by some medications;<br>• The importance of scheduled follow-up visits;<br>• Importance of informing other providers of their use of oral contraceptives;<br>• Information regarding discontinuation of her method. If she does not wish to get pregnant, she should start using another method before the day she was due to start her next cycle;<br>• Information regarding sexually transmitted infections (STIs), including counseling that hormonal contraceptives provide no protection. Use of either male or female condoms should be recommended for clients in need of protection from STIs;<br>• Non contraceptive benefits of the method;<br>• Possible side effects and how to manage side effects; and<br>• Warning signs and symptoms and to seek care immediately for rare but serious adverse events, such as heart attack, stroke, blood clot in extremity or lungs. |
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| **Medical Screening and Evaluation** | • History<br>• Examination<br>• Laboratory |
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| **Provision of POPs** | Follow US SPR recommendations for initiation of POPs<br>http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm<br><br>POPs can be started at any time if it is reasonably certain that the woman is not pregnant. If the health care provider is uncertain whether the woman is pregnant, the benefits of starting hormonal contraceptives likely exceed any risk.<br><br>Starting hormonal contraceptives should be considered at any time with a follow up pregnancy test in 2-4 weeks POPs may be started in lactating and non-lactating women at any time postpartum. The U.S. Medical Eligibility Criteria for Contraceptive Use lists POPs as a Category 2 for breastfeeding women less than one month postpartum.<br><br>A health-care 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:<br>• is ≤7 days after the start of normal menses<br>• has not had sexual intercourse since the start of last normal menses<br>• has been correctly and consistently using a reliable method of contraception<br>• is ≤7 days after spontaneous or induced abortion |

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| | • is within 4 weeks postpartum<br>• is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrhoeic, and <6 months postpartum<br><br>A pregnancy that does occur in a woman taking mini-pills is more likely to be ectopic. Some sources postulate that 10% of pregnancies that occur to mini-pill users are ectopic.<br>POPs inhibit ovulation in about half of cycles, though rates vary widely by individual. Serum levels peak at two hours after taking a POP and return to baseline at 24 hours. Taking POPs at the same time each day is important. It takes 48 hours to achieve the contraceptive effect on cervical mucus.<br><br>A blood pressure must be documented for all women starting a hormonal method and then checked and documented periodically as long as the woman is using the method.<br><br>Provide or prescribe up to a 1-year supply of the contraceptive method, e.g. 13, 28- day pill packs. The more cycles provide, the higher the continuation rates.<br><br>See US SPR for instructions on missed POPs and vomiting or severe diarrhea that occurs within 3 hours after taking a pill. |
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| **Follow-Up** | Routine follow up is not recommended unless indicated. Provider recommendations for follow up visits are based on factors such as whether the woman has certain medical conditions or multiple medical conditions in need of monitoring.<br><br>Advise woman to return to the clinic at any time to discuss side effects, problems or if she wants to change her method.<br><br>At other routine visits the client should be assessed for her satisfaction with her method, changes in health status including medications that would impact the safe use of her method (e.g. category 3 and 4 conditions for the method), assess blood pressure, and consider assessing weight changes.<br><br>Monitor blood pressure as indicated or when client returns for annual visit. |
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## What are fertility awareness-based methods (FAM)?

This policy provides direction for reproductive health clinics to assist clients in their use of fertility awareness- based methods as birth control.

Fertility Awareness-Based (FAB) methods help couples understand how to avoid pregnancy or how to become pregnant. FAB methods are based on: 1) identifying the fertile days of the menstrual cycle through monitoring the cycle days (e.g., Standard Days method and Calendar Rhythm method; 2) observing fertility signs such as cervical secretions, and basal body temperatures (e.g., Two-day Method, the Billings Ovulation Method, Symptothermal Method).

Approximately 25% of women using FAB methods will experience an unintended pregnancy during the first year of typical use. FAB methods are reversible and can be used by women of all ages.

FAB methods do not protect against sexually transmitted infections (STIs).

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| **Protocol** | MDs, NPs, PAs, DOs, and RNs may provide information and counseling to any client who requests the Fertility Awareness-Based method.<br>• No medical conditions become worse by using FAB methods.<br>• The U.S. MEC identifies several conditions which makes using Fertility Awareness-Based method more complicated.<br>o **Delay** (use of calendar or symptom-based methods until the following conditions are evaluated or corrected):<br>▪ Breastfeeding < 6 weeks postpartum - ***both methods***;<br>▪ Breastfeeding ≥ 6 weeks - ***calendar-based method***;<br>▪ Postpartum (in non-breastfeeding women) < 4 weeks - ***both methods***;<br>▪ Postpartum (in non-breastfeeding women) ≥ 4 weeks - ***calendar-based method*** (after completion of three postpartum menses may begin calendar-based method);<br>▪ Post abortion - ***calendar-based method (***the client can start calendar method after she has had at least 1 post abortion menses; clients who before this pregnancy had most cycles of 26-32 days can then use the Standard Days Method). May offer methods appropriate for the postpartum period before that time;<br>▪ Current irregular vaginal bleeding – ***both methods***;<br>▪ Current vaginal discharge – ***symptom-based method until after treatment***;<br>▪ Use of drugs that affect cycle regularity, hormones, and/or fertility signs – ***both methods*** (The condition should be carefully evaluated, and a barrier method offered until the |

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| | degree of effect has been determined or the drug is no longer being used); or<br>▪ Acute diseases that elevate body temperature: – ***symptom-based method***.<br>o **Caution (method is normally provided in routine setting but with extra preparation and precautions - e.g. special counseling to ensure correct usage):**<br>▪ Post menarche – ***both methods***;<br>▪ Perimenopause – ***both methods***;<br>▪ Breastfeeding ≥ 6 weeks – ***symptom-based method***;<br>▪ Breastfeeding - after menses returns – ***both methods***. After 3 postpartum menses and cycles are regular, the client can use calendar method; after 4 postpartum menses and if the most recent cycle lasted 26-32 days the client can use the Standard Days Method. Offer a barrier method if the client plans to use a FAB method later;<br>▪ Post abortion – ***symptom-based method***;<br>▪ Use of drugs that effect cycle regularity, hormones, and/or fertility signs – ***both methods*** (The condition should be carefully evaluated and a barrier method offered until the degree of effect has been determined or the drug is no longer being used); or<br>▪ Chronic diseases that elevate body temperature – ***symptom-based method***. Temperature-based methods are not appropriate for women with chronically elevated temperatures. In addition, some chronic diseases interfere with cycle regularity, making calendar methods difficult to interpret.<br>o **Accept** (no medical reason to deny the FAB method in these circumstances):<br>▪ Postpartum ≥ 4 weeks – ***symptom-based method***;<br>▪ Vaginal discharge – ***calendar-based method***; or<br>▪ Chronic and acute diseases that elevate body temperature- ***calendar-based method***.<br>• Clients with conditions that make pregnancy an unacceptable risk should be advised that FAB methods may not be appropriate for them. |
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| **Procedure** | Provide client-centered care through quality counseling and education using the 5 key principles:<br>• Establish and maintain rapport with the client;<br>• Assess the client's needs and personalize discussions accordingly;<br>• Work with the client interactively to establish a plan; |

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| | • Provide information that can be understood and retained by the client; and<br>• Confirm the client's understanding using a technique such as the teach- back method.<br><br>Review medical history:<br>• Significant illness;<br>• Allergies;<br>• Current medications - prescriptive and OTC;<br>• Use of tobacco, alcohol, and other drugs;<br>• Immunization and Rubella status;<br>• Contraceptive use;<br>• Menstrual history;<br>• Sexual history including risk for STIs;<br>• Obstetrical history;<br>• Gynecological and Pap test history;<br>• Surgical history;<br>• Hospitalizations;<br>• Family History;<br>• In utero exposure to diethylstilbestrol (DES); and<br>• Reproductive life plan.<br><br>Review last menstrual period (LMP) and compliance with contraceptive method (if applicable). Assess for risk of current pregnancy. Offer pregnancy test if indicated.<br>• A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets the following:<br>o Is ≤7 days after the start of normal menses;<br>o Has not had sexual intercourse since the start of last normal menses;<br>o Has been correctly and consistently using a reliable method of contraception;<br>o Is ≤7 days after spontaneous or induced abortion;<br>o Is within 4 weeks postpartum;<br>o Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrhoeic, and < 6 months postpartum. |

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| | Assess for recent sexual activity where intercourse was unprotected and offer emergency contraception (EC) for immediate use if indicated.<br>• Note that if Ella® is the EC formulation administered, a reliable barrier method of contraception should be used with subsequent acts of intercourse that occur within the next 14 days. Because Ella® and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effect. After using Ella® if a woman wishes to use hormonal contraception, she should do so no sooner than 5 days after the intake of Ella®.<br><br>Blood Pressure: normal <140/90; refer clients with blood pressure reading ≥ 140 systolic or ≥ 90 diastolic to a primary care provider for further evaluation.<br><br>Weight/Height: obtain body mass index (BMI)<br><br>Screen for STIs (if the client has not been screened) according to STI screening guidelines (see *STI Screening Policies and Procedures*).<br><br>Discuss the client's reproductive life plan about becoming pregnant by asking:<br>o Do you have children now?<br>o Do you want to have (more) children?<br>o How many (more) children would you like to have and when?<br>▪ If the client does not want a child at this time and is sexually active, then offer contraceptive services.<br>▪ If the client desires pregnancy testing, then provide pregnancy testing and preconception counseling.<br>▪ If the client wants to have a child now, then provide services to help the client achieve pregnancy and provide preconception counseling.<br>▪ If the client wants to have a child and is experiencing difficulty conceiving, then provide basic infertility services.<br><br>Present all birth control method options for which the client has no U.S. MEC category 3 or 4 risk conditions.<br><br>Each client will receive client instructions regarding warning signs, common side effects, risks, method of use, alternative methods, use of secondary method, and |

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| | clinic follow-up schedule. Document client education and understanding of the method of choice. |
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| **Plan** | Initiating the fertility awareness-based methods<br><br>• Standard Days Method (SDM):<br>  o Clients must avoid unprotected sexual intercourse on days 8-19 of the menstrual cycle.<br>  o Clients with 26-32-day menstrual cycles may use this method.<br>  o Clients may use a barrier method of contraception, for pregnancy protection, on days 8-19 if desired.<br>  o If the client has unprotected sexual intercourse during days 8-19, consider the use of EC, if appropriate.<br>  o Clients with 2 or more menstrual cycles of < 26 or > 32 days within any 1 year of SDM use:<br>  ▪ Advise the client that the method might not be appropriate because of higher risk of pregnancy.<br>  ▪ Help the client to consider another method.<br><br>• Calendar Rhythm Method:<br>  o Prior to starting this method, the client must record the length of the previous 6 menstrual cycles to identify the longest and shortest cycles.<br>  o Calculate the fertile period by looking at the calendar.<br>  ▪ The first day of the fertile phase is found by subtracting 18 days from the length of the shortest cycle.<br>  ▪ The last day of the fertile phase is found by subtracting 11 days from the longest cycle.<br>  ▪ Avoid pregnancy by abstaining from sexual intercourse from the first day of the fertile period to the last day of the fertile phase.<br><br>• Two Day Method<br>  o Is based on assessing for the presence or absence of cervical secretions (the presence of secretions conforms sufficiently to the actual fertile window so that further evaluation of the secretions' characteristics is not necessary).<br>  ▪ Clients are counseled to avoid unprotected sexual intercourse on all days there is the presence of secretions; AND on the first day following a day with secretions.<br>  ▪ The mean length of the identified fertile period is 13 days. |

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| | ○ Instruct the client in how to observe, record, and interpret their cervical secretions:<br>▪ Color;<br>▪ Elasticity;<br>▪ Abundance; and<br>▪ Viscosity<br><br>○ Counsel the client on how to recognize if they have secretions:<br>▪ By touching the vulva with the fingers, or using toilet paper to collect secretions and assess their characteristics;<br>▪ Noting secretions on underwear; or<br>▪ Simply feeling for wetness at the vulva.<br><br>○ Advise the client to observe for secretions 2 times per day (adjust observations according to the times they typically have intercourse):<br>▪ Once in the afternoon; and<br>▪ Once before going to bed at night.<br>▪ Clients may start the method anytime during a cycle.<br><br>• Billings Ovulation Methods:<br>○ Advise the client to observe cervical secretions several times each day.<br>○ Instruct the client in how to observe, record and interpret their cervical secretions:<br>▪ Color;<br>▪ Elasticity;<br>▪ Abundance; and<br>▪ Viscosity.<br>○ Advise the client to avoid unprotected sexual intercourse:<br>▪ During menses (menstrual bleeding could obscure the presences of secretions);<br>▪ On preovulatory days following days with intercourse (possible confusion with semen);<br>▪ On all days with wet, slippery, transparent, or stretchy secretions; and<br>▪ Until four days past the last day with wet secretions.<br>○ Based on rules, clients should avoid unprotected intercourse for approximately 14 to 17 days of each cycle. |

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| | • Symptothermal Method:<br>  o Based on changes in cervical secretions and basal body temperature:<br>  ▪ Requires client to observe and evaluate their cervical secretion several times each day.<br>  ▪ Take their temperature each morning before rising (with Basal Body Temperature thermometer).<br>  ▪ Record and interpret their findings to determine whether the day is a fertile day.<br>  ▪ Some may check the position and feel of the cervix (cervix rises to the top of the vagina, becomes softer and moister when approaching ovulation).<br>  o Clients need to abstain or avoid unprotected intercourse for approximately 12 to 17 days each cycle.<br>  o Offer and provide condoms as a back-up method and for STI protection.<br><br>The decision to offer and dispense future-use EC should be made on an individualized basis and should include shared decision making between the provider and the client. The practice of offering and dispensing future-use EC to *all* clients has had no impact on unplanned pregnancy rates. Data shows that clients who had EC available at the time of unprotected intercourse either didn't take it at all or took it incorrectly. Additionally, the practice of providing EC to all clients represents a significant cost to the agency. Clients *requesting* (those that self-identify that they need or want) EC for future use and those using less reliable methods of birth control (tier 3 methods) might benefit most from having future-use EC made available.<br><br>• Instruct the client to wait 5 days after the administration of Ella® before initiating hormonal contraceptives. Recommend the use of a barrier method of contraception with all subsequent acts of intercourse that occur within the next 14 days. |
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| **Routine Follow-Up** | The recommendations listed below address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women and men. Although routine follow-up is not necessary for the use of fertility awareness-based as a birth control method, recommendations for follow- up might vary for different users and different situations. Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple conditions may benefit from more frequent follow-up visits.<br>• Advise the client to return at any time to discuss any problems or concerns or if wanting to change the method being used. No routine return visit is required for this method of birth control.<br>• At other routine visits, healthcare providers should: |

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| | ○ Assess the client's satisfaction with the contraceptive method and whether the client has any concerns about method use; and<br>○ Assess any changes in health status that would change the appropriateness of using the method. |
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| **Client Education** | All women who are planning or capable of pregnancy should be counseled to take a daily supplement containing 0.4 to 0.8 milligrams (400 to 800 µg) of folic acid.<br><br>Provide the client information on all birth control methods; it is important that the client understands all options available to decrease risk of pregnancy.<br><br>Provide educational material or resources to assist the client in being successful in determining their fertile days.<br><br>Advise the client on the importance of her partner's cooperation in order to be successful in preventing an unintended pregnancy.<br><br>Advise the client to use condoms for protection against STIs.<br><br>Advise the client to call the clinic if she has any questions or concerns regarding birth control methods.<br><br>First year typical use failure rates for fertility awareness methods range from 12 % to 25% (Zieman M, Hatcher RA. Managing Contraception. Tiger, Georgia: Bridging the Gap Foundation, 2015, pg. 53). |
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**Criteria for Starting the Standard Days Method**

| **Women whose menstrual cycles are usually between 26 and 32 days** | |
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| Date of last period known | Start immediately |
| Date of last period unknown | Start on first day of next period |
| **Special circumstances** | |
| Postpartum/breastfeeding | **Wait for at least 4 periods** |
| | Start after two most recent periods are about a month apart |
| Three-month DMPA injection used for contraception | **Wait for at least 90 days after last injection** |
| | Start after two most recent periods are about a month apart |
| Pill, patch, implant, EC, IUD, Miscarriage or abortion | **Cycles before using method or pregnancy were 26 to 32 days long** |

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| | Start on first day of next period |
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| **Resources**<br><br>Two Day Method®<br>http://irh.org/twoday-method/<br>http://www.twodaymethod.com/<br><br>Billings Ovulation Method™<br>http://billings.life/en/ | Standards Day Method®<br>http://irh.org/standard-days-method/<br><br>Cycle Beads®<br>Uses color coded beads (Cycle Beads) to monitor the days of a women's menstrual cycle<br>http://www.cyclebeads.com/ |
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## SECTION 8
## Cervical Cancer Screening What

### is management of abnormal cervical cytology?

This policy provides direction for reproductive health clinics to assist clients in the management of abnormal cervical cytology.

The cause of pre-invasive cervical lesions is an accumulation of DNA mutations in immature metaplastic cells as a consequence of persistent human papilloma virus infection (HPV). Genital HPV infections are transmitted by skin-to-skin contact during sexual intercourse. More than 100 DNA types of HPV have been identified; a limited number of these are associated with premalignant and malignant epithelial lesions of the lower genital tract. These high risk (HR) types can be identified through lab testing, often performed in conjunction with the Pap test. Types 16 and 18 account for about 70% of cervical intraepithelial neoplasia (CIN) 2 or 3 lesions and cervical cancers, while the remaining 30% are due to HPV types 31, 33, 35, 39, 45, 51, 52, 56, and 58.
Infections due to HPV types 6 and 11, the cause of genital warts and most low grade cervical lesions, are felt to exhibit no malignant potential.

Women with abnormal Pap screening/testing results will be treated and managed according to the American Society for Colposcopy and Cervical Pathology (ASCCP) 2019 recommendations. The updated guidelines use a risk-based method, including screening history and current test results, to guide the need for surveillance, colposcopy, or treatment. The need for cervical cytology screening or treatment should not hinder or delay initiation of contraceptive services. See individual method specific *Policies and Procedures* for guidance on U.
S. Medical Eligibility Criteria (MEC) risk categories for contraceptive use for women in need of abnormal cervical cytology management.

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| **Protocol** | MDs, NPs, PAs, DOs, and RNs may provide clients with information on abnormal cervical cytology management. A referral to the client's provider of choice will be provided when the determination of follow-up falls outside the agency's scope of practice. |
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| **Procedure** | Provide client-centered care through quality counseling and education using the 5 key principles:<br>• Establish and maintain rapport with the client;<br>• Assess the client's needs and personalize discussions accordingly;<br>• Work with the client interactively to establish a plan;<br>• Provide information that can be understood and retained by the client; and<br>• Confirm the client's understanding using a technique such as the teach- back method.<br><br>All abnormal cervical cytology results will be reviewed by the MD, NP, or PA and follow-up recommendations will be made based on the client's history and |

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| | cytology results. The Medical Director or local OB/GYN will be consulted for clients that fall outside of the ASCCP algorithms.<br><br>Review medical history: subjective information reported by the client when the Pap test was performed, as well as records of prior testing/treatment should be reviewed to help determine appropriate follow-up of results. Items to review:<br><br>• Prior Pap screening history:<br>  o Age screening began;<br>  o Frequency of screening;<br>  o Most recent screening/testing; and<br>  o Any history of abnormalities.<br><br>• Prior history of + high risk (HR) HPV testing and results.<br>• Prior history of abnormal cervical cytology management:<br>  o Colposcopy; and/or<br>  o Treatment for dysplasia.<br><br>• Review of symptoms. Review any client reported symptoms at the time of screening/testing. Most cervical dysplasia and many cancers are asymptomatic, but red flags include unexplained chronic vaginal discharge, or unexplained bleeding or spotting, particularly if post-coital.<br>• History of vaccination against HPV<br><br>The mode and urgency of communicating abnormal results to the client depends on the severity of the abnormality.<br>• Clients who need immediate colposcopy or referral should be contacted by phone; if unable to contact by phone, a letter should be sent (either regular mail or certified). If client does not respond to the first letter within a month, a certified letter should be sent.<br>• For clients who indicate they cannot be contacted, the agency must have a procedure in place to reach them.<br><br>All clients referred for abnormal cervical cytology management will receive verbal and written information on:<br>• HPV;<br>• Abnormal cervical cytology; and<br>• The procedure for which they are being referred.<br>• Document the client education and the client's understanding of information that was provided.<br><br>Actively refer the client to the provider who will perform the cervical procedure (including faxing medical records and scheduling the procedure). |

<table>
<tr><td></td><td>Obtain a signed Release of Information (ROI) for communication with that provider (although a signed ROI is not required for a referral for on-going clinical management, this often facilitates the transfer of information).<br><br>If there is any question as to the need for the colposcopy or the appropriateness of that referral, consultation with that provider should take place via telephone before scheduling the client.<br><br>Pertinent records, including copies of Pap/HR HPV results and a cover letter, should be faxed to the provider's office, well before the day of the procedure. Assist the client as needed in making the appointment.</td></tr>
<tr><td></td><td></td></tr>
<tr><td>HPV Vaccination</td><td>Offer routine vaccinations to all unvaccinated or under-vaccinated clients (males and females) ages 9 to 26.<ul><li>Ideally, HPV vaccinations should be offered and completed prior to potential exposure to HPV through sexual contact.</li><li>The vaccine does not need to be discussed with most adults aged 27-45; however, based on history, some adults may benefit from the discussion and vaccine.</li><li>For under-vaccinated women over age 26 years, complete the series.</li></ul>Women should be advised that the HPV vaccine will have no therapeutic effect on an existing HPV infection, genital warts, or current abnormal cervical cytology.</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Plan</td><td>Examine the patient's current results and history to determine the immediate CIN 3+ risk. (Recommend using the ASCCP phone or computer application.) If the risk is ≥ 4%, then immediate management via colposcopy or treatment is indicated. If the immediate risk is < 4%, the 5-year CIN 3+ risk is examined to determine whether patients should return in 1, 3, or 5 years.<br><br><table><tr><th colspan="2">CIN 3+ Risk Thresholds for Management</th></tr><tr><th>Management Option</th><th>Clinical Action Threshold</th></tr><tr><td>Expedited treatment preferred*</td><td>≥ 60%†</td></tr><tr><td>Expedited treatment or colposcopy acceptable*</td><td>25% to < 60%†</td></tr></table></td></tr>
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| Colposcopy recommended | 4% to < 25%† |
| Repeat test in 1 year | 0.55% to < 4%‡ |
| Repeat test in 3 years | 0.15% to < 0.55%‡ |
| Return to routine screening at 5-year intervals | < 0.15%‡ |

*For nonpregnant patients 25 years or older.

