

Family Planning and Reproductive Health Manual

Bureau of Family Health
Kansas Department of Health & Environment

2016-2017 Edition



Family Planning and Reproductive Health

2016-2017

CLINICAL PROTOCOLS

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Family Planning Clinical Protocols

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Clinician Guidelines for Providing Family Planning Services

DEFINITION:

Clinicians who work in Family Planning Services shall be qualified to:

1. Review and assess a complete health, psychosocial, OB/GYN, and family history and record findings in a systematic, accurate, and succinct form.
2. Perform physical examination screenings for women, with emphasis on the:
 - a. breasts
 - b. abdomen
 - c. pelvis
 - d. visualization of the cervix
 - e. collection of cervical cytology and other specimens
 - f. bimanual
 - g. recto-vaginal
3. Perform physical examination screenings for men, with emphasis on the:
 - a. breasts
 - b. abdomen and inguinal area
 - c. penis
 - d. testicles
 - e. prostate
4. Develop a health maintenance plan, including health education, disease prevention and general anticipatory guidance.
5. Provide periodic health supervision of normal, non-pregnant and asymptomatic women for health promotion and maintenance.
6. Provide periodic health supervision of normal and asymptomatic men for health promotion and maintenance.
7. Provide clinical management with medical protocols for women having uncomplicated gynecologic illness and men having uncomplicated urologic illness.
8. Provide assessment, education and management for family planning.
9. Provide health education and counseling including the psychological dimensions in the areas of nutrition, sexuality, childbearing, parenting, and family life.
10. Arrange referrals as needed.
11. Perform, order, and interpret routine laboratory tests.
12. Initiate and modify medication/treatment therapies.

In addition to the above, the clinician must carry appropriate licensures and have them on file with the Personnel office

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR April 25, 2014;63. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

Office of Population Affairs. Program Requirements for Title X Funded Family Planning Projects. April 2014. <http://www.hhs.gov/opa/pdfs/ogc-cleared-final-april.pdf>

Consents and Counseling

DEFINITION:

Title X Family Planning Sub-recipient service sites must obtain a signed consent from the client for voluntary acceptance of the services. The general consent form states that receipt of family planning services is not a prerequisite to receipt of any other services offered by the service site. This consent must be obtained prior to providing services, and placed in the client's record. The consent must inform the client they may decline or defer a specific service. If a client chooses to decline or defer a service, this must be documented in the client's record. Counseling must include information about the possible health risks associated with declining or delaying preventive screening tests or recommended treatments/procedures.

General consent forms must include the following statements:

- Services provided are voluntary.
- Family planning services are not a prerequisite for receipt of any other services.
- Services will be provided confidentially with a notation of any limitations that may apply.

An individual may give written consent for someone to access their health information or be present for their appointment the day they visit the service site (e.g., family member, boyfriend, etc.) Because of client confidentiality concerns during future visits, KDHE recommends adding a statement to the consent form indicating how long the consent will be effective, such as until revoked by client, one year, etc. The client may not wish the individual to whom they are giving consent to have indefinite access to their medical information.

Clients must provide a way for the agencies to contact them. They must provide contact information that is correct and up to date in order to protect their confidentiality.

A sub recipient service sites may voluntarily choose, but is not required, to obtain the individual's consent for it to use and disclose information about him or her for treatment, payment, and health care operations. A sub recipient that chooses to have a consent process has complete discretion under the HIPPA Privacy Rule to design a process that works best for its clients.

A "consent" document is not a valid permission to use or disclose protected health information for a purpose that requires an "authorization" under the Privacy Rule (see 45 CFR 164.508), or where other requirements or conditions exist under the Rule for the use or disclosure of protected health information.

For most disclosures, such as health information submitted with bills, providers may send only the minimum information needed for the purpose of the disclosure. However, for purposes of treatment, health care providers need to be able to transmit more detailed information to other providers. The final rule gives providers full discretion in determining what personal health information to include when sending patients' medical records to other providers for treatment purposes.

For more information on privacy and consent requirements:

- Consent forms and HIPPA: <http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-treatment-payment-health-care-operations/index.html>
- Privacy Rule: <https://www.gpo.gov/fdsys/pkg/CFR-2011-title45-vol1/xml/CFR-2011-title45-vol1-sec164-508.xml>

CLIENT EDUCATION AND COUNSELING:

The counseling process involves mutual sharing of information. Persons who provide counseling should be knowledgeable, objective, nonjudgmental, sensitive to the rights and differences of clients as individuals, culturally aware and able to create an environment in which the client feels comfortable discussing personal information.

Additionally, the counselor should be knowledgeable about the other services offered by the sub-recipient service site. In many ways, counseling and education become interwoven. The counselor must be sufficiently knowledgeable to provide accurate information regarding the benefits and risks, safety, effectiveness, possible side effects, complications, discontinuation issues, and danger signs of the various contraceptive methods.

The education provided should be appropriate to the client's age, knowledge, language, and should be presented in a non-directive manner. It is important to ensure that clients have processed the information provided and discussed. Accurate documentation of counseling and client's understanding must be included in the client's record.

REFERENCES:

Centers for Disease Control & Prevention. "Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs." MMWR April 25, 2014; 63.(See Appendix C and E). <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

Office of Population Affairs. Program Requirements for Title X Funded Family Planning Projects. April 2014. <http://www.hhs.gov/opa/pdfs/ogc-cleared-final-april.pdf>

US Department of Health and Human Services. Summary of the HIPAA Privacy Rule, revised 5/03. <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>.

Resources for client education materials are available through the CDC: <http://www.cdc.gov/preconception/freematerials.html>

Mandatory Reporting

DEFINITION:

KSA 38-2223 (2009) and KSA 39-1430 define mandatory reporters for abuse of a child or dependent adult (defined as “an individual 18 years of age or older alleged to be unable to protect their own interest and who is harmed or threatened with harm, whether financial, mental or physical in nature”). KSA 39-1431 and KSA 38-2223 define adult or adult abuse/neglect and consequences for not reporting the abuse. KDHE is committed to protecting children and dependent adults from situations of possible abuse or neglect.

http://www.ksrevisor.org/statutes/chapters/ch39/039_014_0030.html

Sub recipient agencies shall have written policies outlining the following:

1. The provision of initial required training opportunities on child/dependent adult abuse identification and reporting of child abuse for appropriate program personnel.
2. The provision of additional required training on child/dependent adult abuse identification and reporting every five years for appropriate program personnel.
3. Documentation of completed training in each staff file.
4. Job classifications considered mandatory assessors and reporters of child/dependent adult abuse.
5. The procedure for filing the reports, both oral and written.

Understanding the victim’s mindset

Due to mistrust and fear, some victims of will decline offers of assistance out of concern for their personal safety, and safety of family and friends. In such cases, the victim’s wishes should be respected. **However if the suspected victim is < 18 years of age Mandatory Reporting laws apply.**

1. These victims find themselves trapped in the sex industry, the service industry, in sweatshops or in agricultural fields – living daily with inhumane treatment, physical and mental abuse, and threats to themselves or their families back home.
2. Victims of trafficking may fear or distrust of the government and police because they are afraid of being deported or because they come from countries where law enforcement is corrupt and feared.
3. Confidentiality is vital for victims of human trafficking. Their lives and the lives of their families are often at great risk if they try to escape or initiate criminal investigations against their captors. Therefore, it is imperative that you minimize the number of staff members who come in contact with the victim. Ensure that all staff who have contact with the victim, understand the importance of confidentiality for the safety of the patient.
4. Many victims do not self-identify as victims. Victims may not appear to need social services because they have a place to live, food to eat, medical care and a “job.”

Reporting Abuse, Neglect and Exploitation of a Child or Dependent Adult

Reports of Abuse, Neglect and Exploitation of a Dependent Adult or Child may be made to the Kansas Protection Report Center online at this website or by calling: **1-800-922-5330**

If there is an emergency situation, call your local law enforcement agency or 911.

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

Office of Population Affairs. Program Requirements for Title X Funded Family Planning Projects. April 2014. <http://www.hhs.gov/opa/pdfs/ogc-cleared-final-april.pdf>

Office on Violence Against Women. Kansas Coalition Against Sexual and Domestic Violence, July 2011. http://governor.ks.gov/docs/documents/2011/01/10/stop_vawa_implementation_plan_2011-2014.pdf

Attorney General's Statement on Human Trafficking in Kansas: <http://ag.ks.gov/public-safety/human-trafficking>

Title X Family Planning Requirements

DEFINITION:

The Title X Family Planning Program is the only Federal program dedicated solely to the provision of family planning and related preventive health services. This program is designed to provide contraceptive supplies and information to all who want and need them, with priority given to persons from low-income families. All Title X-funded projects are required to offer a broad range of acceptable and effective medically approved (by the US Food and Drug Administration (FDA)) contraceptive methods and related services on a voluntary and confidential basis.

Title X services include the delivery of related preventive health services, including patient education and counseling; cervical and breast cancer screening; sexually transmitted disease (STD) and human immunodeficiency virus (HIV) prevention education, testing, and referral; and pregnancy diagnosis and counseling. **By law, Title X funds may not be used in programs where abortion is a method of family planning.**

Providing quality family planning services (QFP) can lead to improved reproductive health outcomes. These services include education, counseling and medical services related to family planning. The QFP recommendations were developed by the Centers for Disease Control and Prevention (CDC) and the Office of Population Affairs (OPA) and couple with OPA's Program Requirements for Title X Funded Family Planning Projects for understanding and utilizing the family planning services grants program authorized by Title X of the Public Health Service Act.

The Title X Family Planning Guidelines consist of two parts (available in the back of this manual)

1. *Program Requirements for Title X Funded Family Planning Projects*
2. *Providing Quality Family Planning Services: Recommendations of CDC and the US Office of Population Affairs*

TITLE X PROGRAM REQUIREMENTS

The following requirements for the Title X Program are based on OPA's *Program Requirements*, the *Quality Family Planning Services* (listed above) and the American College of Obstetricians and Gynecologists (ACOG) expert consensus, opinion guidelines and practice bulletins.

Sub-recipients funded under Title X must provide clinical, informational, educational, social, and referral services related to family planning to clients who request these services.

The clinical care component of this project must operate under the responsibility of a medical director who is licensed in the state of Kansas and who is a qualified physician with special training or experience in family planning. The medical director may be either on staff or established through contract. Clinical services may be provided by Certified Nurse Midwives, Certified Nurse Practitioners and Physician Assistants, who are referred to as a 'clinician.' All clinicians must be licensed in the state of Kansas. Licensed Advanced Practice Registered Nurses and Physician's Assistants must practice in accordance with their governing body's (Board of Nursing and Board of Healing Arts) regulations.

VOLUNTARY PARTICIPATION

Sub-recipient services used by any individual must be solely on a voluntary basis. Clients must not be subjected to coercion to receive services or to use or not to use any particular method of family planning. Acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other service, assistance from or participation in any other programs. Sub-recipient personnel must be informed that they may be subject to prosecution under Federal law if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure.

PROHIBITION OF ABORTION

Section 1008 of the Title X statute and 42 CFR 59.9 (a)(5), prohibit abortion as a method of family planning. Sub-recipients must have written policies that clearly indicate that none of the funds will be used in programs where abortion is a method of family planning.

PROJECT SERVICES AND CLIENTS

All persons who want to obtain family planning care should have access to such services. Comprehensive medical, informational, educational, social, and referral services related to family planning must be provided for clients who want such services. Services must be provided in a manner which protects the dignity of the individual. Services must be provided without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status. Projects must provide for social services related to family planning including counseling, referral to and from other social and medical services, agencies, and any ancillary services. Coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs must be provided. Services must be provided without the imposition of any durational residency requirement or requirement that the client be referred by a physician.

SERVICE PLANS AND PROTOCOLS

The clinical protocols presented in this manual direct services to be delivered within Kansas' Title X Program, however, the clinician's clinical judgment may override these protocols when the patient's history or circumstances dictate a modification. Sub-recipients may develop clinical protocols that are in accordance with national recognized standards of care and approved by the medical director. Sub-recipients may adopt the clinical protocols set forth in this manual as their own, by placing their name on them and updating them regularly as long as local policies are also developed to address all requirements for KDHE and Title X. Each clinical staff member is expected to review the protocols and sign a statement that they have reviewed them annually.

CONFIDENTIALITY

Sub recipients must assure client confidentiality and provide safeguards for individuals against the invasion of personal privacy, as required by the Health Insurance Portability and Accountability Act (HIPPA)

“All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.” (42 CFR 59.11).

For electronic medical records, computer screens must be safeguarded from clients and visitors to guarantee that confidentiality is maintained. When leaving the computer terminal, staff must log out or inactivate their terminal so another person cannot perform any activity under their User ID. All employees must keep their computer passwords secret and secured.