†Refers to immediate CIN 3+ risk.

‡Refers to 5-year CIN 3+ risk.

Data from Perkins RB, Guido RS, Castle PE, Chelmow D, Einstein MH, Garcia F, et al. 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors. J Low Genit Tract Dis. 2020;24(2):102–131.

Abnormal cervical cytology management services are required for the following abnormal cervical results:

- Squamous Cell Carcinoma;
- Atypical Glandular Cells (AGC);
- High-Grade SIL (HSIL);
- Atypical Squamous Cells – Cannot Exclude High Grade Squamous Intraepithelial Lesion (ASC-H);
- Atypical Squamous Cells – Cannot Exclude High Grade Squamous Intraepithelial Lesion (ASC:H) and High Grade Squamous Intraepithelial Lesion (HSIL) in women 21 – 24;
- Low-Grade Squamous Intraepithelial Lesion (LSIL) for women with no HPV test or + high risk (HR) HPV;
- Atypical Squamous Cells of Undetermined Significance (ASCUS) with +HR HPV;
- Women age 30 and older with a negative cytology screening results and +HR HPV;
- Women age 30 and older with an unsatisfactory screening result and +HR HPV.

Referral to Colposcopy:

- All clients will be referred to colposcopy services following the ASCCP guidelines.
- Clinic staff will work with the client to access financial and clinical services within the community to offset the cost if this is a concern for the client.

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| | Referral to loop electrosurgical excision procedure (LEEP):<br>• All clients will be referred for a LEEP procedure following the 2019 ASCCP guidelines, and as determined by the provider performing the colposcopy or by the Medical Director.<br>• Clinic staff will work with the client to access financial and clinical services within the community if this is a concern for the client. |
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| **Routine Follow-Up** | Follow-up after the procedure will be based on the findings from the procedure, recommendations from the provider performing the procedure, and following the ASCCP's recommendations (available at https://www.asccp.org/management-guidelines).<br>Results of the procedure will be recorded in the client's medical record and in the *Client Management Tracking System.* The client's medical record will be flagged indicating when/where next the follow-up will occur. |
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| **Client Education** | All women who are planning or capable of pregnancy should be counseled to take a daily supplement containing 0.4 to 0.8 milligrams (400 to 800 µg) of folic acid.<br><br>Discuss and provide written information on abnormal cervical cytology results, the nature of HPV infections, and the procedure indicated.<br><br>Inform the client that the risk of acquiring cervical cancer (and associated sexually transmitted infections (STIs) such as HPV and HIV) can be reduced by (as appropriate to the individual):<br>• Completing the HPV vaccination series;<br>• Reducing the number of sexual partners;<br>• Using condoms;<br>• Being abstinent; and<br>• Delaying onset of sexual intercourse.<br><br>Educate women that smoking cessation, safer sex practices, and eating a diet rich in fruits and vegetables may also decrease the risk of cervical cancer.<br><br>Advise the client to contact the clinic if she has any questions or concerns. |

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| | • Provide information regarding the provider where the client is being referred. This will help decrease the patient's anxiety.<br><br>Reinforce importance of return for scheduled follow-up care. |
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## Cytology Screening Guidelines

| Population | Recommended screening method | Management of screen results | Comments |
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| < 21 years | No screening | | HPV testing should NOT be used for screening or management of ASC-US in this age group |
| 21-29 years | Cytology alone every 3 years | Examine the patient's current results and history to determine the immediate CIN 3+ risk. (Recommend using the ASCCP phone or computer application.)<br>If the risk is ≥ 4%, then immediate management via colposcopy or treatment is indicated.<br>If the immediate risk is < 4%, the 5-year CIN 3+ risk is examined to determine whether patients should return in 1, 3, or 5 years.<br>All positive primary HPV screening tests, regardless of genotype, should have additional reflex triage testing performed from the same laboratory specimen (e.g., reflex cytology). | HPV testing should NOT be used for screening in this age group |
| 30-65 years | HPV and Cytology "Cotesting" every 5 years (Preferred)<br>Cytology alone every 3 years (Acceptable) | | Screening by HPV *alone* is not recommended for most clinical settings |
| > 65 years | No Screening following adequate negative prior screening | | Women with a history of CIN2 or a more severe diagnosis should continue routine screening for at least 25 years. |
| After posttreatment management of histologic HSIL, CIN 2, CIN 3, or AIS | Continued surveillance with HPV testing or cotesting at 3-year intervals for at least 25 years is recommended after treatment | | Continued surveillance at 3-year intervals beyond 25 years is acceptable for as long as the patient's life expectancy and ability to be screened are not significantly compromised by serious health issues. |
| After Hysterectomy | No Screening | | Applies to women *without* a cervix and *without* a history of CIN2 or a more severe |

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| | | | diagnosis in the past 25 years or cervical cancer free |
| HPV Vaccinated | Follow age-specific recommendations (same as unvaccinated women) | | |

## Reference

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## What is Referral and Follow-up of Abnormal Findings?

The Title X Clinic shall refer and/or treat all clients with abnormal physical findings or laboratory results. Treatment or referral will be determined by Title X Clinic scope or practice, Standard Care Agreement between CNP and Medical Director and Clinic Procedures and Protocols.

Clients of the Title X Clinic shall be provided appropriate referral and/or treatment to expedite follow-up examination, treatment, and care.

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| **Procedure** | Follow-up procedure for Abnormal Pap Smear and/or Abnormal Physical Findings<br><br>• Clinician will document recommendation for follow-up and method of follow-up in interim notes of client record.<br>• Client will be notified by method of choice as indicated in client record to make every attempt to assure client privacy. If "any" method is indicated, client contact method will be at clinician discretion to provide optimal care. If a letter is sent, a copy of will be placed in client record. Contact will be documented.<br>• Tickler system includes a file card with client's name and recommendation for follow-up.<br>• Tickler system also includes memo sticker on client order sheet to remind staff of need for client follow-up with any client contacts.<br>• Card file will be reviewed, and appropriate contact will be made at least monthly, possible more often at clinician discretion.<br>  o Client will be contacted with recommendation for follow-up.<br>  o A minimum of two attempts will be made to encourage compliance of recommended follow-up.<br>  o If no response or attempt for follow-up is made from client, a third and final letter will be sent Certified, encouraging follow-up and releasing the clinic from responsibility for adverse effects of not completing follow-up.<br>• Referrals for abnormal findings during an exam will have a Release of Medical Information obtained from the patient requesting the report of findings and recommendations from physician. |
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| **Colposcopy/physician referral** | Indications for colposcopy/physician referral<br><br>• As indicated under Management of Pap Results<br>• History of physical exam which reveals possible diethylstilbestrol exposure. |

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| | • Obvious or suspected cervical aberration.<br>• Clinician discretion |
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## What is preconception health?

Preconception describes anytime that a woman of reproductive potential is not pregnant but at risk of becoming pregnant, or when a man is at risk for impregnating his female partner. A written protocol and procedure must be current, available and consistent with national standards of care. Agencies must offer preconception health services to females and males as part of core family planning services. Preconception health services promote health before conception thereby reducing pregnancy-related adverse outcomes (low birth weight, premature birth, infant mortality), promote positive birth outcomes and improve the health of male and female clients even if they choose not to have children.

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| **Subjective Data** | Medical history for females must include:<br>• Reproductive life plan<br>• Sexual risk assessment<br>• Reproductive history, including history of prior pregnancy outcomes and complications<br>• Chronic disease management<br>• Gynecological history<br>• Environmental exposures<br>• Medications<br>• Genetic conditions<br>• Family history<br>• Intimate partner violence<br>• Social history/risk behaviors<br>• Immunizations<br>• Depression<br><br>Medical history of males must include:<br>• Reproductive life plan<br>• Sexual health assessment<br>• Past medical and surgical history that impairs reproductive health<br>• Genetic conditions<br>• History of reproductive failures, or conditions that can reduce sperm quality (obesity, diabetes, varicocele)<br>• Social history/risk behaviors<br>• Environmental exposures<br>• Immunizations status<br>• Depression |
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| **Objective Data** | Assessment must include: |

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| | • Height, weight, BMI (screen for obesity)<br>• Vital signs: temperature, heart rate, respiration rate, blood pressure, and pain<br>• BP (screen for hypertension)<br>  o All clients—screen yearly<br>  o If BP <120/80---screen yearly, continue yearly<br>  o If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit and if average BP >140/90 recheck at next visit or in 1 week and refer if sustained BP >140/90.<br>• No physical exam is needed for Preconception. Exams may be needed to evaluate problems raised by review of systems or complaints raised by the client. |
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| **Assessment** | Laboratory testing must be recommended based on risk assessment. Options may include:<br><br>• Diabetes screening (for type 2 diabetes in asymptomatic male and female adults) with sustained BP (either treated or untreated)>140/90.<br>• STI testing<br>• Zika screening if indicated by a Zika Risk Assessment |
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| **Plan** | Identify and modify biomedical, behavioral, and social risks to a woman's health or pregnancy outcomes through prevention and management.<br><br>• Develop an action plan on how to maintain and/or attain a healthy lifestyle to promote a positive planned pregnancy outcome in the future<br>• Zika sexual transmission counseling<br>• Encourage the client to examine potential health risks (including chronic conditions) and make positive changes where indicated---see client education and referrals below.<br>• Facilitate contraceptive services if pregnancy not desired<br>• Provide client with listing of community resources |
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| **Patient Education/Counseling** | • Importance of regular preventive health care and chronic disease management.<br>• Some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (e.g., an obstetrician or midwife).<br>• Provide a daily supplement containing (400-800 mcg) of folic acid (or a prenatal vitamin).<br>• Avoid smoking, alcohol and other drugs |

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| | • Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish)<br>• Offer/Refer for any needed STI screening (including HIV)<br>• Refer for age appropriate vaccinations, if indicated<br>• Zika virus education and prevention strategies<br>  ○ Avoid traveling to impacted areas<br>  ○ Avoiding mosquito bites if traveling to impacted areas<br>  ○ Using condoms to prevent transmission of virus<br>  ○ Avoiding pregnancy if infected or partner infected<br>• "There is no evidence that COVID vaccination affects present or future fertility. The American Society of Reproductive Medicine (ASRM) recommends that eligible patients who are planning to become pregnant should be vaccinated" (Chervenak et al., p. 470-478). |
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| **Consultation/Referral** | • If client desires, refer for further diagnosis and treatment.<br>• Refer male and female clients for additional services if screening results indicate presence of health condition or as indicated (i.e., tobacco cessation, obesity, diabetes, depression, immunizations). |
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| **Resources** | • CDC Show Your Love<br>• CDC Preconception Health<br>• CDC Vaccine Schedule<br>• FDA Fish in Pregnancy Advisory<br>• Reproductive Life Plan example<br>• Baby & Me, Tobacco Free<br>• Healthy Weight Program<br>• Folic Acid fact sheet |
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## References


Centers for Disease Control and Prevention (CDC). (2014). Providing quality family planning services: Recommendations of the CDC and the U.S. Office of Population Affairs. *MMWR, 63*(4). https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

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Chervenak, F.A. et al. (2021). Professionally responsible coronavirus disease 2019 vaccination counseling of obstetrical and gynecologic patients. *Am J Obstet Gynecol*, *224(5)*. https://doi.org/10.1016/j.ajog.2021.01.027

## What is achieving pregnancy?

Achieving Pregnancy is identifying and assessing clients who desire pregnancy. Counseling and education (including key messages on achieving pregnancy) and addressing misperceptions that many women, men and adolescents have about fertility and infertility will occur for clients who respond to the reproductive life plan question with a "desire for pregnancy."

A written protocol and procedure must be current, available, and consistent with national standards of care. Agencies must offer services for clients who want to become pregnant (achieving pregnancy) to females and males as part of the core family planning services. The goal is to address the needs of client who have been trying to become pregnant for less than 12 months. Providers should advise clients who wish to become pregnant in accordance with current standards of practice.

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| **Subjective Data** | History must include:<br>• Reproductive Life Plan (RLP)<br>  ○ RLP may include:<br>  ▪ When she/he/they want to get pregnant<br>  ▪ Length of time she/they have been trying to get pregnant<br>  ▪ History of pregnancies or infertility<br>  ▪ Partner involvement and support system issues - Support system issues may include family and community support, LGBTQ considerations, single parent considerations, cultural/familial considerations, financial concerns and awareness of other concerns or influences.<br>• Medical history<br>• Immunizations<br>• Medications<br>• Present infectious or chronic health conditions<br>• Genetic conditions<br>• Environmental exposures<br>• Social history/risk behaviors<br>• Sexual health assessment and risk assessment<br>• Mental health<br>• Zika Risk Assessment<br><br>Include for Females:<br>• Reproductive history<br>• Obstetrical/gynecology history<br>• Family history<br>• Intimate partner violence<br><br>□ |

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| | Include for Men:<br>• Past medical/surgical history that might impair reproductive health<br>• Medical conditions associated with reproductive failure that could reduce sperm quality |
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| **Objective Data** | Assessment must include:<br>• Height, weight, BMI (screen for obesity)<br>• BP (screen for hypertension)<br>  o All clients—screen yearly<br>  o If BP <120/80---screen yearly, continue yearly<br>  o If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit and if average BP >140/90 recheck at next visit or in 1 week and refer if sustained BP >140/90.<br>• No physical exam is needed for Achieving Pregnancy. Exams may be needed to evaluate problems raised by review of systems or complaints raised by the client. |
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| **Assessment** | Assess and update the client's physical, sexual and medical history. This may reveal additional issues in the person's health history that need to be addressed. The results can also help determine the need for additional information like fertility awareness or other health services such as: STI screening, preconception care and counseling, infertility services, Zika sexual transmission counseling, and other preventative health services.<br><br>Lab testing may include, as indicated based on client medical and sexual history<br>• STI testing<br>• Diabetic screening<br>• Consider Zika screening if indicated by Zika Risk Assessment. |
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| **Plan**<br><br>Also see Fertility Awareness | While Fertility Awareness education is not required for clients who wish to achieve pregnancy, it can be very helpful (and interesting) for them to know:<br><br>• How pregnancy occurs, including the basics of male and female fertility, and<br>• When during the menstrual cycle a woman is most likely to get pregnant,<br>• Different ways to observe and keep track of naturally occurring signs of fertility,<br>• Tips for maximizing fertility while attempting conception, including how certain diet and lifestyle factors can enhance or reduce fertility. |

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| **Patient Education/Counseling**<br><br>Also see Preconception | Remember to document counseling in the patient record.<br><br>• Importance of regular preventive health care and chronic disease management.<br>• Some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (e.g., an obstetrician or midwife).<br>• Encourage to take a daily supplement containing (400-800 mcg) of folic acid (or a prenatal vitamin) while attempting conception.<br>• Avoid smoking, alcohol and other drugs<br>• Nutritional counseling.<br>  o Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish)<br>  o Fertility rates are lower among women who are very thin or obese<br>  o Limit caffeine to 200 mg per day<br>• Offer/Refer for any needed STI screening (including HIV)<br>• Encourage males to avoid hot tubs.<br>• Many commercially available vaginal lubricants lower fertility rates and should be discouraged.<br>• Refer for age appropriate vaccinations, if indicated<br>• Menstrual calendar, cycle beads, fertility awareness,<br>  o Providing education about peak days and signs of fertility (including the 6-day interval ending on the day of ovulation that is characterized by slippery, stretchy cervical mucus and other possible signs of ovulation).<br>  o Advising that vaginal intercourse every 1-2 days beginning soon after the menstrual period ends can increase the likelihood of becoming pregnant (women with regular menstrual cycles).<br>  o Educating on methods or devices designed to determine or predict the time of ovulation (e.g., over-the-counter ovulation kits, digital telephone applications, or cycle beads) should be discussed.<br>• Zika virus education and prevention strategies<br>  o Avoid traveling to impacted areas<br>  o Avoiding mosquito bites if traveling to impacted areas<br>  o Using condoms to prevent transmission of virus<br>  o Avoiding pregnancy if infected or partner infected |
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| **Consultation/Referral** | • If desired, clients should be provided a referral resource listing for further diagnosis and treatment. |

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| **Resources** | • CDC Show Your Love<br>• CDC Preconception Health<br>• CDC Vaccine Schedule<br>• FDA Fish in Pregnancy Advisory<br>• Reproductive Life Plan example<br>• Baby & Me, Tobacco Free<br>• Healthy Weight Program<br>• Folic Acid fact sheet |
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## References

Centers for Disease Control and Prevention (CDC). (2014). Providing quality family planning services: Recommendations of the CDC and the U.S. Office of Population Affairs. *MMWR, 63*(4). Retrieved from https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

Centers for Disease Control and Prevention. (2019). *Zika virus*. https://www.cdc.gov/zika/index.html

## What is pregnancy testing and counseling?

Pregnancy testing and counseling services are part of the core family planning services as outlined in Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs (QFP), April 25, 2014, http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf pages 13-14). Pregnancy diagnosis and counseling must be provided to all clients in need of this service. Visits for pregnancy testing should include discussion around the client's reproductive life plan.