CONSENT

Prior to the client receiving any clinical services, written informed voluntary consent to receive services must be obtained. The general consent form states that receipt of family planning services is not a prerequisite to receipt of any other services offered by the service site. Sub-recipients must obtain a signed consent for release of information from the client allowing disclosure of the medical record to providers for purposes of treatment. See the protocol section "Consents" for details.

COUNSELING AND EDUCATION

In the family planning setting, the primary purpose of counseling is to assist clients in reaching an informed decision regarding their reproductive health and the choice and continued use of family planning methods and services. Information must include 1) safe sex practices to reduce the risk of unintended pregnancies, 2) sexually transmitted diseases and HIV, as well as 3) available family planning services and 4) available resources in the community.

The **Five Principles for Providing Quality Counseling** should be used when providing family planning services (Box 3 and Appendix C, QFP):

1. Establish and maintain rapport with the client.
2. Assess the client's needs and personalize discussions accordingly.
3. Work with the client interactively to establish a plan.
4. Provide information that can be understood and retained by the client.
5. Confirm client understanding.

MEDICAL RECORDS AND DOCUMENTATION

Sub-recipient service sites must establish a medical record for every client who obtains clinical services. These records must be maintained in accordance with accepted medical standards. Records must be readily accessible, systematically organized to facilitate prompt retrieval of a compilation of information, be confidential, safeguarded against loss or use by unauthorized persons, confidentially maintained to comply with HIPAA guidelines, and available upon request to the client.

All services, topics of counseling and education provided to clients in verbal and written formats must be clearly documented in the client's medical record.

The record must contain sufficient information to identify the client; where and how the client can be contacted; accurately document the visit; and justify the clinical diagnosis, treatment and recommended follow up.

The required content of the medical record includes:

1. Personal data;
2. Medical history, physical exam, laboratory test orders, results, and follow-up;
3. Treatment and special instructions;
4. Scheduled revisits;
5. Informed consents – initial and annual updates;
6. Refusal of services; and
7. Allergies and untoward reactions to drug(s) recorded in a prominent and specific location.

The record must also contain reports of clinical findings, diagnostic and therapeutic orders, diagnoses and documentation of continuing care, referral, and follow-up. The record must include entries by counseling and social service staff where appropriate.

Client financial information should be kept separated from the client medical record. If included in the medical record, client financial information should not be a barrier to client services.

PREVENTIVE WELL WOMAN AND WELL MAN VISITS

Preventive clinical visits must include a complete medical history, age appropriate physical examination, appropriate laboratory tests, immunizations, counseling, anticipatory guidance, and risk factor reduction interventions for all female and male clients. Medical histories may be completed by the client, with help from the assistant, nurse, or clinician and must be reviewed by the clinician. Pertinent history must be updated at subsequent clinical visits. See the protocol section on "Preventive Care" for details.

GYNECOLOGIC AND UROLOGIC SERVICES

Minor gynecologic and urologic problem diagnosis and treatment should be provided by family planning programs to avoid fragmentation or lack of health care for clients. Sub-recipients should diagnose and treat such problems as vaginitis or urinary tract infections quickly following microscopic examination of vaginal secretions or urine dipstick. See the protocol section for "Infections" for details.

OTHER RELATED SERVICES

Reproductive health services that relate to family planning must be provided to females and males as a part of Title X services when family planning is included as an aspect of each visit. Family planning services are described as, at a minimum, discussing a client's reproductive plan to prevent or achieve pregnancy and a plan to help them achieve this. This applies to both women and men, discussing with them how they and/or their partner can prevent or achieve pregnancy and the effective use of a contraceptive method, device and practices, if they are trying to prevent pregnancy.

Other services related to reproductive health include screening for breast and cervical cancer. Providers should follow ACOG recommendations. See the protocol section "Preventive Care" for details. Referrals to other medical facilities must be provided when medically indicated, and are not limited to emergency services. Clients should be asked about other sources of primary care and care should be coordinated with those other sources, if relevant.

NOTIFICATION OF ABNORMAL LAB RESULTS

A procedure which addresses client confidentiality must be established to allow for client notification and adequate follow-up of abnormal laboratory results. All patients shall be treated or referred for treatment when laboratory tests have abnormal results. Sub-recipient service sites must have a system must be in place for follow-up of these referrals.

IDENTIFICATION OF ESTROGEN-EXPOSED OFFSPRING

As part of the medical history, clients born in the US between 1940 and 1971 (until the early 1980s born in some European countries) should be asked if their mothers took estrogens during pregnancy to prevent miscarriage. The children (both male and female) of women who received DES or similar hormones during pregnancy may have abnormalities of their reproductive systems or other fertility related risks. Clients prenatally exposed to exogenous estrogens should receive information and special screening either on-site or by referral. See the clinical protocol for "Preventive Treatment and Other Conditions" for details.

MANDATORY REPORTING REQUIREMENTS

Title X Legislative Mandate

Notwithstanding any other provision of law, no provider of services under Title X of the Public Health Service Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.

<http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/legislative-mandates>.

Notification of Reportable Diseases

Health care providers and laboratories are required to notify KDHE regarding patients with suspected or confirmed reportable diseases. The list of reportable diseases is defined by Kansas statute ([K.S.A. 65-118, 65-128 and 65-6001 through 65-6007; and by K.A.R. 28-1-2 and 28-1-18](#)).

Reference for list of reportable diseases, requirements and phone numbers for reporting purposes may be found at: http://www.kdheks.gov/epi/disease_reporting.html#requirements

EMERGENCIES

Sub-recipient services sites must have written plans for the management of on-site medical emergencies. These should include: vaso-vagal reactions, anaphylaxis, syncope, cardiac arrest, shock, hemorrhage, and respiratory difficulties. After-hours management of contraceptive emergencies, clinic emergencies and emergencies requiring transport must also be in place. Appropriate training should be available to staff, including training for CPR.

STERILIZATION

The Kansas Title X program does not pay for permanent contraception/sterilization. A female or male client's sterilization decision must be completely voluntary and should be made with full knowledge of the permanence, risks, and benefits associated with the procedure. Sub-recipients using Title X funding to arrange for sterilization must follow the requirements of 42 CFR Chapter 1 Subpart B – Sterilizations of Persons in Federally Funded Family Planning Programs. Clients who are Title X clients prior to the sterilization, may remain Title X clients for continued care.

REFERRALS:

Sub-recipients must provide all core family planning services in accordance with OPA's Title X Guidelines, either on-site or by referral. When required core services are provided by referral, the sub-recipient must establish formal arrangements for the services and reimbursement of costs, as appropriate. Clients are billed based on a sliding fee schedule.

Sub-recipients must have written policies for follow-up of referrals made as a result of abnormal physical examination or laboratory test findings. These policies must be sensitive to clients' confidentiality and privacy.

Efforts may be made to aid the client in identifying potential resources for reimbursement of the referral provider, but sub-recipients are not responsible for the cost of this care. Sub-recipients must maintain a current list of health care providers, local health and human services departments, hospitals, community agencies, and health services supported by other public programs to be used for referral purposes. Whenever possible, clients should be given a choice of providers from whom to select.

MEDICAL REFERRALS:

A client may be referred for two primary reasons: 1) referral for services not provided on site (e.g., not family planning services); 2) referral for care beyond the scope of practice of the sub recipient.

When a client is referred to other medical providers for services determined to be necessary, sub-recipients must:

- Provide pertinent client information to the referral provider. Sub-recipients must obtain client's consent for release of this information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality.
- Advise client regarding their responsibility with the referral.
- Advise client regarding the importance of the referral and the agreed upon follow-up
- Advise client that these are not Title X funded services or within the scope of practice of the sub recipient and they must be prepared to be financially responsible for the services from non-Title X providers. Assist clients in finding potential alternative sources of reimbursement for the referral care.
- Have a tracking system to follow-up on referrals.

OTHER POSSIBLE REFERRALS AND RECOMMENDATIONS:

Sub-recipients must have a plan to facilitate other referrals and recommendations for comprehensive primary care services, other needed health services, and social services. Formal agreements and linkages for referral services and collaborative agreements with other service providers in the community are encouraged. All referrals and recommendations must be documented in the client's medical record and can include, but are not limited to:

- Nutritional problems
- Primary Care provider for other medical or non-medical issues
- Pregnancy: for prenatal care and delivery; infant care or adoption; or termination
- Substance abuse
- Depression
- Genetic counseling and evaluation
- Human Services
 - Child Support
 - Food Assistance
 - Child Care Assistance
 - Safety and Protection
 - Health Assistance
- Social Services for domestic abuse, child abuse, or violence
- Smoking cessation

QUALITY ASSURANCE AND IMPROVEMENT (QA/QI)

A quality assurance system must be in place that provides for conducting quality improvement, designed to review and strengthen the quality of services on an ongoing basis. Quality improvement is the use of a deliberate and continuous effort to achieve measurable improvements in the identified indicators of quality of care, which improve the health of the community.

Information about the CDC's National Public Health Performance Standards (NPHPS) initiative may be found at: <http://www.cdc.gov/nphpsp/>

Additional information on developing a Quality Assurance Program may be found at: Family Planning National Training Center: <http://fpntc.org/training-and-resources/agency-self-assessment-providing-quality-services>

FAMILY PLANNING SERVICES UNDER TITLE X

1. CONTRACEPTIVE SERVICES

Sub-recipients must provide medical services related to family planning and the effective use of contraceptive methods and services as well as necessary referrals to other medical facilities when medically indicated. Sub-recipients must provide a broad range of acceptable and effective medically (FDA) approved family planning methods and services.

Contraceptive counseling is a process that enables clients to make and follow through on decisions about their contraceptive use. Education given helps them to make informed decisions in order to use their contraceptive methods correctly. Clients who request to start a contraceptive method must be thoroughly counseled on their requested and clinician agreed upon contraceptive method. This includes benefits and risks, safety, effectiveness, possible side effects, complications, discontinuation issues, and danger signs.

All client education and the client's verbalized understanding must be thoroughly documented in the client's medical record. Sub-recipients may continue to use a method specific consent if they wish, but it must be contained in the client's medical record, when electronic records are used.

2. PREGNANCY DIAGNOSIS AND COUNSELING

Pregnancy testing and counseling must be provided to all clients requesting this service, and it must be provided on-site in all Title X sub-recipient service sites. Pregnancy testing is one of the most common reasons for a first visit to a family planning facility. It is therefore important to use this occasion as an entry point for providing education and counseling about family planning. This visit should include a discussion about the client's reproductive life plan and a medical history.

Pregnant women must be offered information and counseling regarding:

- Prenatal care and delivery
- Infant care, foster care, or adoption
- Pregnancy termination

This information must be given in a neutral, factual, and nondirective way for each of the options requested. Clients may indicate they do not wish to receive specific information and counseling.

3. ACHIEVING PREGNANCY

Sub-recipients must counsel their clients who are trying to achieve pregnancy in ways to maximize their fertility. This includes assessing their menstrual cycles, instructing them on how often and when to have vaginal intercourse, methods or devices to predict ovulation, encouraging a healthy lifestyle, and discouraging the use of caffeine, tobacco, alcohol and recreational drugs.

4. BASIC INFERTILITY SERVICES

Infertility is the failure of a couple to achieve a pregnancy after 12 months or longer of regular unprotected intercourse. Conditions that require earlier assessment, at 6 months, are those for women over age 35, women with a history of oligo-amenorrhea, those with known or suspected uterine or tubal disease or endometriosis, or those with a partner known to be “sub-fertile;” and immediate evaluation and treatment for women over age 40.

Sub-recipients must make basic infertility services available to women and men who request such services. Basic infertility services for women and men include initial infertility interview, education, medical history, sexual health assessment and physical examination, and appropriate referral.

5. PRECONCEPTION HEALTH SERVICES

Preconception health services must be provided by sub-recipient services sites. These services are beneficial because of their effect on pregnancy and birth outcomes and their role in improving the health of women and men. Preconception describes any individual of reproductive potential who is not pregnant, but is at risk of becoming pregnant, or who is at risk for impregnating a partner.

The goal for individualized preconception health services is to identify and modify biomedical, behavioral, and social risks to health or pregnancy outcomes through prevention and management. It promotes the health of individuals of reproductive age before conception, and thereby helps to reduce pregnancy-related adverse outcomes, such as low birth weight, premature birth, and infant mortality.

Preconception health services for men include involving them as partners in family planning: in their role of preventing or achieving a healthy pregnancy (reduced STD/HIV transmission).

(See the protocol “Preventative Care” section for details.)

6. SEXUALLY TRANSMITTED DISEASES

Sub-recipient service sites must make available the detection and treatment of common STDs. At risk clients should be urged to undergo examination and treatment as indicated, either onsite or by referral. When treatment is provided on-site, appropriate follow-up measures must be assumed.

Vaccination for HPV and hepatitis B (**Not Title X Funded**) are important components of STD services and preconception care. Sub-recipients must comply with state STD reporting requirements. See the protocol sections “Infections” for details.