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| **Standard** | All clients receiving a pregnancy test will be offered information regarding their test results and, if pregnant and the client desires a referral to prenatal care.<br><br>Information may include the limitations of the test itself, nondirective options counseling, and/or prenatal care referral for a positive test result, and contraceptive choices, preconception counseling or infertility counseling for a negative test result. |
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| **Subjective Data** | Clients complete "Request for Pregnancy Test" form or agency-specific form.<br><br>Data to be included in charting and referral:<br>o Menstrual History<br>▪ First day of last menstrual period<br>▪ Was this a normal period, i.e., amount of flow, time of month?<br>▪ If not, when was last normal menstrual period?<br>▪ Are periods usually regular? How often do periods come? How long do they last? Is the flow heavy, medium, scant?<br>▪ Has client missed a period(s) before?<br><br>o Symptoms of Pregnancy Other Than Amenorrhea<br>▪ Early<br>• Breast tenderness<br>• Nausea or vomiting<br>• Urinary frequency<br>▪ Late<br>• Enlargement of abdomen<br>• Fetal movement<br><br>o Obstetrical History<br>▪ Number of pregnancies (gravida)<br>▪ Number of children (para)<br>▪ Number of spontaneous abortions<br>▪ Number of therapeutic abortions<br>▪ History ectopic pregnancies |

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| | ○ Birth Control History<br>▪ Is the client consistently using a method of birth control? If not, how long has she been having unprotected intercourse?<br>▪ If client is presently using birth control, what method, and is she using it correctly?<br>▪ If client had been using birth control in the past, what method, when, and why did she discontinue its use?<br><br>○ Sexual History - When was the last time that the client had intercourse?<br><br>○ Determine if this is a planned/wanted pregnancy. How does she feel about being pregnant? |
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| **Objective Data** | Physical exam, as indicated<br>○ Client with a positive pregnancy test should be counseled to have a physical exam performed as early as possible if not performed at the time of the pregnancy test.<br><br>Laboratory<br>○ Urine HCG<br>○ CT/GC testing<br><br>Assessment and Plan<br>○ Offer all clients information and counseling about the results of their tests, including accuracy and the chance for false-negative or false-positive results. |
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| **Counseling Results** | Title X grantees and sub recipients **must** be in full compliance with Section 1008 of the Title X statute and 42 CFR 595(a)(5), which requires pregnant clients be offered the opportunity to be provided information and counseling regarding each of the following options:<br>• Prenatal care and delivery;<br>• Infant care, foster care, or adoption; and<br>• Pregnancy termination.<br><br>If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and, referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.<br><br>No Title X project may provide abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion (§ 59.5(a)(5)). |

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| | "[w]hile a Title X project may provide a referral for abortion, which may include providing a patient with the name, address, telephone number, and other relevant factual information (such as whether the provider accepts Medicaid, charges, etc.) about an abortion provider, the project may not take further affirmative action (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the patient." 65 FR at 41281 (July 3, 2000). |
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| **Positive Results** | Positive test results<br><br>o If requested to provide pregnancy information and counseling, it must be neutral, factual, and nondirective. All options may be discussed s, except with respect to any option(s) about which the client indicates not wishing to receive such information and counseling.<br>▪ No Title X project may provide abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion (§ 59.5).<br>▪ Providers not wanting to discuss all options counseling may be covered by federal statutes protecting conscience and/or civil rights.<br>o Evaluate the client's support systems.<br>o Written referrals for primary or prenatal care should be given if requested; referrals for further counseling should be encouraged if deemed necessary by clinic staff.<br><br>Continuing the pregnancy<br>o Provide information on the importance of early and continued prenatal care, basic guidelines regarding drugs, alcohol, smoking, and diet during pregnancy and referral to prenatal services.<br>o Ensure that all clients understand the importance of prenatal care early in pregnancy and on a continuing basis, even if the client has not determined whether the pregnancy will be continued.<br>o Emphasize the dangers to the fetus of smoking, alcohol and substance use (over-the-counter, prescription, and/or illicit drug use).<br>o Provide brochures regarding healthy behaviors during pregnancy and referrals to programs that help clients reduce or stop unhealthy behaviors.<br>o Review danger signs and symptoms of pregnancy. |

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| | o Counsel about the impact of diet on fetal development and appropriate nutrition information, particularly regarding folic acid supplementation.<br>o Counsel about the availability of prenatal care and give referral information. Give information about Medicaid eligibility if applicable. The client may also be referred to a Prenatal Plus or Nurse Home Visitor provider if she meets the eligibility criteria for either of these programs.<br>o Agencies are encouraged to follow-up with clients to determine if they are receiving prenatal care.<br>o Document counseling, referral and follow up attempts in the client's record.<br>o Women should be counseled prenatally about the effective option of immediate postpartum LARC. Systems should be in place to ensure that women who desire LARC can receive it during a comprehensive postpartum visit if immediate postpartum placement is not provided.<br><br>Adoption<br>o Qualified clinic staff are permitted to provide nondirective pregnancy counseling and should be able to impart accurate information regarding adoption. This should include services offered by agencies, birth mother rights, a basic overview of the process, and appropriate referrals.<br>o Clients are made aware of adoption options including designated adoption and open adoption.<br>o Clients should understand that relinquishment is final and permanent, but that at any time up to the signing of the final orders, a woman can change her mind.<br>o Clients are made aware of counseling, financial assistance, housing, and other services that may be available through adoption agencies. In addition, the client is given appropriate referrals to reputable agencies that can provide more extensive, non-coercive counseling, as needed. Each family planning agency should explore the adoption agencies in its particular area and determine services provided and qualifications of staff (adoption agency professionals' education and professional credentials) and assure coercion is not used.<br>o Basic prenatal education, discussion of pregnancy danger signs and referrals for prenatal care, Medicaid and/or Prenatal Plus or Nurse Home Visitor program should always be offered as indicated (see previous section).<br><br>Pregnancy Termination |

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| | o Qualified clinic staff may provide nondirective pregnancy counseling.<br>o No Title X project may provide abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion (§ 59.5(a)(5)).<br>o Basic information about the procedure may be provided. As appropriate, explain medical abortion**,** vacuum aspiration, and amnio abortion procedures, time limitations, and consent requirements.<br>o Explain that there is no evidence of abortion affecting future conception.<br>o Emphasize that abortion is not a method of birth control and discuss methods of birth control that can be used afterwards.<br>o Document all test results, counseling and follow-up in the client's record. |
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| **Negative Results** | Negative Test Results<br>o Work with the client to determine other causes of delayed/missed menses including:<br>▪ Pregnancy, but with hormone levels too low for a positive test and/or testing done too soon after the last act of unprotected intercourse.<br>▪ Not pregnant, with delay or absence of ovulation<br>▪ Absence of menses due to medication, especially hormonal contraceptives, including Mirena IUD<br>o If the client is not using birth control and desires pregnancy, the following information should be given:<br>▪ Information about optimizing chances of conception (i.e., timing and frequency of intercourse).<br>▪ The availability of infertility services, if client has been unable to conceive for 1 year or more (six months if age > 35).<br>▪ The impact of diet on fetal development, specifically, folic acid supplementation.<br>▪ Preconception counseling<br>o If the client is not using birth control and does not want to become pregnant, provide the following information and services:<br>▪ Contraceptive services.<br>▪ Offer emergency contraception and information about emergency contraception. |

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| | ▪ Optimally, offer same day contraceptive services. If this is not possible, the client should be encouraged to return for an express visit or comprehensive visit to obtain contraceptive services.<br>▪ If the client cannot be jump started on a hormonal method of birth control at the visit, an interim method of birth control should be made available (e.g., foam and condoms).<br>▪ If the client desires to start a LARC method and the method cannot be provided on the day of her visit, offer and provide a bridge method (e.g. OCs, DMPA, Ring, and Patch if no risk factors exist) until the client can return for a LARC method.<br><br>o If the client is using birth control, provide the following information:<br>▪ Education, as appropriate, about her birth control method. Correct any misinformation leading to incorrect usage. If the client is not using her method correctly, consider providing emergency contraception as indicated.<br>▪ A referral to the family planning clinic as indicated. Reinforce the fact that all available information is confidential, and that the family planning clinic is available as a resource for emotional support, birth control information, and pregnancy determination.<br>▪ If appropriate, have the client return to clinic in two weeks for a repeat pregnancy test if menses has not occurred or have her return 10-14 days after the last act of unprotected intercourse.<br><br>o Document all test results, counseling and follow-up in the client's record. |
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| **Additional Information on Prohibition of Abortions** | o This program does not provide abortion as a method of family planning.<br>o Permissible abortion-related activities<br>▪ Information and counseling regarding options of pregnancy may be supplied to those clients who do not desire to continue their pregnancies and may be interested in obtaining abortions.<br>▪ Collection of statistical data and information regarding abortion is acceptable.<br>▪ Referral for abortion, which may include providing a patient with the name, address, telephone number, and other relevant factual information (such as whether the provider accepts Medicaid, charges, etc.) about an abortion provider.<br><br>o Non-permissible activities related to abortion<br>▪ "Pregnancy Counseling" in the sense of encouraging persons to obtain abortions is not allowed.<br>▪ Abortion may not be the only option discussed.<br>▪ Appointments for abortions may not be made by program personnel. |

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| | ▪ Provision of transportation to enable a woman to obtain an abortion is not allowed.<br>▪ Production and showing of movies that tend to encourage or promote a favorable attitude toward abortion are prohibited.<br>▪ Providing speakers to debate in opposition to “Right to Life” anti-abortion speakers is prohibited.<br>▪ Providing affirmative action (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the patient. |
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## What are basic infertility services?

A written protocol and procedure must be current, available and consistent with national standards of care. Agencies must offer basic infertility care as part of core family planning services. Infertility is defined as the failure of a couple to achieve pregnancy after 12 months or longer of regular unprotected intercourse.

Infertility visit to a family planning clinic focuses on determining potential causes of the inability to achieve pregnancy and making any needed referrals for specialist care.

Evaluation of both partners should begin at the same time. Earlier evaluation (6 months of regular unprotected intercourse) is justified for:

- Women aged >35 years
- Those with a history of oligo amenorrhea (infrequent menstruation)
- Those with a history of oligo amenorrhea (infrequent menstruation)
- Those with known or suspected uterine or tubal disease or endometriosis
- Those with a partner known to be sub-fertile (the condition of being less than normally fertile though still capable of effecting fertilization).

An early evaluation may be warranted if risk factors of male infertility are known to be present or if there are questions regarding the male partner's fertility potential.

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| **Basic Infertility Care for Women** | The infertility visit should focus on:<br>1. Understanding the client's reproductive life plan and her difficulty in achieving pregnancy.<br><br>2. The medical history must include:<br>• Past surgeries<br>• Previous hospitalizations<br>• Serious illnesses or injuries<br>• Medical conditions associated with reproductive failure (e.g., thyroid disorders, hirsutism, or other endocrine disorders)<br>• Childhood disorders<br>• Cervical cancer screening results and any follow-up treatment<br>• Medication<br>• Allergies<br>• Social history/risk behaviors<br>• Family history of reproductive failures<br>• Reproductive history (i.e., time trying to achieve pregnancy; coital frequency and timing)<br>• Level of fertility awareness<br>• Previous evaluation and treatment results; gravidity, parity, pregnancy outcome(s), and associated complications; age at menarche, cycle length and characteristics, and onset/severity of dysmenorrhea<br>• Sexual history (pelvic inflammatory disease, history of/exposure to STIs) |

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| | • Review of systems (symptoms of thyroid disease, pelvic or abdominal pain, dyspareunia, galactorrhea, and hirsutism)<br><br>3. A physical examination must be offered if clinically indicated:<br>• Height, weight, and body mass index (BMI) calculation<br>• Thyroid examination (i.e., enlargement, nodule, or tenderness)<br>• Signs of androgen excess<br>• A pelvic examination (i.e., pelvic or abdominal tenderness, organ enlargement/mass; vaginal or cervical abnormality, secretions, discharge; uterine size, shape, position, and mobility; adnexal mass or tenderness; and cul-de-sac mass, tenderness, or nodularity). |
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| **Basic Infertility Care for Men** | Infertility services provided to the male partner of an infertile couple should include:<br>• Client's reproductive life plan<br><br>Medical history must include:<br>• Reproductive history (methods of contraception, coital frequency and timing; duration of infertility, prior fertility; sexual history; and gonadal toxin exposure, including heat).<br>• Medical illnesses (e.g., diabetes mellitus)<br>• Medications (prescription and nonprescription)<br>• Prior surgeries<br>• Past infections<br>• Allergies<br>• Lifestyle exposures<br>• Sexual health assessment. Including, female partners' history (pelvic inflammatory disease, STIs, and problems with sexual dysfunction)<br><br>3. A physical examination must be offered if clinically indicated:<br>• Examination of the penis (including the location of the urethral meatus)<br>• Palpation of the testes and measurement of their size<br>• Presence and consistency of both the vas deferens and epididymis<br>• Presence of a varicocele<br>• Secondary sex characteristics<br><br>4. Male clients concerned about their fertility should have a semen analysis. If this test is abnormal, they should be referred for further diagnosis (i.e., second semen analysis, endocrine evaluation, post-ejaculate urinalysis, or others deemed necessary) and treatment. The semen analysis is the first and most simple screen for male fertility. |
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| **Plan** | Based on Agency Protocol the following may be offered (female): |

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| | • If menstruating every 21-35 days, may offer progesterone 7 days before next menses.<br>• If age >35, may offer or refer for Cycle Day 3 FSH.<br>• If unexplained amenorrhea >6 month, may offer or refer for FSH, Estradiol.<br>• If irregular cycling, may offer or refer for TSH, Prolactin.<br>• Chlamydia screening<br>• Obtain preconception labs (if have not been done in last year): see protocol for Preconception Health).<br>• May offer Provera 5-10 mg tabs, 1 tab orally daily x 12 days if she has not had menses in last 35 days and urine pregnancy test negative. Return to provider if no withdrawal bleeding with two weeks after completing medication.<br><br>For males<br>• Chlamydia screening<br>• Semen analysis |
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| **Infertility Counseling & Client Education** | • Counseling provided during the clinic visit is guided by information elicited from the client during the medical and reproductive history and findings from the physical exam.<br>• Prenatal vitamins or other source of folic acid for 3 months prior to conception (some clients may need more folate by prescription); consider condom use if client has not had 3 months of folate supplementation.<br>• Menstrual calendar, cycle beads.<br>• Timed coitus every other day at least 3 times starting 2-3 days prior to ovulation. Ovulation may be calculated using prior cycle lengths, cycle beads or urine ovulation detection tests.<br>• Nutritional counseling and recommend weight loss if client overweight. |
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| **Consultation/Referral** | • Clients (female and male) must be referred for further diagnosis and treatment if indicated or requested. |
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## References

Centers for Disease Control and Prevention (CDC). (2014). Providing quality family planning services: Recommendations of the CDC and the U.S. Office of Population Affairs. *MMWR, 63*(4). https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

## What are adolescent services?

Title X family planning services must be provided without regard to religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status (42 CFR 59.5 (a)(4). Client confidentiality, including for adolescents, must be safeguarded. Adolescents are a priority population for Title X and adolescent services are addressed specifically in Providing Quality Family Planning Services (QFP) pgs. 38-40. Family planning programs should take steps to make services youth friendly. (QFP pg. 40)

Adolescent clients (defined as <18 years of age) have specialized needs when they come to a family planning program for services. Many need skilled counseling and detailed information to avoid contraceptive failure. Comprehensive information should be provided regarding how to prevent pregnancy and STIs.

Title X providers must provide counseling to adolescents on how to resist attempts to coerce them into engaging in sexual activities, sexual risk avoidance, contraception, safer sex practices, and should, to the extent practical, encourage communication between the minor and the parents or guardians regarding seeking family planning services (42 U.S.C. 300 (a). In addition, Title X providers must offer confidential services to minors and adhere to all state mandated reporting laws regarding child abuse, neglect, and human trafficking. However, Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services (42 CFR 59.10)

While research shows most adolescent clients who come to a family planning program have been sexually active nine months to one year, some teenagers are seeking assistance in reaching a decision about sexual activity. Abstinence should be discussed with all teens as a valid and responsible option.

Family planning programs should take steps to make their services youth friendly, client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery with nationally recognized standards of care (42 CFR 59.5 (a)(3).

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| **Contraceptive Services** | Adolescents seeking contraceptive services must be informed about all methods of contraception, including abstinence. Education should include an explanation that LARCs are a safe and effective method for women, including those who have not been pregnant and adolescents.<br><br>Adolescents should be offered information about basic female and male reproductive anatomy and physiology.<br><br>All counseling and education must be documented. |
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| **Confidentiality** | Services provided to adolescents are confidential. Adolescents should be informed that contraceptive services are confidential and do not require parental consent.<br><br>Encourage family participation in the decision to seek family planning services; and, with respect to each minor patient, ensure that the records maintained document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).<br><br>The family planning program recognizes the key role family members have to play in teenagers' lives and ideally as primary sex educators.<br><br>Adolescents must understand that there are certain reportable situations (e.g. positive STI, child abuse, child molestation, sexual abuse, rape, or incest) that supersede confidentiality. Refer to Mandatory Reporting Policies and Procedures.<br><br>Inform teens with private insurance that an explanation of benefits will be generated and sent to the policy holder if services are billed to private insurance. Minors, those under 18 years old, may opt out of using their private insurance if confidentiality is a concern and they can be charged on a sliding fee scale.<br>Individuals 18 -26 years old and covered under their parents' policy may contact their private insurance company and request that EOBs are only sent to the covered individual and not the policy holder. |
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| **Encouraging Family Involvement** | Family involvement includes, but is not limited to, parental awareness of an adolescent's decision to seek family planning services, discussion of family planning options, and encouragement of responsible sexual decision-making. By integrating encouragement of family involvement into the family planning visit, the staff may help adolescents develop the interpersonal skills necessary to involve their families. Provide adolescents information about contraception, safer sex, abstinence, teen pregnancy, STIs, and HIV/AIDS. Adolescents often need to be introduced to the concept of responsible decision-making as regards their sexuality.<br><br>To the extent practical, Title X providers should encourage communication between the minor and his or her parent(s) or guardian(s) about sexual and reproductive health and his or her decision to seek services, except that documentation of such encouragement is not to be required if the Title X provider has documented in the medical record:<br>• That it suspects the minor to be the victim of child abuse or incest; and<br>• That it has, consistent with, and if permitted or required by, applicable State or local law, reported the situation to the relevant authorities.<br><br>Motivating adolescents to involve family should include the following: |

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| | • A straightforward explanation of the confidentiality policy. This would include examples of what information would have to be shared, e.g., situations covered under the mandatory reporting laws, reporting of certain STIs, threats to the client's safety, etc.<br>• Stating it is the clinic policy to talk to all adolescents about family involvement<br>• Asking whether the adolescent has ever talked to his/her parent about sex, birth control, or STIs.<br>• Being positive about the potential benefits of family involvement, while allaying any fears about requiring family involvement.<br>• Getting the adolescent to verbalize what the hardest part about talking to a parent or family member would be; what the worst part of the parent's or family member's response might be; what the best part of involving the parent or family member might be. |
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| **Counseling on Resisting Sexual Coercion** | Sexual coercion is the act of persuading or coercing a person, including an adolescent, into engaging in an unwanted sexual activity through physical force, threat of physical force, or emotional manipulation. It differs from rape in that the coerced individual feels it is easier to consent to sexual activity than to decline, because of an imbalance in power. Coercive situations may not be obvious, even to the coerced individual.<br><br>Education and counseling:<br><br>Information about sexual coercion **must** be provided to all adolescent clients. It should be provided to any other client when there is suspicion of abuse or forced sexual activity. The imbalance of power can present itself through pressuring, intimidation, and threats; and it can be physical, emotional, psychological, or spiritual in nature.<br><br>Education should include, but not be limited to:<br>• an explanation of what coercion is<br>• the right to refuse sex at any time without negative consequences<br>• the right to set limits<br>• an awareness of the different kinds of peer pressure that might lead to sexual coercion and how the influence of drugs and alcohol can affect behavior and decision-making ability<br>• the importance of self-esteem and self-respect in avoiding coercive relationships<br>• a list of any available community resources written information on the topic of sexual coercion that has been approved by your agencies I & E committee. |

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| | Observe all relevant state laws and any legal obligations such as reporting child abuse, child molestation, sexual abuse, rape, incest, and human trafficking.<br>• Maintain records to demonstrate compliance with each of the requirements, including records which:<br>o Indicate the age of minor clients.<br>o Indicate the age of the minor client's sexual partners **if** such age is an element of a State notification law under which a report is required.<br>o Document each notification or report made pursuant to such State notification laws.<br><br>A preliminary screening may be conducted on any minor who presents with a STI, pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor. Projects are permitted to diagnose, test for, and treat STIs. |
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| **Documentation on Education / Counseling** | Education and counseling about family involvement should and sexual coercion **must** be documented in the client chart. Document reasons family involvement counseling was not performed if it was not. Use of a check off box is acceptable.<br><br>Documentation of abstinence or sexual risk avoidance counseling is required. Counseling should encourage sexual risk avoidance by delaying on the onset of sexual activity as the healthiest choice.<br><br>Document mandated state reporting and all compliance requirements. Please be<br><br>sure that your education check-off list covers all the above topics. |
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## What is breast cancer screening?

Breast cancer screening, a related preventive health service, is beneficial to reproductive health, is closely linked to family planning services, and is appropriate to deliver in the context of a family planning visit, it but does not contribute directly to achieving or preventing pregnancy. Providing Quality Family Planning Services (QFP) http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/qfp.htm

Clinics must stress the importance of and provide for breast cancer screening as appropriate.