Other tests such as syphilis, hepatitis C, and HIV/AIDS should be provided as indicated by CDC’s STD treatment and HIV testing guidelines: Centers for Disease Control & Prevention. 2015 Sexually Transmitted Diseases Treatment Guidelines. MMWR June 2015:64
<http://www.cdc.gov/mmwr/pdf/rr/rr6403.pdf>

Kansas Services Sites for STI testing are listed on the KDHE website: *Guide to STI Service in Kansas*. Then go to menu on left side of page. Prevention/Counseling and Testing/STI Test Sites (underlined link in blue near bottom of page provides list by county).
http://www.kdheks.gov/sti_hiv/sti_services.htm

Opt-Out Testing in Kansas

In 2006, the CDC released its “Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings”

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>)

These recommendations advise providers in healthcare settings to:

- Adopt a policy of routine HIV testing for everyone between the ages of **13-64** and all **pregnant women**
- Use *opt-out screening* for HIV—meaning that HIV tests will be done routinely unless a patient explicitly refuses to take an HIV test
- Eliminate the requirements for pretest counseling, *informed consent*, and post-test counseling

“Opt-out testing” does not mean that you **MUST** take an HIV test. **In general, you have the right to refuse an HIV test.** (Exceptions include blood and organ donors, military applicants and active duty personnel, Federal and state prison inmates under certain circumstances, newborns in some states, and immigrants.) See also: The center for HIV Law and Policy.

<http://www.hivlawandpolicy.org/states/kansas>

The CDC believes that opt-out screening for HIV:

- Will help more people find out if they have HIV
- Will help those infected with HIV find out earlier, when treatment works best
- Can further decrease the number of babies born with HIV
- Can reduce stigma associated with HIV testing
- Will enable those who are infected to take steps to protect the health of their partners

7. ADOLESCENT SERVICES

Adolescents who seek family planning services will be encouraged to have family participation and provided counseling on resisting coercive attempts to engage in sexual activities. All state laws requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest will be followed.

Adolescents must be assured confidential services. Title X sub-recipients will not require written consent of parents or guardians for the provision of services to minors. Sub-recipients cannot notify parents or guardians before or after a minor has requested and received Title X family planning services.

Minors must be counseled about all methods of contraception, including abstinence and safer sex practice options to reduce risks for sexually transmitted diseases, HIV, and pregnancy.

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63.

<https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

Centers for Disease Control & Prevention. Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2015. MMWR 2016: Vol 65

<http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6509a3.pdf>

Office of Population Affairs. Program Requirements for Title X Funded Family Planning Projects. April 2014. <http://www.hhs.gov/opa/pdfs/ogc-cleared-final-april.pdf>

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Family Planning Clinical Protocols

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Initiating a Method

DEFINITION:

Clients who wish to delay or prevent pregnancy should be offered a full range of FDA approved contraceptive methods; be assessed to identify the contraceptive methods safe for a client to use; counseled to help a client choose a contraceptive method they will use correctly and consistently; and provided one or more selected contraceptive methods (preferably on site, but may be referred if necessary).

When working with male clients, providers should discuss information about female-controlled methods including emergency contraception, encourage discussion of contraception with partners, and provide information about how partners can access contraceptive services. Male clients should be reminded that condoms should be used correctly and consistently to reduce the risk of STDs/HIV as well as prevent pregnancy.

Most women can safely begin using any contraceptive product at any point in their menstrual cycle. Hormonal contraceptives do not accelerate cervical neoplasia or interfere with cervical cytology, therefore; decisions regarding contraception should be made independent of cervical cytology schedule. Delaying placement of an IUD until management of a severely abnormal pap has been completed should be considered. Delaying initiation of a contraceptive method may decrease adherence and increase risk of undesired conception. Use of contraception may be improved by providing anticipatory guidance about the most common side effects, giving information about available choices, and honoring women's preferences.

Begin the contraceptive method at the time of the visit rather than waiting for next menses. Prescribe and provide (if able) multiple cycles to minimize the number of times a client has to return. If a client chooses a method that is not available on-site or the same day, provide the client another method to use until she or he can start the chosen method. More than one method of contraception can be used simultaneously by a client and may be particularly indicated to minimize the risks of STDs/HIV and pregnancy.

Sub-recipient service sites must develop a plan for follow-up. Discuss with the client an appropriate follow-up plan to meet their individual needs, considering their risk for discontinuation. Follow-up reinforces the perceived accessibility of the provider, increases rapport, and provides an opportunity to evaluate any difficulties the client has with the method.

Confirm the client's understanding of all information presented. The "teach-back" method may be used to confirm client understanding. Ask the client to repeat back messages about risks, benefits, possible side effects and correct use of their method. Document all information regarding the contraceptive method and client's understanding of the information given.

Provide Counseling for Returning Clients

Ask if the client has concerns with the method and assess its use. Assess any changes in the client's medical history, changes in risk factors and medication that might affect safe use of the contraceptive method. If the client or provider has concerns about the method, ask the client if they would be interested in a different method of contraception.

Counseling Adolescent Clients

Give comprehensive information to adolescent clients about how to prevent pregnancy. Include abstinence and contraception information to help them choose a method that is best for them to prevent pregnancy and STDs. Long-acting reversible contraception is a safe and effective option for many adolescents, including those who have not been pregnant or given birth.

Adolescents should be offered confidential services while observing all relevant state laws, such as notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest, and human trafficking.

Encourage adolescents to communicate with their parents or guardians about sexual and reproductive health. Educational materials and programs can be provided to adolescents and parents or guardians that help them talk about sex and share their values with each other. Adolescent services should be provided in a “youth-friendly” manner, meaning they are accessible, equitable, acceptable, appropriate, comprehensive, effective and efficient.