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| **Prevention** | According to American College of Obstetricians and Gynecologists (ACOG) recommendations, the clinical breast exam (CBE) may be offered to asymptomatic, average risk women in the context of an informed, shared decision-making approach. If performed for screening, intervals of every 1-3 years for women aged 25-39 years and annually for women 40 years and older are reasonable.<br><br>Clients should be told about breast self-awareness and that any breast changes should be reported to her health care provider**.** The benefits and limitations of breast self-examination (BSE) should be explained. BSE is not recommended in average-risk women because there is a risk of harm from false-positive results and lack of evidence of benefit. |
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| **Screening Mammograms** | Clients should be told about the benefits and limitations of routine mammograms.<br>• Under age 35<br>o Mammography is not indicated unless a woman has a first-degree relative diagnosed with breast cancer at age 35 or younger. Clients should be referred for physician consultation and follow-up. There is evidence to support a mammogram ten years before the age of diagnosis of the relative's breast cancer, but no sooner than the age of 25 years.<br><br>• Age 35-39<br>o Mammographic imaging should be limited to clients with a first-degree relative with a history of early breast cancer, unless signs or symptoms are present. Clients with a personal history of breast cancer should receive a diagnostic mammogram, as well as other follow-up determined by the physician in charge of her breast cancer care.<br><br>• Women in their 40's should have mammogram screening based on their individual risk and preferences. Mammography recommendations may also depend on physical exam findings or a radiologist's recommendations.<br><br>• Screening recommendations vary for women considered to be at average or high risk for breast cancer. Breast cancer risk can be calculated using a screening tool such as the Breast Cancer Risk Assessment Tool from the National Cancer Institute and based on the Gail Model https://bcrisktool.cancer.gov/ |

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| | • See ACS recommendations for women at higher than average risk for breast cancer http://www.cancer.org/cancer/breastcancer/moreinformation/breastcancerearlydetection/breast- cancer-early-detection-acs-recs<br>• National screening recommendations/guidelines<br>o ACOG recommends annual or biennial screening mammograms starting at age 40 https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2017/07/breast-cancer-risk-assessment-and-screening-in-average-risk-women<br>o US Preventive Screening Guidelines (USPSTF) screening mammogram recommendations (2016) for woman at average risk for breast cancer. See the following link for more in-depth information. http://www.uspreventiveservicestaskforce.org/BrowseRec/Search?s=breast+cancer<br>▪ Women age 50-74 years – biennial screening mammography (Grade B)<br>▪ The decision to start screening mammography before the age of 50 years should be an individual one.<br>▪ Women who place a higher value on the potential harms may choose to begin biennial screening between the ages of 40 and 49.<br>▪ Women with a parent, sibling or child with breast cancer are at higher risk for breast cancer and thus may benefit more than average risk women from beginning screening in their 40s.<br>• American Cancer Society (ACS) -Recommendations for woman at average risk for breast cancer ((JAMA, 2015; 314(15): 1599-1614))<br>▪ Women ages 40 - 44 should have the choice to start annual screening mammograms if they wish to do so (qualified recommendation).<br>▪ Woman should start mammogram screening at age 45 (strong recommendation)<br>▪ Women ages 45 – 54 should get a mammogram every year (qualified recommendation).<br>▪ Women age 55 and older should switch to mammograms every 2 years or have the choice to continue yearly screening (qualified recommendation) |
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| **Management** | • Clients with a family history of first-degree relatives with premenopausal breast cancer should be encouraged to have a baseline evaluation with a specialist. These clients should be counseled regarding risks, benefits, and limitations of monthly BSE and the importance of annual clinical breast exams.<br>• Any breast pathology - a lesion, mass, cyst, lump, breast pain, nipple discharge, change in appearance or deviation from the normal breast of an individual requires careful follow-up.<br>• Palpable mass/unusual or suspicious unilateral thickening:<br>o Document complete description of mass. The client must be given a written referral to a physician. In women under 30 years of age with a well-circumscribed mass and |

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| | no skin changes, it is acceptable to re-check the breast after the next menses for resolution of the mass.<br>o A negative mammogram in the presence of a palpable mass is NOT sufficient to rule out pathology.<br>o Follow-up contact, to document client compliance, should be made with the patient within two (2) weeks, per agency tracking and follow-up guidelines.<br><br>• Nipple change or discharge:<br>o Women with skin breakdown on the nipple or areola or skin changes, such as dimpling, puckering, or peau d'orange (orange peel-like skin) should be referred.<br>o For women with nipple discharge, document the complete description and history, including use of any medications.<br>▪ Bloody discharge, unilateral discharge, a palpable mass, or abnormal mammogram increases the suspicion of malignancy.<br>▪ If spontaneous galactorrhea is present, serum prolactin levels/ thyroid function tests may be drawn.<br>▪ Referral should be made either in house or to an outside provider for:<br>• Galactorrhea with headaches, amenorrhea and/or involuntary infertility, or galactorrhea in the presence of an abnormal prolactin or thyroid function test result. Any non-milky discharge.<br>• Breast pain: If the clinical breast exam is negative, reassure the patient; suggest an analgesic and a supportive bra. A follow-up breast exam may be done in two months. If conservative measures do not relieve symptoms, a referral is indicated. Any other undiagnosed, unilateral breast pain or non-cyclic breast pain should be referred.<br>• Clients may be followed on hormonal contraceptives or hormonal replacement therapy for up to three months while the breast findings are investigated.<br>• Referrals for solitary breast masses are considered urgent, requiring follow-up within two weeks. |
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## What is menopause?

Perimenopause - the interval of approximately 5-10 years that precedes and follows the last menses. It is characterized by fluctuating ovarian estrogen production secondary to decreased ovarian function. This transition may be relatively asymptomatic or can be associated with a wide variety of symptoms.

Menopause - the cessation of ovarian ovulatory function evidenced by the cessation of menses for a period of one year. Menopause may also be induced surgically (oophorectomy) or medically (chemotherapy or radiation treatment). The average age of menopause in the United States is 52. Smokers reach menopause 1.5 years earlier than non-smokers.

Premature ovarian failure/insufficiency – transient or permanent loss of ovarian function prior to age 40 resulting in cessation of menses and associated signs and symptoms of menopause.

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| **Perimenopausal / Menopausal Signs and Symptoms** | The signs and symptoms associated with the perimenopausal period are primarily due to estrogen deficiency (and/or wide swings in estrogen levels) and can include:<br>• Hot flashes or flushes<br>• Insomnia / night sweats / poor quality sleep leading to fatigue<br>• Mood changes / anxiety / depression<br>• Memory impairment / difficulty concentrating<br>• Irregular menses / vaginal bleeding<br>• Vulvovaginal itching, pain, or dryness / vulvovaginal atrophy (usually a late sign)<br>• Urinary symptoms such as frequency, urgency, dysuria, frequent UTIs<br>• Dyspareunia / decreased libido<br>• Loss of bone density / osteoporosis |
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| **Assessment/Examination** | Comprehensive History - obtain a complete personal and family history including medical/surgical, family history of osteoporosis or hip fracture, personal history of fracture, Ob/Gyn history including menstrual, sexual, and contraceptive history, psychosocial history including lifestyle issues relative to nutrition, substance use, domestic violence, and vaccination history.<br>• Physical Exam - complete<br>• Laboratory / Screening Tests<br>o Cervical cancer screening as indicated, according to ASCCP guidelines<br>o Fasting lipid screen (total cholesterol, HDL, LDL, triglycerides) every 5 years beginning at age 45 (US Preventive Services Task Force 2008). |

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| | ○ Pregnancy test, if indicated<br>○ Baseline mammogram or negative mammogram result is recommended prior to initiation of menopausal hormone therapy (MHT). MHT may be started and a mammogram ordered within 3 months.<br>○ Fecal occult blood testing annually or sigmoidoscopy every 5 years or colonoscopy every 10 years after age 50; younger if risk factors are present.<br>○ Fasting blood sugar (FBS) should be considered in all clients > age 45. If normal, repeat every 3 years.<br>○ Bone mineral density (BMD) at age 65 or earlier if indicated by FRAX score assessment of risk factors.<br>• Special circumstances lab testing:<br>○ Serum follicle stimulating hormone (FSH) –This test is only helpful when evaluating for premature ovarian failure/insufficiency (<40 years old). An elevated FSH implies that the ovary is unable to produce sufficient estradiol (secondary to depletion of ovarian follicles) to provide negative feedback to the anterior pituitary where FSH is released. This is an expensive test and only reflects the "snapshot in time" when the test is drawn. Symptom resolution following estrogen treatment is a reliable indicator for diagnosis of perimenopausal status. Treatment, if indicated, should be started without drawing an FSH, unless the client is <40 years old. If an FSH is drawn, it should be drawn on Day 3 of the menstrual cycle, if possible.<br>○ Endometrial biopsy or ultrasound assessment of the endometrial thickness as indicated for irregular bleeding. |
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| **Diagnosis** | The diagnosis of menopause is usually made presumptively on the basis of amenorrhea (at least 12 months) and presence of menopausal symptoms in a woman at least 40 years of age.<br><br>Perimenopause can be diagnosed with menopausal symptoms prior to complete cessation of menstrual periods and may also be an indication for treatment. |
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| **Treatment Alternatives** | In July 2002, the Women's Health Initiative announced that it was ceasing the estrogen/progestin arm of the trial (women with an intact uterus) |

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| | because researchers found that patients who were assigned to the treatment group demonstrated risks that outweighed benefits. While the estrogen and progestin therapy (EPT) users in the study did have a reduced risk of colorectal cancer and fractures (including hip fractures), they also experienced more strokes, heart attacks, blood clots, and an increased risk of invasive breast cancer. Subsequent analysis of the data revealed that the risk of coronary heart disease was primarily in women who began EPT after age 60. In this and other more recent studies, EPT or ET appeared to decrease cardiac risk in women who initiated the therapy before age 60. This may open up a safer therapeutic window for younger women, who are the most likely to require MHT to control menopausal symptoms.<br><br>The estrogen alone (ET) treatment arm was stopped in March 2004 because it also showed an increase in the rate of strokes and deep vein thrombosis/venous thromboembolism. However, there appeared to be no increased risk of coronary heart disease in this group. Like the EPT arm, the ET arm of the study demonstrated a reduction in osteoporosis and the risk of hip and other fractures. And in the final analysis, ET appeared to be associated with an actual decrease in breast cancer risk.<br><br>Treatment of moderate to severe vasomotor symptoms is the primary indication for MHT. The benefits outweigh the risks for most healthy, symptomatic women aged younger than 60 or within 10 years of the final menstrual period (NAMS 2014). The scale tilts even more toward benefits in women who have had a hysterectomy and require only ET. A woman's decision for therapy should be highly individualized based on her unique risk/benefit profile. The lowest dose necessary to relieve symptoms should be prescribed. ET/EPT is not recommended for long-term treatment to prevent cardiovascular or other chronic disease.<br><br>The decision to have hormone replacement therapy (HRT) prescribed is a joint decision between the client and provider. It should be personalized to the client and her risks, benefits to HRT, and alternatives must be discussed.<br><br>Menopausal Hormone Therapy (MHT)/Estrogen Therapy (ET)/Estrogen Progestin Therapy (EPT)<br>• Contraindications<br>  • Known or suspected pregnancy<br>  • Undiagnosed abnormal vaginal bleeding<br>  • History of deep vein thrombosis or venous thromboembolism<br>  • Known thrombophilic disorder |

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| | • History of stroke or ischemic heart disease<br>• Active liver disease, liver dysfunction<br>• History of or suspected breast or other estrogen-sensitive cancer<br>• Women with a history of malignant melanoma must have a consultation with an oncologist/dermatologist prior to receiving MHT<br><br>Note: ET/EPT is not contraindicated in women with hypertension, fibroids, diabetes, migraines, and/or varicosities.<br><br>• Side Effects<br>▪ Gastrointestinal – nausea/vomiting, bloating, abdominal cramping<br>▪ Breast tenderness/enlargement<br>▪ Vaginal bleeding/spotting<br>▪ Weight gain/changes, fluid retention<br>▪ Chloasma<br>▪ Headache<br>▪ Mood changes<br>▪ Gallstones, cholecystitis<br><br>• Benefits<br>▪ Relief of menopausal symptoms<br>▪ Protection against bone loss and osteoporosis<br>▪ May decrease risk of coronary heart disease if begun before age 60<br><br>• Risks<br>▪ Increased breast cancer risk in women using combination MHT (EPT) continuously for more than 3-5 years<br>▪ Increased coronary heart disease in women who begin EPT after age 60<br>▪ Increased risk of DVT/PE, primarily with oral therapy<br>▪ Increased stroke risk, may be higher with oral therapy<br><br>• MHT Regimens<br>▪ **Continuous Combined Regimen (for clients with an intact uterus):**<br><br>**Estrogen and progestin/progesterone daily**. |

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| | ▪ Withdrawal bleeding and spotting may occur for the first 6-12 months. However, most women on continuous HRT experience amenorrhea within 6 months - 1 year.<br>▪ Any woman with irregular uterine bleeding who has risk factors for hyperplasia (obese, diabetic, hypertensive, history of taking unopposed estrogen) or any woman with bleeding that persists for 6 months, should receive an ultrasound evaluation of endometrial thickness or an endometrial biopsy. If the endometrial stripe is greater than 4mm on ultrasound, an endometrial biopsy is indicated.<br>▪ Based on the apparent negative effect of medroxyprogesterone acetate in the EPT arm of WHI, clinicians may wish to consider prescribing regimens formulated with other progestins such as norethindrone acetate, levonorgestrel, drospirenone, norgestimate, or progesterone itself.<br><br>**Equivalent Doses of Progestins**<br>*Brand Name* — *Dosage*<br>Provera®, medroxyprogesterone acetate (generic) — 2.5, 5.0 mg<br>Aygestin®, norethindrone acetate (generic) — 2.5, 5.0 mg<br>Prometrium®, micronized progesterone (generic) — 100, 200 mg<br><br>▪ Although off label for this use, the levonorgestrel containing intrauterine system is an excellent means of delivering progestin to the endometrium and protecting the patient from hyperplasia. Side effects of oral progestins are avoided with this treatment modality.<br><br>• **Cyclic Regimen (for clients with an intact uterus):**<br><br>**Daily estrogen plus progestin/progesterone for the first 14 days of every month**. |

- Withdrawal bleeding can be expected during or after the completion of the progestin cycle, although some women experience very light or no bleeding.
- Many clinicians start perimenopausal/newly menopausal women on a cyclic regimen, switching later to the continuous combined regimen.

- **Estrogen alone**
  - Post-hysterectomy, estrogen alone is taken every day. However, women with prior endometriosis and possible remaining endometriotic implants should consider adding progestin/progesterone.
  - With an *intact* uterus, estrogen alone requires yearly endometrial biopsy or ultrasound evaluation of endometrial thickness and is quite likely over time to lead to endometrial hyperplasia (which will necessitate higher-dose progestin therapy or even hysterectomy).

| **Equivalent Doses of Estrogens**<br>*Brand Name* | *Dosage* |
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| Premarin®, Cenestin®, Enjuvia, Menest®, esterifed or conjugated estrogens (generic) | 0.3, 0.45, 0.625 mg |
| Estrace®, estradiol (generic) | 0.5, 1.0 mg |
| Ogen®, Ortho-Est®, estropipate (generic) | 0.625 mg |
| Vivelle®, Vivelle Dot®, Minivelle®, Climara®, Alora®, Estraderm®, or generic estradiol patch | 0.025, 0.0375, 0.05 mg |

Estradiol can also be prescribed in a systemic vaginal ring (Femring® .05 mg), creams, gels or a spray (Evamist®).

Combination pills (e.g. PremPro®, Activella®, Angeliq®) and patches (Climara Pro®, Combipatch®) combine estrogen and progestin in one vehicle.

- **Other Regimens**

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| | ▪ Duavee®, a combination of 0.45 mg conjugated equine estrogens and the SERM bazedoxifene taken orally every day, is an innovative hormonal treatment for menopausal symptoms and prevention of osteoporosis. The SERM inhibits endometrial growth so that a progestin is not required for women with a uterus. Contraindications are the same as those for EPT/ET.<br>▪ Low-dose vaginal estrogen is preferred for women experiencing only urogenital symptoms:<br>• Estring® one ring every 90 days<br>• Estradiol or Premarin® vaginal cream intravaginal 1/4 applicatorful each day x 1-2 weeks then twice a week as indicated<br>• Vagifem® vaginal tablets 1 tablet intravaginal each day X 2 weeks followed by maintenance of 1 tablet intravaginal twice a week<br>• A progestin is not required with this therapy, but all bleeding that occurs while using it should be investigated with endometrial biopsy or ultrasound of the endometrial stripe.<br>▪ Osphena® (ospemifene), a SERM given orally 60 mg/day, is a newer option for management of vulvovaginal symptoms that may be particularly useful for women who are uncomfortable with vaginal application. Contraindications are the same as those for estrogen therapy, and as with vaginal estrogen, any bleeding should be thoroughly investigated.<br>• Follow Up<br>▪ The first follow up visit should be scheduled in 3 months to assess symptom relief and evaluate side effects.<br>▪ Continue annual well-woman checks.<br>Low dose oral contraceptives are effective in controlling perimenopausal symptoms and re-establishing cycle control in women with fluctuating levels of estrogen. They can be continued for this purpose up to age 52, but should be used only in non-obese nonsmokers without cardiovascular risk factors.<br>**Non-hormonal Options**<br>• SSRIs, SSNRIs (such as venlafaxine), gabapentin, and clonidine have all been shown to be effective alternatives for reducing hot flashes. Use |

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| | of these medications for vasomotor symptoms is off label, with the exception of Brisdelle® 7.5 mg. nightly at bedtime, a low-dose paroxetine that has been approved for this purpose. Most SSRIs, including Brisdelle®, should not be used in women taking tamoxifen, as they may compromise the efficacy of the tamoxifen.<br><br>Artificial lubrication and/or vaginal moisturizers (e.g. Replens®, Luvena®) can help alleviate vaginal symptoms and dyspareunia.<br><br>Clinical trials generally demonstrate benefits of complementary and alternative treatments for menopausal symptoms to be no better than placebo. In addition, herbs and botanicals are not regulated by the FDA, so safety is not assured and efficacy information is not available.<br><br>Lifestyle recommendations for symptom relief include cooler environments, avoiding triggers (e.g. spicy foods, red wine), relaxation techniques such as meditation and yoga, aerobic exercise, weight loss, and discontinuing smoking. |
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| **Counseling and Education** | • Emphasize that menopause is a normal physiologic event and discuss normal changes in body systems and sexuality associated with aging.<br><br>• Inquire about symptoms that may need to be addressed. Ask about sexual problems in particular, since the client may be uncomfortable bringing them up.<br><br>• Stress that the menopausal transition is an important time for women to implement behavioral changes to ensure healthy aging.<br><br>• Discuss the importance of good nutrition and adequate calcium intake (1200 mg each day if not on ET/EPT; 1000mg if on ET/EPT) and vitamin D at least 600 IU/day. Dietary calcium should be assessed, and supplements added if needed to reach the RDA.<br><br>• Encourage regular exercise for heart health. Weight-bearing exercise also enhances bone density.<br><br>• Promote a healthy lifestyle<br><br>• Maintain normal body weight.<br><br>• Stop smoking.<br><br>• Decrease alcohol consumption.<br><br>• Counsel regarding the need for preventive health screenings such as cervical cancer screening according to ASCCP guidelines, breast self- |

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| | awareness, annual clinical breast exam, mammography, bone mineral density, colon, lipid and diabetes screens.<br>• Discuss the importance of recommended immunizations, including a Tdap booster every 10 years, influenza immunization yearly, Zostavax® shingles vaccine at age 60, and pneumococcal vaccine at age 65.<br>• Counsel regarding contraception if client has not experienced cessation of menses for 1 year. Serum levels achieved with EPT do not suppress ovulation and are **NOT** adequate for contraception. (Hormone levels are ~1/6 the levels of a pill containing 20 mcg of estrogen.)<br>  • Combined oral contraception (COC) or vaginal ring may be continued to the early 50s unless contraindicated. As noted above, combined hormonal methods may be used for non-obese, nonsmoker clients without cardiovascular risk factors. Women using COC or vaginal ring cyclically may experience hot flashes and difficulty sleeping at the end of the week of placebo pills because of lack of estrogen. They may choose to use the COC continuously, which will help control these symptoms, or they may transition to EPT if using a backup method of contraception. Intrauterine contraception, the subdermal implant, and depot medroxyprogesterone may be continued to the early 50s unless contraindicated.<br>  • If a patient has a levonorgestrel IUS or is using depot medroxyprogesterone acetate, she may initiate estrogen therapy with her method serving as the progestin.<br>• Discuss issues pertinent to STI & HIV prevention as indicated.<br>• Discuss treatment options for menopausal symptoms; refer to community and other supportive resources as needed.<br>  • Assess client risk factors for osteoporosis, cardiovascular disease, breast cancer and other pertinent conditions.<br>  • Discuss risks and benefits of MHT and alternative treatments.<br>  • Assess client expectations/attitudes about menopause and symptom treatment.<br>  • Menopause.org is an excellent internet site maintained by the North American Menopause Society providing information for both patients and providers. |
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## SECTION 10
## Vaginal Infections and Sexually Transmitted Infections What is

### Expedited Partner Therapy?

Expedited partner therapy (EPT) is a practice that allows healthcare providers to provide a patient with antibiotics or a prescription intended to the patient's sex partner(s) without the partner being physically examined by the healthcare provider.

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| **Qualifications for expedited partner therapy** | According to Mississippi Revised Code § 4723.4810, Mississippi physicians, advance practice registered nurses, and physician assistants are authorized to prescribe or personally furnish a drug for a sexual partner of a patient diagnosed with chlamydia, gonorrhea, or trichomoniasis, without examining the sexual partner, if all the following conditions are met:<br>1) The intended recipient is a sexual partner of the prescriber's patient;<br>2) The patient has been diagnosed with chlamydia, gonorrhea, or trichomoniasis; and<br>3) The patient reports to the prescriber that the sexual partner is unable or unlikely to be evaluated or treated by a health professional |
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| **Prescription label** | A prescription issued using expedited partner therapy (EPT) shall include the individual's name and address, if known. If the provider is unable to obtain the individual's name and address, the prescription shall include the patient's name and address and the words "expedited partner therapy" or the letters "EPT." A separate prescription should be issued for the patient's partner. This applies to paper and electronic prescriptions. |
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| **Number of prescriptions** | A provider may prescribe or personally furnish a drug under this section for not more than a total of two individuals who are sexual partners of the provider's patient. |
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| **Requirements of the prescriber** | For each drug prescribed or personally furnished under this section, the provider shall do all the following:<br>(1) Provide the patient with information concerning the drug for the purpose of sharing the information with the individual, including directions for use of |

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| | the drug and any side effects, adverse reactions, or known contraindications associated with the drug;<br><br>(2) Recommend to the patient that the individual seek treatment from a health professional;<br><br>(3) Document all the following in the patient's record:<br><br>(a) The name of the drug prescribed or furnished and its dosage;<br><br>(b) That information concerning the drug was provided to the patient for the purpose of sharing the information with the individual;<br><br>(c) If known, any adverse reactions the individual experiences from treatment with the drug. |
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| **Provider contact with patient's partner** | A provider who prescribes or personally furnishes a drug under this section may contact the individual for whom the drug is intended.<br><br>(1) If the provider contacts the individual, the provider shall do all the following:<br><br>(a) Inform the individual that the individual may have been exposed to chlamydia, gonorrhea, or trichomoniasis;<br><br>(b) Encourage the individual to seek treatment from a health professional;<br><br>(c) Explain the treatment options available to the individual, including treatment with a prescription drug, directions for use of the drug, and any side effects, adverse reactions, or known contraindications associated with the drug;<br><br>(d) Document in the patient's record that the nurse contacted the individual.<br><br>(2) If the provider does not contact the individual, the provider shall document that fact in the patient's record. |
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| **Liability protections** | A provider who in good faith prescribes or personally furnishes a drug under this section is not liable for or subject to any of the following: |

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| | (1) Damages in any civil action;<br><br>(2) Prosecution in any criminal proceeding;<br><br>(3) Professional disciplinary action. |
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## References

Revised Code 4723.4810 Authority to prescribe or furnish drugs to sexual partner of a patient diagnosed with chlamydia, gonorrhea, or trichomoniasis. Amended by 131st General Assembly File No. TBD, HB 216, §1, eff. 4/6/2017. Retrieved from http://codes.ohio.gov/orc/4723.4810

## What is Chlamydia?

Chlamydia is the most frequently reported STI in the United States, and it is a leading cause of infertility in women. It is usually caused by sexual contact through oral, anal, or vaginal intercourse. Chlamydia infections are most commonly diagnosed in persons aged 15-24 years.