CONSENT:

A general consent for service must be signed prior to receiving services

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- During return visits update medical and surgical health history

OBJECTIVE:

- Height/Weight/BMI
- Blood Pressure
- Physical examination as indicated, consistent with ACOG guidelines

LABORATORY:

- STD screening, as indicated
- Pregnancy test, as indicated

ASSESSMENT:

- Eligible candidate for initial start of contraceptive method
- No desire for pregnancy within 12 months, for injectable, implantable, and intrauterine contraceptives

PLAN:

- Prescribe contraceptive method for up to one year
- Provide back-up method of contraception as indicated
- Authorize Emergency Contraception

- Follow Up: 3 months as indicated (should not be linked to prescription refills) to assess satisfaction and correct use of method, check weight and BP, and address any problems or concerns
- Return for age appropriate periodic assessment

CLIENT EDUCATION:

All education topics and the client’s understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options if they are new or undecided about methods of contraception
- Information about their chosen method of contraception including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
- FDA-approved product information/ package insert
- Education about on how to use the method correctly
- Instruction to inform other providers of contraceptive method
- Review of the common side effects and possible drug interactions
- Information about managing missed pills, late patch and ring placement, patch falling off, ring falling out, use of back-up method
- Instruction about health promotion and disease prevention
- Counseling about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Information that contraceptives do NOT provide STD/HIV protection, correct and consistent use of condoms is recommended for STD/HIV protection
- Instruction about Emergency Contraception use and availability
- Information about when and how to contact clinic with questions or concerns *before* stopping a method (Unless one of the danger/warning signs listed below)
- Information about danger/warning signs with use of contraceptive method and what to do if any of these symptoms occur including emergency plans and phone numbers

Contraceptive Warning Signs (Acronym **ACHES**)

Abdominal Pain
Chest Pain
Headaches
Eye Problems
Severe Leg Pain

Heavy bleeding
 Depression
 Prolonged pain, redness, pus, bleeding, or itching at injection or insertion site

WHEN TO INITIATE TAKING/USING CONTRACEPTIVES:

Quick Start ALGORITHM

The Quick Start method allows most clients with a negative urine pregnancy test to begin using the birth control pill, patch, or vaginal ring immediately after an office visit, at any point in the menstrual cycle. This strategy eliminates the delay between receiving a prescription and starting

the new contraceptive method. With standard delayed contraceptive initiation, about 25% of individuals given a contraceptive prescription never fill it, and about 50 % individuals who start using birth control pills discontinue use within one year.

In the quick start trial, clients who took their first birth control pill during an office visit had significantly higher adherence three months later than women randomized to the delayed start group.

The quick start method:

- Significantly improves the continuation rate
- Has demonstrated better compliance at 3 months in adolescents
- Reduces likelihood of a potential unplanned pregnancy

The Quick Start method is preferred because the other approaches leave a gap of time between the day prescribed and the start day. 25% of young clients failed to start their contraceptive as instructed, when they were instructed to start it in the traditional methods. Reasons given were due to conception in the interim, forgotten instructions, failure to fill the prescription, or they had second thoughts about using a contraceptive after their visit. Consider the Quick Start method when initiating any contraception method.

The IUDs and the implant may be inserted at any time, if it is reasonably certain that the client is not pregnant. Same day insertion is encouraged to prevent an unintended pregnancy. The copper IUD can also be inserted within 5 days of the first act of unprotected sexual intercourse as an emergency contraceptive. If the day of ovulation can be estimated, the copper IUD can also be inserted > 5 days after sexual intercourse as long as insertion does not occur > 5 days after ovulation. No additional contraceptive protection is needed after copper IUD insertion.

How to be reasonably certain that a client is not pregnant:

They have no symptoms or signs of pregnancy and meets any one of the following criteria:

- Is ≤ 7 days after the start of normal menses
- Has not had sexual intercourse since the start of last normal menses
- Has been correctly and consistently using a reliable method of contraception
- Is ≤ 7 days after spontaneous or induced abortion
- Is within 4 weeks postpartum
- Is fully or nearly full breastfeeding, amenorrheic, and < 6 months postpartum

First-Day Start

First-day start is used to gain early control of ovarian follicles during the first cycle. Instruct client to initiate hormonal contraceptive method (pills, patch, and ring) on the first day of the next normal menstrual cycle. No backup contraception is needed when hormonal contraceptive methods are started on the first day of the menses. It is important that the client be certain that the next menses is normal, that it occurs at the predicted time and is preceded by normal symptoms. If there is any question that her menses is not normal, the client may want to rule out pregnancy prior to starting contraception.

Sunday Start

For decades, the Sunday start was the most common method for starting pills. Instruct the client to initiate hormonal contraceptive method (pills, patch, and ring) on the first Sunday, after her menstrual cycle has started. **If the client's menses are more than 5 days before starting her contraceptive method, a backup method should be used for 7 days.**

MANAGEMENT OF INCORRECT USE

Combined Oral Contraceptives (COCs)

- If 1 hormonal pill is late OR has been missed (<24 to <48 hours since a pill should have been taken)
 - Take the late or missed pill as soon as possible
 - Continue taking the remaining pills at the usual time (even if taking 2 pills on the same day)
 - No additional contraceptive protection is needed
 - EC is not usually needed but can be considered if hormonal pills were missed earlier in the cycle or in the last week of the previous cycle

- If 2 or more consecutive hormonal pills have been missed (\geq 48 hours since a pill should have been taken)
 - Take the most recent missed pill as soon as possible (any other missed pills should be discarded)
 - Continue taking the remaining pills at the usual time (even if taking 2 pills on the same day)
 - Use back-up contraception (condoms) or avoid sexual intercourse until hormonal pills have been taken for 7 consecutive days
 - If pills were missed in the last week of hormonal pills (days 15-21 for 28-day pill packs)
 - Omit the hormone-free interval by finishing the hormonal pills in the current pack and starting a new pack the next day
 - If unable to start a new pack immediately, use back-up contraception (condoms) or avoid sexual intercourse until hormonal pills from a new pack have been taken for 7 consecutive days
 - EC should be considered if hormonal pills were missed during the first week and unprotected sexual intercourse occurred in the previous 5 days
 - EC may also be considered at other times as appropriate

Patch

- Delayed application or detachment* for <48 hours since a patch should have been applied or reattached
 - Apply a new patch as soon as possible (if detachment occurred <24 hours since the patch was applied, try to reapply the patch or replace with a new patch)
 - Keep the same patch change day
 - No additional contraceptive protection is needed
 - EC is not usually needed but can be considered if delayed application or detachment occurred earlier in the cycle or in the last week of the previous cycle

- Delayed application or detachment* for \geq 48 hours since a patch should have been applied or reattached
 - Apply a new patch as soon as possible
 - Keep the same patch change day
 - Use back-up contraception (condoms) or avoid sexual intercourse until a patch has been worn for 7 consecutive days
 - If the delayed application or detachment occurred in the third patch week
 - Omit the hormone-free interval by finishing the third week of patch use (keeping the same patch change day) and starting a new patch immediately
 - If unable to start a new patch immediately, use back-up contraception (condoms) or avoid sexual intercourse until a new patch has been worn for 7 consecutive days

- EC should be considered if the delayed application or detachment occurred within the first week of patch use and unprotected sexual intercourse occurred in the previous 5 days
- EC may also be considered at other times as appropriate

*If patch detachment takes place but the client is unsure when the detachment occurred, consider the patch to have been detached for ≥ 48 hours since a patch should have been applied or reattached.