Chlamydial infections may affect the cervix, urethra, salpinges, uterus, nasopharynx, and epididymis. *C trachomatis* infections may also cause other diseases, such as, conjunctivitis, pneumonia, afebrile pneumonia syndrome, Fitz-Hugh-Curtis syndrome, and trachoma. If left untreated, chlamydia may cause pelvic inflammatory disease, infertility, ectopic pregnancy, and chronic pelvic pain.

Antibiotic treatment is 95% effective for first time therapy. Reinfection is extremely common, and it is often associated to the lack of treatment of infected sexual partners or acquiring it from a new partner. All sexual partners should be treated. Most men and women are asymptomatic.

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| **Subjective Data/Symptoms** | *History may include:*<br>• History of STIs, including chlamydia<br>• Sexual activity without condoms or condom failure<br>• Recent change in sex partner<br>• Partner with chlamydia symptoms<br>• Multiple sex partners or partner with concurrent partners<br><br>*Symptoms may include:*<br>• Dysuria<br>• Yellow mucopurulent discharge from urethra<br>• Vaginal discharge or abnormal vaginal bleeding<br>• Proctitis or rectal discharge<br>• Slow onset and progression of lower abdominal pain for women or unilateral pain and swelling of the scrotum for men<br>• Fever<br>• No symptoms |
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| **Objective Data** | *Physical Findings:*<br>• Women<br>  ○ Cervical friability<br>  ○ Mucopurulent cervical, vaginal, or rectal discharge<br>  ○ Cervical motion tenderness<br>  ○ Abdominal pain upon exam<br><br>• Men<br>  ○ Mucopurulent urethral or rectal discharge<br>  ○ Urinary urgency or frequency |

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| | o Scrotal swelling or epididymitis |
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| **Assessment** | *Lab testing:*<br><br>Nucleic Acid Amplification Test (NAAT)<br>• First catch urine sample or collecting swab specimens<br>• Vaginal or rectal swab specimens can be provider or self-collected<br><br>Persons who receive a diagnosis of chlamydia should also be tested for gonorrhea, syphilis, and HIV.<br><br>A pregnancy test for females with suspected chlamydial infection is recommended. Obtaining a pregnancy test helps with early diagnosis and guidance of treatment. Because pregnancy is a contraindication for the use of doxycycline and ofloxacin, it is critical to obtain a pregnancy test before beginning treatment with these drugs. |
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| **Plan / Pharmacologic Treatment** | *Medication:*<br>Partner treatment is necessary to prevent reinfection from the same partner and infection of other partners. Treatment should be provided promptly for all persons with chlamydial infection.<br><br>**<u>Recommended Regimens</u>**<br>• Doxycycline 100 mg orally twice a day for 7 days<br><br>**<u>Alternative Regimens</u>**<br>• Azithromycin 1g orally in a single dose<br>OR<br>• Levofloxacin 500 mg orally once daily for 7 days<br><br>*Partner notification:*<br>Contact sexual partners within the previous 60 days and most recent partner<br><br>*Management of sex partners:*<br>• Sexual partner and any sexual contacts in the last 60 days preceding onset of symptoms or diagnosis should be informed of possible infection and provided written materials about the importance of seeking evaluation for any symptoms suggestive of complications (e.g., testicular pain in men and pelvic or abdominal pain in women).<br>• Timely treatment of sex partners is essential for decreasing the risk for re-infection.<br>• Use Expedited Partner Treatment (EPT) if necessary |

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| | o Shared clinical decision making regarding use of EPT is recommended for MSM with chlamydia diagnoses. There is a high risk for coexisting infections among their partners, and seeing a provider for screenings, treatment, and PrEP discussions is beneficial.<br><br>*Other testing:*<br>• Persons who receive a diagnosis of chlamydia should be tested for HIV, gonorrhea, and syphilis.<br>• MSM who are HIV negative with rectal chlamydia should be offered HIV PrEP. |
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| **Special Considerations** | *Pregnancy:*<br>• Test of cure via NAAT approximately 4 weeks after treatment<br>• If diagnosed with chlamydia, should be retested 3 months after treatment<br>• Women aged <25 years and those at increased risk for chlamydia should be rescreened during the third trimester to prevent maternal postnatal complications and chlamydial infection in the infant<br>• Doxycycline, ofloxacin, and levofloxacin are contraindicated in pregnancy.<br>• Treat with azithromycin 1 g orally in a single dose or alternatively amoxicillin 500 mg orally 3 times a day for 7 days<br><br>*HIV infection:*<br>• Persons who have chlamydia and HIV infection should receive the same treatment regimen as those who do not have HIV infection. |
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| **Patient Education/Counseling** | • Implement behavioral counseling interventions to reduce the likelihood of acquiring additional STIs.<br>• Sexual contact should be avoided<br>o for 7 days if take single-dose therapy OR<br>o until completion of a 7-day regimen<br>o until all partners have been evaluated and/or treated<br>o and symptoms are resolved, if they were present<br>• Inform patients of long-term risks and complications, including the risk of infertility, of chlamydia and other STIs.<br>• Provide information to prevent reinfection. For example, proper use latex condoms.<br>• Chlamydia can be spread through unprotected vaginal, anal, or oral sex<br>• Chlamydia can be spread to a baby during delivery<br>• Chlamydia can be cured. Reinfection is common. |

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| | • Washing genitals, douching, or urinating after sex will not prevent chlamydia or other STIs.<br>• Provide medication information sheet, STI education and information, contraception information (if indicated), and offer STI testing<br>• To prevent chlamydia, abstain from vaginal, oral, and anal sex or be in a long-term, mutually monogamous relationship with a partner who has been tested and is known to be uninfected. |
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| **Follow-up** | • Test-of-cure to detect therapeutic failure is not advised for nonpregnant persons treated with the recommended or alterative regimens, unless therapeutic adherence is in question, symptoms persist, or reinfection is suspected<br>• Men and women who have been treated for chlamydia should be retested approximately 3 months after treatment<br>• If retesting at 3 months is not possible, clinicians should retest whenever persons next present for medical care in the 12-month period following initial treatment. |
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| **Consultation/Referral** | • Refer pregnant patients to primary or prenatal care<br>• Refer clients with multiple incidents of reinfections |
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| **Screening** | • Recommendations<br>o Annual screening of all sexually active women aged <25<br>o All pregnant women <25 and older pregnant women who are at increased risk. Retest during third trimester for women under 25 years of age or at risk.<br>o Annual screening of women ≥ 25 that are at an increased risk for infection (e.g., new sex partner, more >1 sex partner, sex partner with concurrent partners, or sex partner with a STI)<br>o The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for chlamydia and gonorrhea in men.<br>o Screen at least annually for sexually active MSM at sites of contact (urethra, rectum) regardless of condom use and every 3 to 6 months if at increased risk (i.e., MSM on PrEP, with HIV infection, or if they or their sex partners have multiple partners).<br>o For transgender and gender diverse persons, screening recommendations should be adapted based on anatomy (i.e., annual, routine screening for gonorrhea in cisgender women <25 years old should be extended to all transgender men and gender |

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| | diverse people with a cervix. If over 25 years old, screen if at increased risk). Consider screening at the pharyngeal and rectal site based on reported sexual behaviors and exposure.<br>o For sexually active persons with HIV, screen at first HIV evaluation, and at least annually thereafter. More frequent screening may be appropriate depending on individual risk behaviors and the local epidemiology. |
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| **Reporting** | • Mandated state reporting is required. |
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## What is Gonorrhea?

Gonorrhea is the second most common reportable sexually transmitted disease, and it has the highest prevalence rates among persons >25 years. *Neisseria gonorrhoeae* is a gram-negative diplococcal bacterium and causes gonorrhea, which is a purulent infection of mucus membrane surfaces. It may be spread through sexual contact or childbirth. According to the CCD, patients diagnoses with gonorrhea should also be treated for chlamydia.

Gonorrhea typically presents as urethritis, cervicitis, proctitis, salpingitis, pharyngitis or asymptomatic. Complications may include pelvic inflammatory disease, ectopic pregnancy, infertility, and chronic pelvic in women; prostatitis, epididymitis and proctitis in men; conjunctivitis or pharyngeal infection in men and women. Rarely, gonorrhea may also invade the bloodstream leading to disseminated gonococcal infection, which is characterized by arthritis and skin lesions. If gonorrhea is transmitted to the newborn, the neonatal conjunctiva, pharynx, respiratory tract, or anal canal may become infected and there is a risk of in corneal perforation and blindness.

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| **Subjective Data/Symptoms** | *History may include:*<br>• Inconsistent or incorrect condom use<br>• Sexual contact outside of a mutually monogamous relationship<br>• Previous or coexisting STI<br>• Exchanging sex for money or drugs<br>• New or multiple sex partners<br>• Living in urban area where gonorrhea prevalence is high<br><br>*Symptoms may include:*<br><br>• Women<br>  o Thin, purulent, mildly odorous vaginal discharge<br>  o Dysuria<br>  o Intermenstrual bleeding<br>  o Lower abdominal pain<br>  o Dyspareunia<br>• Men<br>  o Burning with urination with serous discharge<br>  o Discharge that becomes more profuse, purulent, may be tinged with blood<br>  o Decreased or abnormal urine stream<br>  o Unilateral epididymitis with urethral exudate<br>  o Rectal pain, pruritus, discharge, or tenesmus<br>• Disseminated gonococcal infection<br>  o Joint or tendon pain<br>  o Rash or lesions |

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| **Objective Data** | *Physical Findings:*<br>• Women<br>  o Purulent or mucopurulent vaginal, urethral, or cervical discharge<br>  o Cervical friability<br>  o Cervical motion tenderness upon exam<br>  o Abdominal pain upon exam<br>• Men<br>  o Mucopurulent or purulent urethral discharge<br>  o Epididymitis<br>  o Penile edema<br>  o Urethral stricture |
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| **Assessment** | *Lab testing:*<br>• Nucleic Acid Amplification Test (NAAT) and point of care NAATs can be used for<br>  o endocervical swabs, vaginal swabs, urethral swabs (men), and urine (from both men and women)<br>  o Collect specimen from anatomic sites of exposure for most accurate detection<br>• Culture is available for detection of rectal, oropharyngeal, and conjunctival gonococcal infection<br>• Should have other STI testing (chlamydia, syphilis, HIV) and, if female, a pregnancy test to guide further care and determination of which medications to use |
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| **Plan / Pharmacologic Treatment** | *Medication:*<br>**Uncomplicated Gonorrhea of the Cervix, Urethra, and Rectum**<br>**<u>Recommended Regimens</u>** – for any anatomic site<br>Ceftriaxone 500 mg in a single intramuscular dose for persons weighing < 150 kg<br>Ceftriaxone 1 g in a single intramuscular dose for persons weighing ≥ 150 kg<br>*If chlamydial infection has not been excluded, treat for chlamydia with doxycycline 100 mg orally twice daily for 7 days |

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| | **<u>Alternative regimens:</u>**<br><br>If ceftriaxone allergy:<br><br>Gentamicin 240 mg in a single intramuscular dose<br>PLUS<br>Azithromycin 2 g orally in a single dose<br><br>If ceftriaxone is not available:<br><br>Cefixime 800 mg in a single oral dose<br><br>*If chlamydial infection has not been excluded, treat for chlamydia with doxycycline 100 mg orally twice daily for 7 days<br><br>**Uncomplicated Gonorrhea of the Pharynx**<br><br>**<u>Recommended Regimens</u>** – (no reliable alternative treatments are available) Ceftriaxone<br><br>500 mg in a single intramuscular dose for persons weighing < 150 kg<br><br>Ceftriaxone 1 g in a single intramuscular dose for persons weighing ≥ 150 kg<br><br>*If chlamydial infection has not been excluded, treat for chlamydia with doxycycline 100 mg orally twice daily for 7 days<br><br>*Partner notification:*<br>• Sexual partner and any sexual contacts in the previous 60 days preceding onset of symptoms and/or gonorrhea diagnosis must be informed and provided written materials about the importance of seeking evaluation for any symptoms suggestive of complications.<br>• May use expedited partner treatment (EPT)<br><br>*Management of sex partners:*<br>• Persons having sexual contact with the infected patient within the 60 days preceding onset of symptoms or gonorrhea diagnosis should be referred for evaluation, testing, and presumptive dual treatment.<br>• If the patient's last potential sexual exposure was >60 days prior to onsetof symptoms or diagnosis, the most recent sex partner should be treated.<br>• To avoid reinfection, sex partners should be instructed to abstain from unprotected sexual intercourse for7 days after they and their sexual partner(s) have completed treatment. |

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| | • If there are concerns the sex partner will not seek prompt clinical evaluation, EPT with cefixime 800 mg and doxycycline 100 mg 2 times/day for 7 days can be delivered to the partner by the patient, a disease investigation specialist, or a collaborating pharmacy as permitted by law |
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| **Special Considerations** | *Allergies:*<br>• While allergic reactions to first generation cephalosporins occur in <2.5% of person with a history of penicillin allergy and are uncommon with 3rd generation cephalosporins (e.g., ceftriaxone and Cefixime), use of ceftriaxone or cefixime is contraindicated in persons with a history of an IgE-mediated penicillin allergy.<br>• The following alternative treatment regimen may be considered when the patient has a history of such an allergy.<br>o **<u>If patient is allergic to penicillin</u>**:<br>Gentamicin 240 mg in a single intramuscular dose<br>PLUS<br>Azithromycin 2 g orally in a single dose<br>• Providers treating persons with cephalosporin or IgE-mediated penicillin allergy should consult an infectious-disease specialist.<br><br>*Pregnancy:*<br>• Pregnant women should be treated with ceftriaxone 500 mg in a single intramuscular dose plus treatment for chlamydia if infection has not been excluded.<br>• Pregnant women should not be treated with any fluoroquinolone or any tetracycline drug.<br>• Pregnant women who cannot tolerate a cephalosporin should be evaluated by an infectious disease specialist.<br><br>*HIV infection:*<br>• Should have gonorrhea screening at initial evaluation and at least annually thereafter. Collect samples from the anatomic sites of sexual exposure.<br>• Persons who have gonorrhea and HIV infection should receive the same treatment regimen as those who do not have HIV. |
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| **Patient Education/Counseling** | • Abstain from sexual activity for 7 days after treatment and until all sex partners are adequately treated (7 days after receiving treatment and resolution of symptoms, if present).<br>• Inform patient of long-term risks and importance of testing and treatment.<br>• Provide medication information sheet, STI education and information, contraception information (if indicated), and offer STI testing |

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| | • Gonorrhea is spread via oral, vaginal, and anal sex, as well as from mother to baby during childbirth.<br>• Persons with gonorrhea are more likely to transmit and acquire HIV.<br>• Discuss prevention strategies such as abstinence, mutual monogamy with an uninfected partner, use of latex condoms, and limited the number of sex partner.<br>• Implement behavioral counseling interventions to reduce the likelihood of acquiring additional STIs. |
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| **Follow-up** | • A test-of-cure is not needed for persons who receive a diagnosis of uncomplicated urogenital or rectal gonorrhea who are treated with any of the recommended or alternative regimens.<br>• A test-of-cure is recommended patients with pharyngeal gonorrhea7-14 days after initial treatment by using a culture of NAAT. Testing at 7 days may increase the likelihood of false-positive results.<br>• For all patients with gonorrhea, repeat testing should occur approximately 3 months after treatment to identify recent reinfection. |
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| **Consultation/Referral** | • Refer pregnant patients to primary or prenatal care<br>• Refer clients with multiple reinfections or persistent symptoms<br>• Refer patients with penicillin allergy to infectious disease specialist |
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| **Screening** | • Annual screening for gonorrhea is recommended for all sexually active women aged <25 years and for older women at increased risk for infection (e.g., those who have a new sex partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has an STI). Pharyngeal and rectal gonorrhea screening can be considered based on reported sexual behaviors and exposure,<br>• Pregnant women should be screened for gonorrhea at the first prenatal visit for women >25 years or older if at increased risk for gonorrhea. Retest during the third trimester for women under 25 years of age or at risk.<br>• Subgroups of MSM are at high risk for gonorrhea infection and should be screened at sites of exposure. Screen at least annually for sexually active MSM at sites of contact, regardless of condom use. Screen every three to six months if at increased risk.<br>• For transgender and gender diverse persons, screening recommendations should be adapted based on anatomy (i.e., annual, routine screening for gonorrhea in cisgender women <25 years old should be extended to all transgender men and gender diverse people with a cervix. If over 25 years |

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| | old, screen if at increased risk). Consider screening at the pharyngeal and rectal site based on reported sexual behaviors and exposure.<br>• For sexually active persons with HIV, screen at first HIV evaluation, and at least annually thereafter. More frequent screening may be appropriate depending on individual risk behaviors and the local epidemiology.<br>• Screening for gonorrhea in men and older women who are at low risk for infection is not recommended |
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| **Reporting** | • Mandated state reporting is required. |
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## What is Pelvic Inflammatory Disease (PID)?

Pelvic inflammatory disease (PID) is an infectious and inflammatory disorder of the upper female genital tract, including the uterus, fallopian tubes, and adjacent pelvic structures. PID can spread into the abdomen and perihepatic structures. Sexually transmitted organisms, especially *N. gonorrhea* and *C. trachomatis*, are implicated in many cases, but PID may also be caused by vaginal flora or cytomegalovirus (CMV), *M. hominis*, *U. urealyticum*, and *M. genitalium.*

Many cases of PID go unrecognized. Some patients have few or no symptoms whereas others will present with acute, serious illness. There are several important differentials to consider including appendicitis, cervicitis, urinary tract infection, endometriosis, ectopic pregnancy, ovarian torsion and adnexal tumors.
Providers should use a low threshold for PID diagnosis due to the risk of infertility and damage to the reproductive health of women.

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| **Subjective Data/Symptoms** | *History may include:*<br>• Multiple sex partners<br>• Lives in an area with high prevalence of STIs<br>• Prior or current STIs<br>• Partner with STIs, current or present<br>• Age younger than 25 years<br>• Age of first sexual intercourse was younger than 16 years<br>• Use of non-barrier contraception<br><br>*Symptoms may include:*<br>• Lower abdominal pain<br>• Abnormal vaginal discharge<br>• Abnormal vaginal bleeding<br>• Dyspareunia<br>• Fever<br>• Dysuria |
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| **Objective Data** | *Physical Findings:*<br>• Uterine, adnexal, or cervical motion tenderness upon exam<br>• Cervical friability<br>• Mucopurulent cervical discharge |
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| **Assessment** | Presumptive treatment for PID should be initiated in sexually active young women and other women at risk for STIs if they are experiencing pelvic or lower abdominal pain, if no cause for the illness other than PID can be |

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| | identified, and if <u>one or more</u> of the following minimum clinical criterial are present of pelvic examination:<br>• Cervical motion tenderness, or<br>• Uterine tenderness, or<br>• Adnexal tenderness<br><br>Additional criteria to enhance the specificity of the minimum clinical criteria and support a diagnosis of PID:<br>• oral temperature >101°F (>38.3°C)<br>• abnormal cervical mucopurulent discharge or cervical friability<br>• presence of abundant numbers of WBC on saline microscopy of vaginal fluid<br>• elevated erythrocyte sedimentation rate<br>• elevated C-reactive protein<br>• laboratory documentation of cervical infection with *N. gonorrhoeae* or *C. trachomatis.*<br><br>*Lab testing:*<br>• Wet prep to look for white blood cells and other infections (e.g., bacterial vaginosis [BV], trichomoniasis)<br>• A pregnancy test for women of childbearing age who are presenting with lower abdominal pain to rule out ectopic pregnancy<br>• Test for HIV<br>• Use NAAT to test for gonorrhea and chlamydia |
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| **Plan / Pharmacologic Treatment** | *Medication:*<br><br>**For mild-to-moderately severe acute PID who do not fit any of the hospitalization criteria listed below**<br><br><u>Recommended Intramuscular/Oral Regimens</u><br>Ceftriaxone 500 mg IM in a single dose* PLUS<br>Doxycycline 100 mg orally twice a day for 14 days<br>WITH<br>Metronidazole 500 mg orally twice a day for 14 days<br><br>*OR*<br><br>Cefoxitin 2 g IM in a single dose and Probenecid 1 g orally administered concurrently in a single dose<br>PLUS<br>Doxycycline 100 mg orally twice a day for 14 days<br>WITH |

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| | Metronidazole 500 mg orally twice a day for 14 days<br><br>*OR*<br>Other parenteral third-generation cephalosporin (e.g., ceftizoxime or cefotaxime)**<br>PLUS<br>Doxycycline 100 mg orally twice a day for 14 days<br>WITH<br>Metronidazole 500 mg orally twice a day for 14 days<br><br>*For persons weighing >150 kg (~300 lbs.) with documented gonococcal infection, 1 g of ceftriaxone should be administered.<br>** The recommended third generation cephalosporins are limited in the coverage of anaerobes. Therefore, until it is known that extended anaerobic coverage is not important for treatment of acute PID, the addition of metronidazole to treatment regimens with third generation cephalosporins should be considered (Source: Walker CK, Wiesenfeld HC. Antibiotic therapy for acute pelvic inflammatory disease: the 2006 CDC Sexually Transmitted Diseases Treatment Guidelines. Clin Infect Dis 2007;28[Supp 1]:S29–36).<br><br>*Management of sex partners:*<br>• Persons who have had sexual contact with a woman with PID during the 60 days preceding the onset of symptoms should be evaluated, tested, and presumptively treated for chlamydia and gonorrhea.<br>• If the woman's last sexual intercourse was >60 days before the onset of symptoms or diagnosis, the most recent sex partner should be treated.<br>• Expedited partner treatment (EPT) should be used if partner is likely to delay or not seek care for chlamydia and/or gonorrhea.<br>• Partners should abstain from sexual intercourse until they and their partners have been adequately treated. |
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| **Special Considerations** | *Allergies:*<br>• If the patient has a cephalosporin allergy, the community prevalence and individual risk for gonorrhea are low, and follow-up is likely, alternative therapy can be considered with one of the following alternative regimens:<br>o combination therapy of levofloxacin 500 mg orally once daily with metronidazole 500 mg orally 2 times/day for 14 days,<br>o monotherapy with moxifloxacin 400 mg orally once daily for 14 days, or |

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| | monotherapy with azithromycin 500 mg IV daily for 1–2 days, followed by 250 mg orally daily for a total azithromycin duration of 7 days or in combination with metronidazole 500 mg 3 times/day for 12–14 days<br><br>*Pregnancy:*<br>• Pregnant women with suspected PID should be emergently referred to the prenatal provider and sent to the hospital for parenteral treatment.<br>• There is a high risk of maternal morbidity and preterm delivery with PID in pregnancy.<br><br>*HIV infection:*<br>• Manage a patient with HIV the same as a person without HIV.<br><br>*Intrauterine Contraceptive Devices:*<br>• There is a slight risk of PID associated with IUDs in the first three weeks after insertion.<br>• If a patient has an IUD and PID, the IUD does not need to be removed. However, if there is no improvement in PID symptoms after 48-72 hours of therapy, then providers should consider removing the IUD. |
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| **Patient Education/Counseling** | • Abstain from sexual intercourse until therapy is completed, symptoms have resolved, and sex partners have been adequately treated.<br>• Information regarding reducing risk factors for PID and STIs, such as limiting the number of sex partners, avoiding unsafe sex practices, and routinely using appropriate barrier protection.<br>• Adolescents are at an increased risk for PID and should be advised to delay the onset of sexual activity until age 16 or older.<br>• PID can be caused by infections that are not sexually transmitted, such as BV.<br>• Possible long-term effects of PID are infertility, ectopic pregnancy, and chronic pelvic pain.<br>• Implement behavioral counseling interventions to reduce the likelihood of acquiring additional STIs. |
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| **Follow-up** | • Follow-up appointment in 3 days.<br>• If no clinical improvement within 72 hours of therapy, then hospitalization, assessment of the antimicrobial regimen, and additional diagnostics are recommended.<br>• Women with a diagnosis of chlamydial or gonococcal PID should be retested in 3 months, regardless of whether their sex partners were treated. If retesting at 3 months is not possible, these women should be |

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| | retested whenever they next present for medical care in the 12 months following treatment. |
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| **Consultation/Referral** | • Hospitalization is necessary for any of the following criteria:<br>  ○ Surgical emergencies (e.g., appendicitis) cannot be excluded<br>  ○ Tubo-ovarian abscess<br>  ○ Pregnancy<br>  ○ Severe illness, nausea and vomiting, or high fever<br>  ○ Unable to follow or tolerate an outpatient oral regimen<br>  ○ No clinical response to oral antimicrobial therapy within 72 hours |
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| **Screening** | • Screening for lower genital tract chlamydial and gonorrhea infections in younger and high-risk populations is recommended to reduce the incidence of PID. Asymptomatic disease should be treated. |
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| **Reporting** | • No state mandated reporting is required for PID.<br>• Gonorrhea and chlamydia infections must be reported. |
| | |

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## What is Genital Herpes Simplex Virus (HSV)?

Genital herpes is a chronic, life-long viral infection. Genital herpes is usually caused by HSV-2, but it can also be caused by HSV-1. HSV is transmitted through direct contact (e.g., kissing, oral sex, sexual contact) from a person who is actively shedding the virus. Most cases of recurrent genital herpes are caused by HSV-2; however, an increasing proportion of anogenital herpetic infections have been attributed to HSV-1 infection, which is especially prominent amount young women and men having sex with men (MSM). Lesion location is not necessarily indicative of viral type.

Up to 80% of HSV infections are asymptomatic. Most persons infected with HSV-2 have not had the condition diagnosed. Persons with mild or unrecognized infections spread the infection unknowingly during intermittent periods of viral shedding. HSV management should address the chronic nature of the disease and not only the acute episode.

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| **Subjective Data/Symptoms** | *History may include:*<br>• Prior HSV infection<br>• Partner with past or present HSV symptoms or STIs<br>• Recent change in sex partners<br>• Multiple partners or partner with multiple partners<br>• Lack of condom use (STI protection)<br><br>*Symptoms may include:*<br>• Fever, headache, malaise, and myalgia<br>• Local symptoms include pain, itching, dysuria, vaginal and urethral discharge, and tender lymphadenopathy<br>• Prodrome of tenderness, pain, and burning at the site of eruption |
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| **Objective Data** | *Physical Findings:*<br><br>Clinical diagnosis of genital herpes can be difficult because the self-limited, recurrent, painful, and vesicular or ulcerative lesions classically associated with HSV are absent in many infected persons at the time of clinical evaluation.<br><br>Primary genital herpes infection<br>• Herpetic vesicles may appear on external genitalia, labia majora, labia minora, vaginal vestibule, and introitus of women or glans penis, the prepuce, the shaft of the penis, and sometimes on the scrotum, thighs, and buttocks of men.<br>• Ulcers or pustules or encrusted pustules<br>• Vaginal mucosa that is inflamed and edematous |

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| | • Cervix with ulcerative or necrotic cervical mucosa<br>• Mucoid discharge in male urethra<br><br>Recurrent genital herpes infection<br><br>• In women, the vesicles are found on the labia majora, labia minora, or perineum.<br>• In men, one or more patches of grouped vesicles on the shaft of the penis, prepuce, or glans. |
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| **Assessment** | *Lab testing:*<br><br>• HSV NAAT, culture, or polymerase chain reaction (PCR) testing<br>o Cultures and PCR tests should be typed to determine which type of HSV is causing the infection.<br>o Failure to detect HSV, especially in the absence of active lesions, does not indicate an absence of HSV because viral shedding is intermittent.<br><br>• Accurate type-specific HSV serologic assays are based on the HSV-specific glycoprotein G2 (HSV-2) and glycoprotein G1 (HSV-1).<br>o Providers should only request type-specific glycoprotein G (gG)-based serologic assays when serology is performed for their patients<br>o Examples: *HerpeSelect* ELISA, *HerpeSelect* immunoblot, *POCkit*-HSV-2<br><br>• Additional STI testing, including HIV testing |
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| **Plan / Pharmacologic Treatment** | *Medication:*<br><br>**First clinical episode of genital herpes**<br><br><u>Recommended Regimens*</u><br>Acyclovir 400 mg orally three times a day for 7–10 days OR<br>OR<br>Valacyclovir 1 g orally twice a day for 7–10 days<br>OR<br>Famciclovir 250 mg orally three times a day for 7–10 days<br>* Treatment can be extended if healing is incomplete after 10 days of therapy<br>* Acyclovir 200 mg orally five times a day for 7–10 days is effective but not recommended because of frequency of dosing. |

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| | **Established HSV-2 infections – Suppressive therapy for recurrent genital herpes**<br><br><u>Recommended Regimens</u> Acyclovir<br>400 mg orally twice a day OR<br>Valacyclovir 500 mg orally once a day*<br>OR<br>Valacyclovir 1 g orally once a day<br>OR<br>Famiciclovir 250 mg orally twice a day<br>* Valacyclovir 500 mg once a day might be less effective than other valacyclovir or acyclovir dosing regimens in persons who have very frequent recurrences (i.e., ≥10 episodes per year).<br><br>**Established HSV-2 infections – Episodic therapy for recurrent genital herpes**<br><br><u>Recommended Regimens</u><br>Acyclovir 800 mg orally twice a day for 5 days<br>OR<br>Acyclovir 800 mg orally three times a day for 2 days OR<br>Valacyclovir 500 mg orally twice a day for 3 days<br>OR<br>Valacyclovir 1 g orally once a day for 5 days<br>OR<br>Famciclovir 125 mg orally twice daily for 5 days<br>OR<br>Famciclovir 1 gram orally twice daily for 1 day<br>OR<br>Famciclovir 500 mg once, followed by 250 mg twice daily for 2 days<br><br>*Acyclovir 400 mg orally 3 times/day is also effective, but are not recommended because of frequency of dosing.<br><br>*Management of sex partners:*<br>• Symptomatic sex partners should be evaluated and treated in the same manner as patients who have genital herpes.<br>• Asymptomatic sex partners of patients who have genital herpes should be questioned concerning histories of genital lesions and offered type- specific serologic testing for HSV infection. |
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| **Special Considerations** | *Allergies:*<br>• Allergic and other adverse reactions to oral acyclovir, valacyclovir, and famciclovir are rare.<br>• Can be desensitized to acyclovir.<br><br>*Pregnancy:*<br>• Pregnant women without HSV should abstain from having sex with a partner who is known to have or suspected to have HSV during the third trimester.<br>• Risk of spreading HSV to the neonate is high if HSV is acquired late in the pregnancy but low if she has recurrent HSV or acquired HSV in the first half of pregnancy.<br>• Women who acquire HSV in the second half of pregnancy should be managed in consultation with maternal-fetal medicine and infectious disease specialists.<br>• All pregnant women should be asked if they have a history of genital herpes.<br>• Suppressive therapy is recommended starting at 36 weeks gestation for pregnant women with known HSV with acyclovir 400 mg orally three times/day OR valacyclovir 500 mg orally two time/day.<br><br>*HIV infection:*<br>• Immunocompromised patients can have prolonged or severe episodes of genital, perianal, or oral herpes.<br>• Lesions caused by HSV are common among persons with HIV infection and might be severe, painful, and atypical.<br>• HSV shedding is increased in persons with HIV infection. Although antiretroviral therapy reduces the severity and frequency of symptomatic genital herpes, frequent subclinical shedding still occurs.<br><br>**Recommended Regimens for Daily Suppressive Therapy in Persons with HIV**<br>Acyclovir 400–800 mg orally twice to three times a day OR<br>Valacyclovir 500 mg orally twice a day<br>OR<br>Famciclovir 500 mg orally twice a day<br><br>**Recommended Regimens for Episodic Infection in Persons with HIV**<br>Acyclovir 400 mg orally three times a day for 5–10 days OR<br>Valacyclovir 1 g orally twice a day for 5–10 days<br>OR<br>Famciclovir 500 mg orally twice a day for 5–10 days |

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| **Patient Education/Counseling** | The following topics should be discussed when counseling persons with genital HSV infection:<br><br>• the natural history of the disease, with emphasis on the potential forrecurrent episodes, asymptomatic viral shedding, and the attendant risks of sexual transmission<br>• the effectiveness of suppressive therapy for persons experiencing a first episode of genital herpes in preventing symptomatic recurrent episodes<br>• use of episodic therapy to shorten the duration of recurrent episodes<br>• importance of informing current sex partners about genital herpes and informing future partners before initiating a sexual relationship<br>• potential for sexual transmission of HSV to occur during asymptomatic periods<br>• importance of abstaining from sexual activity with uninfected partners when lesions or prodromal symptoms are present<br>• effectiveness of daily use of valacyclovir in reducing risk for transmission of HSV-2, and the lack of effectiveness of episodic or suppressive therapy in persons with HIV<br>and HSV infection in reducing risk for transmission to partners who might be at risk for HSV-2 acquisition<br>• effectiveness of male latex condoms, which when used consistently and correctly can reduce (but not eliminate) the risk for genital herpes transmission<br>• HSV infection in the absence of symptoms<br>• risk for neonatal HSV infection<br>• increased risk for HIV acquisition among HSV-2 seropositive persons who are exposed to HIV<br>• HSV does not cause cancer.<br>• Implement behavioral counseling interventions to reduce the likelihood of acquiring additional STIs. |
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| **Follow-up** | • As needed |
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| **Consultation/Referral** | • Pregnant patients with HSV should be referred to a prenatal care provider<br>o Pregnant women who acquire HSV infection during late pregnancy should be referred to maternal-fetal medicine and infectious disease providers<br><br>• May refer outpatients that are immunocompromised<br>• Patients with antiviral-resistant HSV need an infection disease specialist |

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| | • Severe cases may need IV medication and hospitalization |
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| **Screening** | • Screening for HSV-1 and HSV-2 in the general population is not indicated.<br>• HSV serologic testing should be considered for persons presenting for an STI evaluation (especially for those persons with multiple sex partners), persons with HIV infection, and MSM at increased risk for HIV acquisition. |
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| **Reporting** | • Mandated state reporting is not required. |
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## What is syphilis?

Acquired syphilis is typically a sexually transmitted disease caused by *Treponema pallidum*. Syphilis is systemic and has an incubation time of 10-90 days. It is classified into four stages: primary, secondary, tertiary, and latent. If syphilis is treated during the primary or secondary stages, prognosis is good.

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| **Subjective Data/Symptoms** | *History may include:*<br>• History of syphilis<br>• Lack of STI protection<br>• Recent change in sex partner<br>• Partner that has syphilis or related symptoms<br>• Multiple partners or partners(s) with multiple partners<br>• Illicit drug use<br>• Commercial sex work or coerced sex<br>• Men who have sex with men (MSM)<br>• HIV+<br>• Being pregnant<br><br>*Symptoms may include:*<br>• Painless lesion (chancre)<br>• Rash on palms of hands, soles of feet, and in mouth<br>• Malaise<br>• Fever<br>• Myalgias and/or arthralgias<br>• Lymphadenopathy |
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| **Objective Data** | *Physical Findings:*<br>• Primary syphilis<br>  ○ Ulcer or chancre at the infection site<br>  ○ The lesion has a punched-out base and rolled edges<br>• Secondary syphilis<br>  ○ Skin rash<br>  ○ Mucocutaneous lesions<br>  ○ Lymphadenopathy<br>  ○ Condylomata lata (gray-white lesions in warm, moist sites)<br>  ○ Alopecia<br>• Tertiary syphilis<br>  ○ Cardiac lesions which can cause aortitis and aortic aneurysms, aortic valvular insufficiency, and narrowing of the coronary ostia which could potentially cause heart failure and myocardial infarction. |

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| | ○ Gummatous lesions<br>○ Tabes dorsalis<br>○ General paresis<br>• Latent syphilis<br>○ No clinical manifestations but can detect with serologic testing.<br>• Neurologic manifestations of syphilis<br>○ Early (first few months or years) – cranial nerve dysfunction, meningitis, stroke, acute altered mental status, and auditory or ophthalmic abnormalities<br>○ Late (10-30 years after infection) – tabes dorsalis (loss of pain sensation, loss of peripheral reflexes, impairment of vibration and position senses, progressive ataxia, bladder incontinence, loss of sexual function, lancinating pain, charcot joints, trophic ulcers, paralysis) and general paresis (dementia related psychiatric symptoms often manifesting in depression, confusion, and severe impairment of memory and judgement). |
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| **Assessment** | *Lab testing:*<br>• A presumptive diagnosis of syphilis requires two tests:<br>1. Non-treponemal tests: VDRL or RPR<br>▪ A person with a positive non-treponemal test needs to have the treponemal test to confirm the syphilis diagnosis.<br>2. Treponemal tests: FTA-ABS tests, TP-PA assay, various EIAs, or chemiluminescence immunoassay<br>• A definitive method to diagnosis syphilis is via darkfield examination of lesion exudate or tissue<br>• Additional STI and HIV testing is recommended. |
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| **Plan / Pharmacologic Treatment** | Family Planning Clinics are recommended to consult with the medical director and/or communicable disease director to collaboratively diagnose, treat, and care for clients with syphilis.<br>*Medication:*<br>**Recommended Regimen for Adults with Primary or Secondary syphilis**<br>• Benzathine penicillin G 2.4 million units IM in a single dose<br>**Recommended Regimen for Adults with Latent syphilis**<br>• Early Latent Syphilis = Benzathine penicillin G 2.4 million units IM in a single dose |

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| | • Late Latent Syphilis or Latent Syphilis of Unknown Duration = Benzathine penicillin G 7.2 million units total, administered as 3 doses of 2.4 million units IM each at 1-week intervals<br><br>**Recommended Regimen for Adults with Tertiary syphilis**<br>• Tertiary Syphilis with Normal CSF Examination = Benzathine penicillin G 7.2 million units total, administered as 3 doses of 2.4 million units IM each at 1-week intervals<br><br>*Management of sex partners:*<br><br>Sexual transmission of T. pallidum is thought to occur only when mucocutaneous syphilitic lesions are present. Such manifestations are uncommon after the first year of infection. Persons exposed sexually to a person who has primary, secondary, or early latent syphilis should be evaluated clinically and serologically and treated according to the following recommendations:<br><br>• Persons who have had sexual contact with a person who receives a diagnosis of primary, secondary, or early latent syphilis within 90 days preceding the diagnosis should be treated presumptively for early syphilis, even if serologic test results are negative.<br>• Persons who have had sexual contact with a person who receives a diagnosis of primary, secondary, or early latent syphilis >90 days before the diagnosis should be treated presumptively for early syphilis if serologic test results are not immediately available and the opportunity for follow-up is uncertain. If serologic tests are negative, no treatment is needed. If serologic tests are positive, treatment should be based on clinical and serologic evaluation and stage of syphilis.<br>• In some areas or populations with high rates of syphilis, health departments recommend notification and presumptive treatment of sex partners of persons with late latent syphilis who have high nontreponemal serologic test titers (i.e., >1:32), because high titers might be indicative of early syphilis. These partners should be managed as if the index case had early syphilis.<br>• Long-term sex partners of persons who have late latent syphilis should be evaluated clinically and serologically for syphilis and treated on the basis of the evaluation's findings.<br>• The following sex partners of persons with syphilis are considered at risk for infection and should be confidentially notified of the exposure and need for evaluation: partners who have had sexual contact within<br>1) 3 months plus the duration of symptoms for persons who receive a diagnosis of primary syphilis, 2) 6 months plus duration of symptoms for those with secondary syphilis, and 3) 1 year for persons with early |

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| | latent syphilis. |
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| **Special Considerations** | *Allergies:*<br>• Multiple therapies might be effective for nonpregnant persons with penicillin allergy who have primary or secondary syphilis. Doxycycline (100 mg orally 2 times/day for 14 days) and tetracycline (500 mg orally 4 times/day for 14 days) have been used for years and can be effective.<br>• Persons with a penicillin allergy whose compliance with therapy or follow-up cannot be ensured should be desensitized and treated with benzathine penicillin G.<br>• The Jarisch-Herxheimer reaction is an acute febrile reaction frequently accompanied by headache, myalgia, fever, and other symptoms that can occur within the first 24 hours after the initiation of any therapy for syphilis.<br>o Patients should be informed about this possible adverse reaction and how to manage it if it occurs.<br>o The Jarisch-Herxheimer reaction occurs most frequently among persons who have early syphilis, presumably because bacterial burdens are higher during these stages.<br>o Antipyretics can be used to manage symptoms, but they have not been proven to prevent this reaction.<br>o The Jarisch-Herxheimer reaction might induce early labor or cause fetal distress in pregnant women, but this should not prevent or delay therapy<br><br>*Pregnancy:*<br>• Parenteral penicillin G is the only therapy with documents efficacy for syphilis during pregnancy.<br>• Pregnant women with syphilis in any stage who report penicillin allergy should be desensitized and treated with penicillin.<br><br>*HIV infection:*<br>• Persons with HIV infection who have syphilis should be treated as those without HIV infection. |
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| **Patient Education/Counseling** | • Stress importance of compliance with the entire antibiotic course of treatment and follow-up appointments.<br>• Discuss use of clean needles and avoiding sharing needles to those who abuse IV drugs.<br>• Stress the importance of safer sex practices and the need for evaluation and treatment of chancres and STI symptoms. |

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| | • All MSM who test positive for syphilis should be considered at risk for HIV, and if not infected with HIV, should start taking PrEP.<br>• Counsel patient to notify their partners of infection and to inform them of the need to be treated.<br>• Conditions such as autoimmune diseases, older age, pregnancy, immunizations, and IV drug use may cause false positives in the non-treponemal test.<br>• Implement behavioral counseling interventions to reduce the likelihood of acquiring additional STIs. |
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| **Follow-up** | • For primary and secondary syphilis, clinical and serologic evaluation should be performed at 6 and 12 months after treatment.<br>• Clients who have symptoms that persist or recur after treatment should be evaluated and retested.<br>• HIV status should be evaluated. |
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| **Consultation/Referral** | • Refer pregnant clients to primary or prenatal care.<br>• Referral to another provider must be made if syphilis treatment and management is not provided in your clinic. |
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| **Screening** | • Asymptomatic adult women and men who have sex with women should be screened when at increased risk (i.e., history of incarceration or transactional sex work, geography, race/ethnicity, and being a male younger than 29 years)<br>• Pregnant women should be screened at first prenatal visit.<br>• If at high risk (i.e., using drugs, STIs during pregnancy, multiple partners, a new partner, partner with STIs) , pregnant women should be retested at 28 weeks and at delivery.<br>• MSM who are sexually active should be tested at least annually.<br>• MSM who are at an increased risk should be tested every 3-6 months.<br>• For transgender and gender diverse people, Consider screening at least annually based on reported sexual behaviors and exposure.<br>• For sexually active individuals with HIV, screen at first HIV evaluation and at least annually thereafter. More frequent screening might be appropriate depending on individual risk behaviors and the local epidemiology. |
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| **Reporting** | • Syphilis is a state mandated reportable disease. |
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## What is human immunodeficiency virus (HIV)?