Ring

- Delayed insertion of a new ring or delayed reinsertion* of a current ring for <48 hours since a ring should have been inserted:
 - Insert the ring as soon as possible
 - Keep the ring in until the scheduled ring removal day
 - No additional contraceptive protection is needed
 - EC is not usually needed but can be considered if delayed insertion or reinsertion occurred earlier in the cycle or in the last week of the previous cycle
- Delayed insertion of a new ring or delayed reinsertion* of a current ring for ≥ 48 hours since a ring should have been inserted:
 - Insert the ring as soon as possible
 - Keep the ring in until the scheduled ring removal day
 - Use back-up contraception (condoms) or avoid sexual intercourse until a ring has been worn for 7 consecutive days
 - If the ring removal occurred in the third week of ring use:
 - Omit the hormone-free week by finishing the third week of ring use and starting a new ring immediately
 - If unable to start a new ring immediately, use back-up contraception (condoms) or avoid sexual intercourse until a new ring has been worn for 7 consecutive days
 - EC should be considered if the delayed insertion or reinsertion occurred within the first week of ring use and unprotected sexual intercourse occurred in the previous 5 days
 - EC may also be considered at other times as appropriate

*If removal takes place but the client is unsure how long the ring has been removed, consider the ring to have been removed for ≥ 48 hours since a ring should have been inserted or reinserted.

Progestin Only Pills (POPs)

- A dose is considered missed if it has been >3 hours since it should have been taken
 - Take 1 pill as soon as possible
 - Continue taking the remaining pills at the usual time each day (even if taking 2 pills on the same day)
 - Use a back-up contraception (condoms) or avoid sexual intercourse until pills have been taken correctly, on time, for 2 consecutive days
 - EC should be considered if unprotected sexual intercourse occurred

CHOOSING A PATTERN OF USE

This section applies only to combined oral and vaginal ring contraceptives.

Monthly cycling (21/7)

Conventional pills, patch and ring packaging instruct clients to use them for 3 weeks of hormones followed by a 1 week hormone-free interval to provide a predictable, coordinated withdrawal bleed.

Shortened hormone-free interval

A 7-day hormone-free interval may allow too much time for follicular development and may increase the failure rate with low-dose contraceptives. By shortening the hormone-free interval from 7 to 5 days, ovarian activity is suppressed more effectively. Have the client use the “first-day start” for every cycle, where the client will start a new package of contraception on the first day of her withdrawal bleeding. If the client has no menses by the 5th hormone-free day, they should start a new package anyway. A pregnancy test may provide reassurance to the client, but is not necessary.

Extended use

Recent studies have shown, many clients prefer to bleed less frequently than monthly. Some reported symptoms include headache, breast tenderness, bloating, cramping, and/or swelling which can occur during the hormone-free week. There is no biological need to induce a withdrawal bleeding episode on a monthly basis unless the client wants to be reassured that there is no pregnancy. Clients with dysmenorrhea, menstrual migraines, menorrhagia, or those with demanding activities or jobs may be particularly attracted to the extended use contraceptive regimen. They will need to purchase a few extra packages of pills or rings.

OPTIONS FOR EXTENDED USE

Off-label extended use of hormonal contraception is intended for combined oral contraceptives, and may be considered for the vaginal ring, but should not be used for the transdermal patch. The vaginal ring is effective for four weeks and may remain in place for four consecutive weeks. The risks versus benefits must be weighed.

Brief manipulation for convenience:

Extended use options may be utilized for special occasions, such as for a honeymoon, trip, athletic event, camping, business meetings, examinations or presentations.

Bi-cycling:

Two packages of hormonal contraceptives are used back-to-back, without a 7 day hormone-free interval. Three weeks for hormonal contraceptives are immediately followed by the second package with 3 weeks of hormonal contraceptives immediately followed by a 7 day hormone-free interval. Studies found that longer cycles had significant reduction in the days of bleeding and in annual costs for feminine hygiene products.

Tri-cycling:

Three packages of 3 week hormonal contraceptives are used continuously followed by a 7 day hormone-free week.

No cycling:

The active hormonal contraceptives are used indefinitely without stopping for a hormone-free week, as long as the client does not have bothersome spotting or breakthrough bleeding.

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES

ACOG Committee Opinion #534, “Well-Woman Visit.” August 2012, Reaffirmed 2014.
http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Gynecologic_Practice/Well-Woman_Visit

Centers for Disease Control & Prevention. “Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs.” MMWR 2014;63. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

Centers for Disease Control & Prevention. Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2015. MMWR 2016: Vol 65. <http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6509a3.pdf>

Centers for Disease Control & Prevention. Update to CDC’s U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: Revised Recommendations for the Use of Contraceptive Methods During the Postpartum Period. MMWR 2011;60:878-883. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6026a3.htm>.

Centers for Disease Control & Prevention. U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: Adapted from the World Health Organization Medical Eligibility Criteria for Contraceptive Use, 4th edition. (US MEC). MMWR 2010:59 (No. RR-4). <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5904a1.htm>

Centers for Disease Control & Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2013: Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition. MMWR 2013;62:1-60. <http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>

Changing Methods

DEFINITION:

Clients may desire to change their method of contraception due to a variety of reasons, including side effects, complications, inability to use the method correctly, or because they just do not like it. If the client has difficulty remembering to take a pill every day at the same time, the patch will not stay on, the vaginal ring is uncomfortable or easily comes out, it is important that the client finds a method they will use correctly and consistently. The best method of contraception for a client is a method that is safe and affordable.

CONSENT:

Clients must sign a general consent for service prior to receiving services.

SUBJECTIVE:

Initial healthcare encounter should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems.
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current Contraception Method
- During return visits update medical and surgical health history.