HIV is a blood-borne virus that is most commonly transmitted through sexual contact, sharing intravenous (IV) drug needles, and mother-to-child transmission. An HIV infection may first present with a brief, acute retroviral syndrome. Without treatment, HIV will advance into chronic illness and ends with symptomatic, life-threatening acquired

immunodeficiency syndrome (AIDS). Persons who receive early effective treatment may have a near normal lifespan. In addition to medications that slow the progression of HIV, there are medications designed to lower the risk of getting HIV for high-risk individuals. There are pre-exposure prophylaxis (PrEP) and post- exposure prophylaxis (PEP) medications.

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| **Subjective Data/Symptoms** | *History may include:*<br>• Unprotected sexual intercourse, especially receptive anal intercourse<br>• Previous or current STIs<br>• Partner history of HIV or STIs<br>• Sharing IV drug needles or syringes<br>• Multiple sex partners, high-risk partners, MSM<br>• Report of engaging in commercial sex work or human trafficking<br>• Needle-stick injuries or mucosal contact with infected blood<br>• Receipt of blood products before 1985 in the US<br><br>*Symptoms may include:*<br>• Within 2-4 weeks of exposure, flu-like symptoms that may last a few days to several weeks<br>o fever, chills, rash, night sweats, muscle aches, sore throat, fatigue, swollen lymph nodes, or mouth ulcers<br>• No symptoms<br>• HIV wasting syndrome (chronic diarrhea and weight loss with no identifiable cause) |
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| **Objective Data** | *Physical Findings:*<br><br>• Acute retroviral syndrome<br>o Generalized rash<br>o Generalized lymphadenopathy<br>• Advanced HIV infection<br>o Weight loss<br>o Oral candidiasis<br>o Cough |
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| **Assessment** | *Lab testing:*<br><br>• HIV testing begins with a laboratory-based HIV-1/HIV-2 Ag/Ab combination assay.<br>• If it is repeatedly reactive, then followed with a laboratory-based assay with a supplemental HIV-1/HIV-2 antibody differentiation assay.<br>• RNA testing should be performed on all specimens with reactive immunoassay but negative supplemental antibody test results to determine whether the discordance represents acute HIV infection.<br>• Rapid POC HIV tests can enable clinicians to make a preliminary diagnosis of HIV infection in <20 minutes.<br>o The majority of rapid antibody assays become reactive later in the course of HIV infection than conventional laboratory-based assays and thus can produce negative results among persons recently infected (e.g., acutely infected persons).<br>o If early or acute infection is suspected and a rapid HIV antibody assay is negative, confirmatory testing with combined laboratory- based assays or RNA testing should be performed. CDC recommends that all persons with reactive rapid tests be assessed with a laboratory-based Ag/Ab assay. |
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| **Plan / Pharmacologic Treatment** | *Management and treatment of HIV is not within the scope of Title X services,* but RHWP clinics must perform<br>• HIV risk assessments,<br>• counsel on HIV-risk reduction, and<br>• provide a list of referrals for HIV testing sites if the testing is not done on site.<br><br>*Partner notification:*<br>• Notification of partners (includes sexual and persons with who syringes or other injection equipment is shared) of possible HIV exposure is required.<br>• Partners should be tested.<br>• Many health departments have partner notification programs to help contact partners.<br>• If a partner has been reached and is not known to have HIV infection, he or she should be offered postexposure prophylaxis (PEP) with combination antiretrovirals if he or she was exposed to genital secretions or blood of a partner with HIV infection though sex or injection-drug use within the preceding 72 hours.<br><br>If the client tests negative for HIV, discussions, referral, or prescription for PreP may be warranted if the client has: |

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| | • had anal or vaginal sex in the past six months and has a partner with HIV, has not consistently used a condom, and/or has been diagnosed with a STI in the past sic months,<br>• injected drugs and has a partner with HIV or shares needles, syringes, or other equipment to inject drugs,<br>• been prescribed PEP and report continuing risky behavior or have had multiple courses of PEP, or<br>• are planning to become pregnant and have a partner with HIV. |
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| **Special Considerations** | *Pregnancy:*<br>• If pregnant, offer HIV testing. Starting early treatment reducing the risk of transmission to the baby to 1% or less.<br>• All pregnant women should be screened. |
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| **Patient Education/Counseling** | • HIV home-test kits only detect HIV antibodies and therefore will not detect acute HIV infection.<br>• Post-test counseling in cases of HIV positive result is required.<br>  o Importance of prompt medical care for own health and reducing transmission rates<br>  o Effectiveness of HIV treatments<br>  o What to expect as the enter medical care for HIV<br>• SBIRT for HIV<br>  o Treatment as prevention<br>  o Barrier protection (condoms, dental dams)<br>  o Clean needles (needle exchange programs/ not sharing needles, etc.)<br>  o Post-exposure prophylaxis (PEP)<br>  o Pre-exposure prophylaxis (PrEP)<br>  o Routine STI screening and treatment<br>• Advice on safe sex practices<br>• If positive, avoid donating blood or blood products<br>• If positive, start taking medication to reduce the viral load. If the viral load is undetectable, the risk of transmitting HIV to another person is basically gone.<br>• A window period is the time between when a person may have been exposed to HIV and when a test can tell for sure if a person has HIV.<br>  o A NAT test can tell if a person has HIV 10-33 within days after the exposure<br>  o An antigen/antibody test with venipuncture detects HIV in 18-45 days and with a finger prick 18-90 days after exposure |

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| | ○ An antibody test takes 23-90 days after exposure to detect HIV<br>• You can only be sure you are HIV-negative if:<br>○ Your most recent test is after the window period, and<br>○ You have not had a potential HIV exposure during the window period.<br>○ If you get an HIV test after a potential HIV exposure and the result is negative, get tested again after the window period.<br>• Implement behavioral counseling interventions to reduce the likelihood of acquiring additional STIs.<br>• Discussions regarding PrEP to prevent getting HIV from sex or injection drug use. When taken as prescribed, PrEP is highly effective for preventing HIV. |
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| **Follow-up** | • Ensure that patients with positive HIV screens are receiving HIV services and have established ongoing medical care. |
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| **Consultation/Referral** | • Newly diagnosed patients may need immediate medical care and support for case management, substance abuse, mental health, reproductive counseling, emotional distress, risk-reduction counseling, etc.<br>• Patients experiencing psychological distress should be referred accordingly.<br>• Refer to provider with experience in managing HIV.<br>• If negative test result and agency does not provide PrEP, offer referral. |
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| **Screening** | • Women and men who have sex with women aged 13-64 years should be screened annually for HIV in healthcare settings<br>○ Screening should be routine.<br>○ Persons should be notified that testing will be performed, but have the option to opt-out<br>○ Do not use a separate consent form for HIV testing.<br>○ If a person is considered high-risk, and has early syphilis, gonorrhea, or chlamydia, they should be screened for HIV at the time of STI diagnosis, even if a recent HIV test was performed.<br>• Persons seeking STI evaluation and/or treatment should also be screened for HIV,<br>• All pregnant women should be screened at the initial prenatal visit. Use the opt-out method. Retest in third trimester if at high risk. Rapid test performed at delivery if not previously screened during pregnancy.<br>• At least annually for sexually active MSM if HIV status is unknown or negative and the patient or their sex partner(s) have had more than one sex partner since most recent HIV test. Consider the benefits of offering |

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| | more frequent HIV screening (e.g., every 3–6 months) to MSM at increased risk for acquiring HIV infection.<br>• HIV screening should be discussed and offered to all transgender and gender diverse persons. Frequency of repeat screenings should be based on level of risk. |
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| **Reporting** | • Mandated state reporting is required in Mississippi. |

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## What is Human Papillomavirus (HPV)?

Human Papillomavirus (HPV) infections are typically self-limited, asymptomatic, and very common as most sexually active persons will have at least one HPV infection in their lifetime. Low-risk HPV infection (e.g., HPV types 6 and 11) cause genital warts and recurrent respiratory papillomatosis. High-risk, oncogenic HPV infections (e.g., HPV types 16 and 18) cause most cervical, penile, vulvar, vaginal, anal, and oropharyngeal cancers and precancers. Having a persistent oncogenic HPV infection is the strongest risk factor of developing HPV-associated precancers and cancers.

The Centers for Disease Control and Prevention recommend that all girls and boys aged 11-12 years receive the HPV vaccine, and children may start the series as early as 9 years old. If the series is started before the 15th birthday, two doses are required. The three-dose series should be given to persons aged 15-26 years.
Some adults aged 27-45, with shared clinical decision-making, may receive the vaccine. Please see https://www.cdc.gov/hpv/hcp/schedules-recommendations.html for vaccination schedules, dosing, and common questions and answers about the HPV vaccine schedule.

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| **Subjective Data/Symptoms** | *History may include:*<br>• Cervical disease (low- or high-grade squamous intraepithelial lesion [LGSIL or HGLIS, respectively]) or previous abnormal pap results<br>• Personal or partner history of STIs<br>• Partner symptoms<br>• Multiple sex partners<br>• Dyspareunia<br><br>*Symptoms may include:*<br>• Genital warts – smooth and papular or keratotic, generally not painful but may itch or bleed<br>• Genital or anal pruritis<br>• Bumps, growths, or lesions on genital area (vulva, perineum, vagina, urethra penis, and/or rectum) or oral cavity (mouth, throat)<br>• Asymptomatic |
| | |
| **Objective Data** | *Physical Findings:*<br>• No findings or subclinical infection<br>• Anogenital warts<br>  ○ Condylomata acuminate (cauliflower-like appearance and may be skin-colored, pink, or hyperpigmented and often on multiple moist surfaces),<br>  ○ smooth papules (usually dome-shaped and skin colored),<br>  ○ flat papules (macular to slightly raised skin-colored, and have a smooth surface), or |

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| | o keratotic warts (with a thick keratinized layer that can resemble common warts or seborrheic keratosis; often on dry surfaces)<br><br>• Dysplasia and cancers<br>o Cervical dysplasia may be apparent on physical exam with visual inspection of cervix<br>o May find gross erosion, bleeding, ulcer, or mass (internal or external) |
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| **Assessment** | • Visual inspection<br>• Most cases of anogenital warts are diagnosed clinically, but confirmation by biopsy may be needed when<br>o The patient is immunocompromised<br>o Warts are pigmented, indurated, or fixed<br>o Lesions do not respond to or worsen with standard treatment<br>o There is persistent ulceration or bleeding<br>o The diagnosis us uncertain<br>o Postmenopausal women<br>o Women with a history of vulvar dysplasia<br>• External genital warts are not an indication for cervical colposcopy or type-specific HPV DNA testing<br>• Screen persons with newly diagnoses anogenital warts for additional STIs (e.g., chlamydia, gonorrhea, HIV, syphilis)<br>• Application of 3-5% acetic acid is not routinely recommended because it does not influence clinical management and there are many false-positives<br><br>*Lab testing that may be considered:*<br>• Cervical cytologic testing with the Papanicolaou (Pap) test to screen for cervical neoplasia<br>o Please refer to the *2019 ASCCP Risk-Based Management Consensus Guidelines at* http://www.asccp.org/guidelines<br>• HPV DNA testing (e.g., with Hybrid Capture II or polymerase chain reaction [PCR] assay) for detection of HPV and posttreatment follow-up of cervical intraepithelial neoplasia. These tests should not be used for male partners of women with HPV or women aged <25 years, for diagnosis of genital warts, or as a general STI test.<br>• The acetic acid test: This test is sometimes used in conjunction with colposcopy to examine cervical lesions; however, it is reserved for suspicious lesions and should not be used for routine screening because the results do not influence clinical management. |
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| **Plan / Pharmacologic Treatment** | **Recommended Regimens for External Anogenital Warts** (i.e., penis, groin, scrotum, vulva, perineum, external anus, and perianus*) |

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| | Patient-Applied:<br>Imiquimod 3.75% or 5% cream†<br>OR<br>Podofilox 0.5% solution or gel OR<br>Sinecatechins 15% ointment†<br><br>Provider–Administered:<br>Cryotherapy with liquid nitrogen or cryoprobe<br>OR<br>Surgical removal either by tangential scissor excision, tangential shave excision, curettage, laser, or electrosurgery<br>OR<br>Trichloroacetic acid (TCA) or bichloroacetic acid (BCA) 80%–90% solution<br><br>* Many persons with external anal warts also have intra-anal warts. Thus, persons with external anal warts might benefit from an inspection of the anal canal by digital examination, standard anoscopy, or high-resolution anoscopy.<br>† Might weaken condoms and vaginal diaphragms.<br><br>**Recommended Regimens for Vaginal, Cervical, or Intra-Anal Warts** Cryotherapy with liquid nitrogen. The use of a cryoprobe in the vagina is not recommended because of the risk for vaginal perforation and fistula formation. OR<br>Surgical removal OR<br>TCA or BCA 80%–90% solution<br><br>Management of cervical warts should include consultation with a specialist. For women who have exophytic cervical warts, a biopsy evaluation to exclude HSIL should be performed before treatment is initiated.<br><br>Management of intra-anal warts should include consultation with a colorectal specialist.<br><br>**Recommended Regimens for Urethral Meatus Warts**<br>Cryotherapy with liquid nitrogen<br>OR<br>Surgical removal*Management of sex partners:*<br>• Clients with genital warts should inform current sex partner(s) because the HPV infection can be passed on to others. |

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| | • Partners may have HPV infection, even if they have no signs of genital warts.<br>• Partners may want to consider genital wart exam and STI screening.<br>• Patients should have no sexual activity with new partners until warts are gone or removed.<br>• Patients can still potentially transmit HPV to sexual partners after visible warts are gone since HPV can remain persistent in the tissues. |
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| **Special Considerations** | *Pregnancy:*<br>• HPV vaccines are not recommended during pregnancy.<br>• Genital warts may proliferate rapidly and become friable during pregnancy.<br>• Watchful waiting is acceptable with smaller lesions.<br>• Cytotoxic agents (e.g., podophyllin, podofilox, imiquimod) should not be use during pregnancy.<br>• Cesarean section should not be performed solely to prevent HPV transmission to the neonate.<br><br>*HIV infection:*<br>• The general approach is the same.<br>• Persons with advanced immunosuppression may have larger or more numerous warts that do not respond as well to therapy.<br>• HSIL and invasive cancers arising with the region of a genital wart are more common, so hyperpigmented and persistent lesions should be evaluated with biopsy.<br>• Women with HIV infection have an increased risk of cervical precancers and cancers and require more frequent Pap screening. |
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| **Patient Education/Counseling** | • Abstaining from sexual activity is the most reliable method to prevent genital HPV infections.<br>• Correct and consistent condom use and limiting the number of sex partners can reduce the chances of getting an HPV infection.<br>• Anogenital HPV infections are very common. Most sexually active people get HPV, although many people do not know they have it.<br>• Most persons who acquire HPV clear the infection spontaneously and have no associated health problems. When the HPV infection does not clear, genital warts, precancers, and cancers of the cervix, anus, penis, vulva, vagina, head, and neck might develop.<br>• The types of HPV that cause genital warts are different from the types that can cause cancer.<br><br>• HPV may be transmitted by oral, vaginal, and/or anal sex, along with genital to genital contact without penetration. |

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| | • HPV vaccines are FDA approved and recommended for persons aged 9-26 years.<br>• Implement behavioral counseling interventions to reduce the likelihood of acquiring STIs. |
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| **Follow-up** | • Most anogenital warts respond within 3 months of therapy.<br>• Although genital warts can be treated, the treatment does not cure the virus. Thus, it is common for genital warts to return.<br>• Women with genital warts do not need Pap tests more often than other women.<br>• If HPV is found on cervical cytology/Pap test, follow ASCCP guidelines http://www.asccp.org/guidelines |
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| **Consultation/Referral** | • Patients with cervical or intra-anal warts should see a specialist.<br>• If a biopsy of an atypical wart reveals HSIL or cancer of the anogenital tract, referral to a specialist is needed.<br>• If results of a Pap test are abnormal and the clinic cannot manage (see http://www.asccp.org/guidelines), then refer for proper follow-up care. |
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| **Screening** | • Women aged 30 to 65 may have a HPV test with their Pap test (co-testing) every 5 years or every 3 years with cutologu to test for cervical cancer<br>• Women aged 21-29 should have a Pap test every 3 years but do not need co-testing because HPV is extremely common in women those ages and the virus tends to clear on its own.<br>• Pregnant women should be screened at same intervals as nonpregnant cis- gender women.<br>• MSM should have a digital rectal exam.<br>• Transgender and gender diverse people with a cervix should follow current screenings guidelines for cervical cancer.<br>• Women with HIV should be screened within 1 year of sexual activity using conventional or liquid-based cytology; testing should be repeated 6 months later. With 3 normal and consecutive Pap tests, screening should be every 3 years.<br>• There is no FDA-approved HPV test for men or for the mouth or throat, only the cervix. |
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| **Reporting** | • HPV infection is not reportable. |
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## What is Bacterial Vaginosis (BV)?

BV is a gynecologic condition related to changes in the normal vaginal flora, and it is the most prevalent cause of vaginitis and malodorous vaginal discharge among women of reproductive age. It is caused by normal vaginal lactobacilli being replaced by anaerobic bacteria which leads to polymicrobial clinical syndrome.
BV is related to having multiple partners, a new sex partner, douching, lack of condom use, and lack of vaginal lactobacilli; women who have never been sexually active are rarely affected.

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| **Subjective Data/Symptoms** | *History may include:*<br>• Multiple sexual partners<br>• Recent changes in sexual partner<br>• Lack of condom use<br>• Non-best practice vaginal hygiene practices<br>ex) Douching, improper wiping techniques, using unclean sex toys, using soap on vagina<br><br>*Symptoms may include:*<br>• Up to half of women with BV are asymptomatic<br>• "Fishy odor" discharge<br>• Increased amount of discharge<br>• Odor and amount of discharge increase after sex or end of menses<br>• Burning with urination<br>• Itching on outside of vagina or vaginal irritation |
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| **Objective Data** | *Physical Findings:*<br>• Homogeneous, thin, milky-white or dull gray discharge that coats vaginal walls<br>• Amine odor |
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| **Assessment** | *Lab testing:*<br><br>The presence of three of the four Amsel's Criteria will diagnose BV<br>1. pH of vaginal fluid > 4.5<br>2. "Clue cells" on wet mount exam<br>3. Homogeneous, nonviscous, milky-white discharge that coats the vaginal walls<br>4. Positive amine or "whiff" test (ability to smell amines with or without addition of 10% KOH)<br>Other diagnostic approaches:<br>• Gram's stain with Nugent scoring |

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| | • BV NAATs<br>• BD Affirm VPIII assay<br>• Pap testing and cultures are not recommended<br><br>All women with BV should be tested for HIV and other STIs |
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| **Plan / Pharmacologic Treatment** | Treatment is recommended for women with symptoms<br><br>*Medication:*<br><br>**<u>Recommended Regimens</u>**<br>• Metronidazole 500 mg orally twice a day for 7 days<br>*OR*<br>• Metronidazole gel, 0.75%, one full applicator (5 g) intravaginally, once a day for 5 days<br>*OR*<br>• Clindamycin cream, 2%, one full applicator (5 g) intravaginally at bedtime for 7 days+<br><br>**<u>Alternative Regimens</u>**<br>• Tinidazole 2 g orally once daily for 2 days<br>*OR*<br>• Tinidazole 1 g orally once daily for 5 days<br>*OR*<br>• Clindamycin 300 mg orally twice daily for 7 days<br>*OR*<br>• Clindamycin ovules 100 mg intravaginally once at bedtime for 3 days.<br>*OR*<br>• Secnidazole 2g oral granules<br><br>+Clindamycin ovules is oil-based and might weaken latex condoms and diaphragms for 72 hours following treatment (refer to clindamycin product labeling for additional information). |

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| | **<u>Regimens for Recurrent BV</u>**<br>• May repeat initial treatment regimen after first occurrence<br>• If there are multiple recurrences after completion of a recommended regimen, try<br>  o 0.75% metronidazole gel or 750 mg metronidazole vaginal suppository twice weekly for >3 months<br>  *OR*<br>  o oral nitroimidazole (metronidazole or tinidazole 500 mg twice daily for 7 days) followed by intravaginal boric acid 600 mg daily for 21 days and then suppressive 0.75% metronidazole gel twice weekly for 4–6 months<br>  *OR*<br>  o Monthly oral metronidazole 2 g administered with fluconazole 150 mg<br><br>*Partner notification:*<br>• Is not state mandated<br><br>*Management of sex partners:*<br>• Treatment of male sex partners has not been beneficial in preventing recurrence.<br>• The option of screening and treatment of female sex partners may be considered due to frequent concurrent infections |
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| **Special Considerations** | *Allergies:*<br>• Intravaginal clindamycin cream is preferred in case of allergy or intolerance to metronidazole or tinidazole.<br>• Intravaginal metronidazole gel can be considered for women who are not allergic to metronidazole but do not tolerate oral metronidazole.<br>• Intravaginal metronidazole should not be administered to women allergic to metronidazole.<br><br>*Pregnancy:*<br>• BV has been associated with late miscarriage, premature delivery and rupture of membranes, and low-birth weight<br>• Treatment is recommended for all symptomatic pregnant women<br>• Tinidazole should be avoided in pregnant women<br><br>*HIV infection:*<br>• Having BV may increase your risk of contracting HIV, HSV-2, chlamydia, and gonorrhea<br>• Patients with HIV should follow the same treatment regimen as patients without HIV |

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| **Patient Education/Counseling** | • BV is common and is caused by a shift in normal vaginal flora<br>• Condoms and oral contraceptive pills are protective against BV<br>• BV is not a STI, but having sex more often, with multiple partners, at younger ages, orally or anally, or without condoms increases the risk of getting BV<br>• Women with BV are at an increased risk for STI acquisition.<br>• Clindamycin ovules is oil-based and might weaken latex condoms and diaphragms for 72 hours following treatment.<br>• Refrain from sexual activity or use condoms consistently and correctly during the treatment regimen.<br>• Do not douche<br>• Sexual partner treatment is not recommended<br>• Use best-practice vaginal hygiene practices<br>  ○ Wipe front to back (vagina to anus)<br>  ○ Do not use soap to wash the inside or outside of your vagina |
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| **Follow-up** | • Unnecessary if symptoms resolve<br>• Encourage patient to return if symptoms return or do not resolve |
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| **Consultation/Referral** | • Refer pregnant patients to primary or prenatal care<br>• Refer clients with persistent or recurrent BV |
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| **Screening** | • Screening for BV in asymptomatic women is not recommended<br>• Screening for BV before a vaginal related surgery may be considered to reduce rates of post-surgical infections<br>• Due to high concordance in female same-sex relationships, if one partner has BV, the provider may want to screen the other female partner(s) |
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| **Reporting** | Mandated state reporting is not required |
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## What is trichomoniasis?

Trichomoniasis, commonly called Trich, is the most prevalent nonviral STI. It is caused by a motile parasitic protozoan *Trichomonas vaginalis*. The prevalence of trichomoniasis is low among men that have sex with men (MSM), but it affects men and women and is easily passed via penile-vaginal sex. *T. vaginalis* infection is associated with an increased risk of infection with several STIs, including gonorrhea, human papillomavirus (HPV), herpes simplex virus (HSV), and, most importantly, HIV. Trichomoniasis is also associated with adverse pregnancy outcomes, infertility, postoperative infections, and cervical neoplasia.

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| **Subjective Data/Symptoms** | *History may include:*<br>• New or multiple sex partners<br>• Exchanging sex for money or drugs<br>• Sexual contact with an infected partner<br>• Not using barrier protection<br>• History or current STI<br>• History of or present use of injection drugs<br><br>*Symptoms may include:*<br>• Vaginal discharge that is diffuse, malodorous, and/or yellow-green<br>• Vulvar irritation – itching, burning, or soreness<br>• Postcoital bleeding<br>• Lower abdominal pain<br>• Dyspareunia<br>• Dysuria (from urethritis or prostatitis)<br>• Scrotal pain and swelling (from epididymitis)<br>• Penile discharge |
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| **Objective Data** | *Physical Findings:*<br>• Abnormal vaginal discharge – purulent, frothy, or bloody<br>• Abnormal vaginal odor – "musty"<br>• Cervicitis - easily induced endocervical bleeding and purulent discharge in endocervical canal<br>• Petechiae on ectocervix ("strawberry cervix")<br>• Purulent to mucoid urethral discharge |
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| **Assessment** | *Lab testing options:*<br>• Nucleic acid amplification test (NAAT)<br>• RNA assay<br>• DNA assay |

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| | • Trichomonas Rapid Test<br>• Culture<br>• Wet prep<br>  o The wet prep is very common because it is convenient and low cost, but it has low sensitivity.<br>  o When highly sensitive (e.g., NAAT) testing on specimens in not feasible, a testing algorithm (e.g., wet mount first, followed by NAAT if negative) can improve diagnostic sensitivity in persons with an initial negative result by wet mount.<br><br>Testing for additional STIs should be performed. |
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| **Plan / Pharmacologic Treatment** | *Medication:*<br><br>**Recommended Regimen Among Women**<br>Metronidazole 500 mg orally twice a day for 7 days<br><br>**Recommended Regimen Among Men**<br>Metronidazole 2 g orally in a single dose<br><br>**Alternative Regimen for Men and Women**<br>Tinidazole 2 g orally in a single dose<br><br>*Management of sex partners:*<br>• Sexual partner(s) of the infected patient should be treated.<br>• Both the patient and the partner(s) should abstain from sexual activity until the pharmacological treatment has been completed and they have no symptoms.<br>• In Mississippi, expedited partner therapy (EPT) is allowed for treatment of trichomoniasis. |
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| **Special Considerations** | *Allergies:*<br>• Desensitization to nitroimidazoles can be managed in consultation with a specialist.<br><br>*Pregnancy:*<br>• Pregnant patients should be referred to primary or prenatal care.<br>• Tinidazole should be avoided.<br>• Symptomatic pregnant women, regardless of pregnancy stage, should be tested and considered for treatment. |

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| | *Breastfeeding*<br>• Consider deferring breastfeeding for 12-24 hours following maternal treatment with a single 2g dose of metronidazole.<br>• Breastfeeding should be deferred for 72 hours following single 2g dose of tinidazole.<br><br>*HIV infection:*<br>• Among women with HIV infection, *T. vaginalis* infection is associated with increased risk for PID and increased viral load and viral shedding.<br>• Likelihood of adverse outcomes in women with HIV is reduced with *T. vaginalis* therapy.<br>• Recommended treatment for patients with HIV and a trichomoniasis infection is metronidazole 500mg twice daily for 7 days.<br>• Rescreen in 3 months, and at least annually thereafter. |
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| **Patient Education/Counseling** | • Among sexually active persons, the best method to prevent trichomoniasis is through consistent and correct use of condoms during all penile-vaginal sexual encounters.<br>• Douching is not recommended because it might increase the risk for vaginal infections.<br>• Stress the importance of additional STI testing and treatment.<br>• Encourage patient to inform sexual partner(s) of diagnosis and to receive testing or EPT.<br>• Implement behavioral counseling interventions to reduce the likelihood of acquiring STIs. |
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| **Follow-up** | • Rescreening at 3 months posttreatment is recommended for women.<br>• Data are insufficient to support retesting men.<br>• If treatment failure occurs in a woman, retreat with metronidazole 500mg twice a day for 7 days.<br>  ○ If no reexposure has occurred, a woman should be treated with metronidazole or tinidazole 2 g once daily for 7 days.<br>• If a man has persistent *T. vaginalis* after a single 2-g dose of metronidazole and has been reexposed to an untreated partner, the client should be retreated with a single 2-g dose of metronidazole.<br>  ○ If there has not been reexposed, the man should be administered a course of metronidazole 500 mg 2 times/day for 7 days.<br>• If treatment failure occurs repeatedly, clinicians should request a kit from CDC to perform drug-resistance testing. |
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| **Consultation/Referral** | • Refer pregnant patients to primary or prenatal care. |

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| **Screening** | • Testing for *T. vaginalis* infection is recommended in all women seeking care for vaginal discharge.<br>• Consider screening women receiving care in high-prevalence settings (e.g., STI clinics and correctional facilities) and for women at high risk for infection (e.g., women with multiple sex partners, exchanging sex for payment, illicit drug use, and a history of STI)<br>• Recommended for sexually active women with HIV at entry to care and at least annually thereafter.<br>• Rectal and oral screenings are not recommended. |
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| **Reporting** | • Mandated state reporting is not required. |
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## What is vulvovaginal candidiasis?

Vulvovaginal candidiasis (VVC), commonly referred to as a yeast infection, is usually caused by *Candida albicans,* and is not generally considered to be a sexually transmitted infection. Approximately75% of women will have a least one VVC infection. A VVC infection can be classified as uncomplicated or complicated and acute, chronic, recurrent or persistent.

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| **Subjective Data/Symptoms** | *History may include:*<br>• Being pregnant<br>• Using birth control with high levels of estrogen<br>• Compromised immune system – ex) diabetes, HIV<br>• Recent use of antibiotics, chemotherapy, or corticosteroids<br><br>*Symptoms may include:*<br>• Vulvar puritus and burning<br>• Thick, white, curdy vaginal discharge<br>• Vulvar pain, swelling, and redness<br>• External dysuria<br>• Dyspareunia |
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| **Objective Data** | *Physical Findings:*<br>• Edema and erythema of the vestibule, labia majora, and labia minora<br>• Thrush patches may be found loosely attached to the vulva<br>• May have rash extending to perineum and thighs<br>• Fissures or excoriation<br>• Thick, white, curdy vaginal discharge |
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| **Assessment** | *Lab testing:*<br>• Vaginal pH of 4.0-4.5<br>• Wet preparation (10% KOH or saline) or Gram stain of discharge showing budding yeasts, pseudohypahe, or hyphae<br>• A yeast culture may be used if the diagnosis is uncertain |
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| **Plan / Pharmacologic Treatment** | *Medication:*<br><br>**<u>Recommended Regimens</u>** |

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| | **Over-the-Counter Intravaginal Agents:**<br><br>Clotrimazole 1% cream 5 g intravaginally for 7–14 days OR<br>Clotrimazole 2% cream 5 g intravaginally for 3 days OR<br>Miconazole 2% cream 5 g intravaginally for 7 days OR<br>Miconazole 4% cream 5 g intravaginally for 3 days OR<br>Miconazole 100 mg vaginal suppository, one suppository for 7 days OR<br>Miconazole 200 mg vaginal suppository, one suppository for 3 days OR<br>Miconazole 1,200 mg vaginal suppository, one suppository for 1 day OR<br>Tioconazole 6.5% ointment 5 g intravaginally in a single application<br><br>**Prescription Intravaginal Agents:**<br><br>Butoconazole 2% cream (single dose bioadhesive product), 5 g intravaginally for 1 day OR<br>Terconazole 0.4% cream 5 g intravaginally for 7 days OR<br>Terconazole 0.8% cream 5 g intravaginally for 3 days OR<br>Terconazole 80 mg vaginal suppository, one suppository for 3 days<br><br>**Oral Agent:**<br>Fluconazole 150 mg oral tablet, one tablet in single dose (Avoid in pregnancy)<br><br>For recurrent VVC, try to maintain clinical and mycologic control with a longer duration of initial therapy (e.g., 7–14 days of topical therapy or a 100-mg, 150-mg, or 200-mg oral dose of fluconazole every third day for a total of 3 doses [days 1, 4, and 7]) is recommended, to attempt mycologic remission, before initiating a maintenance antifungal regimen. The first line maintenance regimen<br><br>o Oral fluconazole (100 mg, 150 mg, or 200 mg) weekly for six months<br>o If this regimen is not feasible, topical treatments used intermittently can also be considered. |

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| | For Severe VVC, treating with either 7–14 days of topical azole or 150 mg of fluconazole in two sequential oral doses (second dose 72 hours after initial dose) is recommended.<br><br>For nonalbicans *Candida*, the optimal treatment is unknown, but treatment options include the following:<br>• longer duration of therapy (7–14 days) with a non-fluconazole azole regimen (oral or topical) as first-line therapy.<br>• If recurrence occurs, 600 mg of boric acid in a gelatin capsule is recommended, administered vaginally once daily for 3 weeks.<br><br>*Management of sex partners:*<br>• VVC is not usually sexually acquired, so treatment of sex partners is not warranted.<br>• Male sex partners may have balanitis.<br>  o Glans of penis may be erythematous and have pruritus or irritation<br>  o May treat with topical antifungal agents to relieve symptoms |
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| **Special Considerations** | *Allergies:*<br>• The topical agents usually cause no systemic effects, but they may result in local burning or irritation<br>• Oral azoles may cause headache, abdominal pain, and nausea<br><br>*Pregnancy:*<br>• VVC infections are common in pregnancy<br>• Only use 7-day topical azole therapies for treatment<br><br>*HIV infection:*<br>• Patients with HIV may not respond well to short-term therapies, so a longer, 7-14 day, treatment may be necessary.Long-term prophylactic therapy with fluconazole 200 mg weekly is not recommended for women with HIV infection in the absence of complicated VVC.<br>• Rates of VVC are higher in women with HIV infections as compared to seronegative women. |
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| **Patient Education/Counseling** | • VVC is not a sexually transmitted infection<br>• Limiting dietary intake of (sucrose and lactose) sugars may reduce the number of VVC infection<br>• Wear loose fitting, nonocclusive clothing<br>• Wear cotton underwear<br>• The creams and suppositories in the recommended regimens are oil- based and may weaken latex condoms and diaphragms. |

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| | • If symptoms persist or there is a recurrence of symptoms within two months of treatment, a patient should be clinically evaluated and treated<br>• If diabetic, maintaining good glycemic control may help prevent VVC |
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| **Follow-up** | • Follow-up is not usually required unless symptoms persist or return<br>• If symptoms return within two months of treatment, patient should schedule a follow-up visit |
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| **Consultation/Referral** | • Patients with persistent or chronic infections<br>• Patients who are pregnant should be referred to primary or prenatal care |
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| **Screening** | • Screening for VVC in asymptomatic women is not recommended |
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| **Reporting** | • Mandated reporting is not required |
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**References**


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## What is Nongonococcal Urethritis (NGU)?

NGU is an inflammation of the urethra that is not caused by a gonorrheal infection. It can be transmitted sexually or during birth. It can also be caused from a urinary tract infection, bacterial prostatitis, urethral stricture, phimosa, or catheterization. It is more common in males than females.

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| **Signs or Symptoms** | In men, urethral infection, symptoms may include the following:<br>• Discharge from the penis<br>• Burning or pain when urinating<br>• Itching, irritation or tenderness<br>• Underwear stain<br><br>Symptoms of NGU in women can include:<br>• Discharge from the vagina<br>• Burning or pain when urinating<br>• Abdominal pain or abnormal vaginal bleeding may be an indication that the infection has progressed to pelvic inflammatory disease (PID)<br><br>Anal or oral infections may occur in both men and women. Anal infections may result in rectal itching, discharge or pain during a bowel movement. Oral infections may occur but most (90 percent) of these infections are asymptomatic. Some people might have a sore throat. |
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| **Diagnosis** | NGU is confirmed for symptomatic men when diagnostic evaluation of urethral secretions indicates inflammation, without evidence of diplococci by Gram, MB, or GV smear on microscopy.<br><br>If microscopy is unavailable, urine testing for leukocyte esterase can be performed on first-void urine, and microscopic examination of sediment from a spun first-void urine demonstrating ≥10 WBCs/HPF has a high negative predictive value.<br><br>All men who have suspected or confirmed NGU should be tested for chlamydia and gonorrhea by using NAATs.<br><br>*M. genitalium* testing should be performed for men who have persistent or recurrent symptoms after initial empiric treatment.<br><br>Testing for *T. vaginalis* should be considered in areas or among populations with high prevalence, in cases where a partner is known to be infected, or for men who have persistent or recurrent symptoms after initial empiric treatment. |

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| **Treatment** | If diagnostic information is not immediately available, presumptive treatment should be initiated at NGU diagnosis.<br>To minimize transmission and reinfection, men treated for NGU will be instructed to abstain from sexual intercourse until they and their partner(s) have been adequately treated (i.e., for 7 days after single-dose therapy or until completion of a 7-day regimen and symptoms resolved).<br><br>Men who receive a diagnosis of NGU should be tested for HIV and syphilis.<br><br>**RECOMMENDED REGIMENS**<br>**Doxycycline** 100 mg orally twice a day for 7 days<br><br>**ALTERNATIVE REGIMENS**<br>**Azithromycin** 1 g orally in a single dose ***--OR--***<br>**Azithromycin** 500 mg orally in a single dose; then 250 mg orally for 4 days ***-- OR--***<br><br>Administration of the first dose of any treatment regimen will be directly observed in the clinic.<br><br>*Management of sex partners:*<br>• All sex partners of men with NGU within the preceding 60 days should be referred for evaluation and testing and presumptive treatment with a drug regimen effective against chlamydia.<br>• All partners should be evaluated and treated according to the management section for their respective pathogen.<br>• EPT could be an alternate approach if a partner is unable to access timely care.<br>• To avoid reinfection, sex partners should abstain from sexual intercourse until they and their partners are treated. |
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| **Follow-Up** | Men will be provided results of the testing obtained as part of the NGU evaluation, and those with a specific diagnosis of chlamydia, gonorrhea, or trichomonas will be offered partner services and instructed to return 3 months after treatment for repeat testing because of high rates of reinfection, regardless of whether their sex partners were treated. |

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| | Clients will also be instructed to return for evaluation if symptoms persist or recur after completion of therapy. They should be tested for *M. genitalium* and *T. vaginalis*.<br><br>Symptoms alone, without documentation of signs or laboratory evidence of urethral inflammation, are not a sufficient basis for retreatment.<br><br>Providers should be alert to the possibility of chronic prostatitis/chronic pelvic pain syndrome in male clients experiencing:<br>• Persistent pain (perineal, penile, or pelvic);<br>• Discomfort;<br>• Irritative voiding symptoms;<br>• Pain during or after ejaculation; or<br>• New-onset premature ejaculation lasting for >3 months.<br><br>Men with persistent pain will be referred to a urologist. |
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| **Special Considerations** | **HIV Infection:**<br>• Gonococcal urethritis, chlamydial urethritis, and nongonococcal, nonchlamydial urethritis might facilitate HIV transmission.<br>• Clients co-infected with HIV will receive the same treatment regimen as those who are HIV negative. |
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| **Client Education** | How to reduce the risk of getting NGU:<br><br>• Practice abstinence. Not having sex is the best protection against acquiring NGU and other STIs.<br>• Use latex condoms, consistently and correctly, from start to finish every time you have sexual intercourse.<br>• Have sex with only one uninfected partner who only has sex with you (mutual monogamy).<br>• Have regular checkups if you are sexually active.<br>• If you have an STI, don't have sex (oral, vaginal, anal) until all partners have been treated.<br>• Seek prompt, qualified and appropriate medical intervention, treatment and follow-up to break the disease cycle.<br>• Know your partner(s). Careful consideration and open communication between partners may protect all partners involved from infection.<br><br>If left untreated, NGU and its causes, can lead to serious complications: For men, complications may include: |

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| | • Epididymitis (inflammation of the epididymis, the elongated, cordlike structure along the posterior border of the testes) which can lead to infertility if left untreated.<br>• Reiter's syndrome (arthritis)<br>• Conjunctivitis<br>• Skin lesions<br>• Discharge<br>In women:<br>• Pelvic Inflammatory Disease (PID) which can result in ectopic (tubal) pregnancy.<br>• Recurrent PID which may lead to infertility.<br>• Chronic pelvic pain<br>• Urethritis<br>• Vaginitis<br>• Mucopurulent cervicitis<br>• Spontaneous abortion (miscarriage)<br><br>For men or women, infections caused by anal sex may lead to severe proctitis.<br><br>Infants exposed to the germs causing NGU during passage through the birth canal may develop conjunctivitis (eye infection) and/or pneumonia.<br><br>Encourage clients to inform sexual partner(s) and have them seek evaluation and treatment. Sexual activity should not resume until all partners have been treated. |
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**References**

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