OBJECTIVE (clinical):

- Height/Weight/BMI
- Blood Pressure
- Physical Examination as indicated, consistent with ACOG guidelines

LABORATORY:

- STD screening, as indicated
- Pregnancy test, as indicated

ASSESSMENT:

- Eligible candidate for contraceptive start or change
- No desire for pregnancy within 12 months for injectable, implantable, and intrauterine contraceptives

PLAN:

- Prescribe contraceptive method for up to one year (except long acting methods)
- Provide back-up method of contraception as indicated
- Authorize Emergency Contraception as indicated
- Follow Up: 3 months as indicated (should not be linked to prescription refills) to assess satisfaction and correct use of method, check weight and BP, and address any problems or concerns
- Return for age appropriate periodic assessment

CLIENT EDUCATION

All education topics and the client’s understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options if they are new or undecided about methods of contraception
- Information about their chosen method of contraception including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
- FDA-approved product information/ package insert
- Education on how to use the method correctly
- Instruction to inform other providers of contraceptive method
- A review of common side effects and possible drug interactions
- Information about managing missed pills, late patch and ring placement, patch falling off, ring falling out, use of back-up method
- Instruction about health promotion and disease prevention
- Counseling about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Information that contraceptives do NOT provide STD/HIV protection, correct and consistent use of condoms is recommended for STD/HIV protection
- Instruction about Emergency Contraception use and availability
- Instruction to contact clinic with questions or concerns *before* stopping a method (Unless one of the danger/warning signs listed below)
- Information about danger/warning signs with use of contraceptive method and what to do if any of these symptoms occur including emergency plans and phone numbers

Contraceptive Warning Signs (Acronym **ACHES**)

- A**bdominal Pain
- C**hest Pain
- H**eadaches
- E**ye Problems
- S**evere Leg Pain

- Heavy bleeding
- Depression
- Prolonged pain, redness, pus, bleeding, or itching at injection or insertion site

WHEN CHANGING METHODS:

When changing methods, refer to the most current guidelines presented in the United States Medical Eligibility Criteria (USMEC) published in July 2016:

<http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf>

The references listed below contain recommendations for the safe use of contraceptives by women with various characteristics and medical conditions. These references are intended to assist staff and providers in counseling clients about choosing a contraceptive method and are meant to be a source of clinical guidance.

Initiation and continuation of a contraceptive method must always reflect the medical judgment of the health care provider based on the individual client's clinical circumstance. Staff should seek the guidance of their agency's health care provider if or when a determination of medical eligibility is required.

Package Inserts

- 1) The package inserts contain information on the following: Contraindications; Warnings and Precautions; Drug interactions; and use in Specific Populations.
- 2) If initiating or continuing a method, the agency's health care provider must provide guidance.

The CDC adapted the Medical Eligibility Criteria as a national practice standard. It provides guidance on the safe use of contraceptive methods for clients with particular medical conditions or physical characteristics.

Guidance is divided into four categories:

- 1 = A condition for which there is no restriction for the use of the contraceptive method.
- 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method
- 4 = A condition that represents an unacceptable health risk if the contraceptive method is used

Medical consultant should determine which criteria are used. There may be some variations between the package inserts and the USMEC recommendations.

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

Centers for Disease Control & Prevention. "Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs." MMWR 2014;63.

<https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

Centers for Disease Control & Prevention. Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2015. MMWR 2016: Vol 65. <http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6509a3.pdf>

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<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6026a3.htm>.

Centers for Disease Control & Prevention. U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: Adapted from the World Health Organization Medical Eligibility Criteria for Contraceptive Use, 4th edition. (US MEC). MMWR 2010:59 (No. RR-4).

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5904a1.htm>

Centers for Disease Control & Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2013: Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition. MMWR 2013:62:1-60.

<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>

Standing Orders

DEFINITION:

When a client comes to the clinic requesting a contraceptive method, but the clinician is not available or no appointment is available that day, it is imperative to start a contraceptive method as soon as possible to avoid risking a possible unplanned pregnancy. Proper use of contraceptives may be improved by providing anticipatory guidance about the most common side effects, giving information about available choices, and honoring the client's preferences.

The Quick Start method is preferred because the other approaches leave a gap of time between the time prescribed and the time to start taking/using it. (See protocol for "Initiation" in this section)

According to national experts, it is not necessary to have a physical exam to obtain contraception. **With recent changes in recommended initiation and frequency of cervical cytology and the availability of urine and self vaginal swab STD test collection, it is not necessary to do a routine pelvic examination on an asymptomatic female under the age of 21.** The decision whether or not to perform a complete pelvic examination at the time of the periodic health examination for the asymptomatic patient should be a shared decision after a discussion between the patient and her health care provider.

CONSENT:

Clients must sign a general consent for service prior to receiving services

CONTRAINDICATIONS:

See individual method specific protocol for contraindications to each method can be found in the United States Medical Eligibility Criteria (USMEC) published in July 2016:

<http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf>

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- During return visits update medical and surgical health history.

OBJECTIVE:

- Height/Weight/BMI
- Blood Pressure

An appointment with a clinician should be encouraged and scheduled. The following information should be included in the medical record:

- A medical examination or annual preventive visit from other health care providers may be used if performed within the past 12 months. (A copy of the patient's previous medical record, including lab results should be requested for the file.)
- The client must complete health history using sub-recipient's health history form
- Components of the physical exam routinely performed by the sub-recipient but not performed by the transferring provider must be offered to the client
- Information and instructions on the contraceptive method must be provided
- The date of the transferred examination will be used to determine the next annual date
- The client must have their next "annual" visit with the sub-recipient

LABORATORY:

- Pregnancy test, as indicated

ASSESSMENT:

- Eligible candidate for initial start of contraceptive method
- No desire for pregnancy within 12 months for injectable contraceptive
- Client has no contraindications to birth control method (weight, blood pressure, smoking or health history)

PLAN:

- If a clinician is not immediately available, a verbal order may be given after reviewing client's health history. The clinician may also authorize Emergency Contraception (EC) in conjunction with the maintenance contraception. Client chart must be given to the clinician as soon as possible for review, approval and signature
- Prescribe contraceptive method for up to one year (pills, patch or ring x 13 cycles, injection x 5)
- Provide back-up method of contraception as indicated
- Choose a pattern of use
- If the client is 40 years old or over, recommend a breast exam and screening mammogram per ACOG guidelines

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options if they are new or undecided about methods of contraception
- Information about their chosen method of contraception including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
- FDA-approved product information/ package insert

- Educate client on how to use the method correctly
- Instruction to inform other providers of contraceptive method
- A review of common side effects and possible drug interactions
- Information about managing missed pills, late patch and ring placement, patch falling off, ring falling out, use of back-up method
- Instruction about health promotion and disease prevention
- Counseling about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid if they choose to become pregnant
- Information that contraceptives do NOT provide STD/HIV protection, correct and consistent use of condoms is recommended for STD/HIV protection
- Instruction about EC use and availability
- Information about contacting clinic with questions or concerns *before* stopping a method (Unless one of the danger/warning signs listed below)
- Information about danger/warning signs with use of contraceptive method and what to do if any of these symptoms occur including emergency plans and phone numbers

Contraceptive Warning Signs (Acronym **ACHES**)

Abdominal Pain

Chest Pain

Headaches

Eye Problems

Severe Leg Pain

Heavy bleeding

Depression

Prolonged pain, redness, pus, bleeding, or itching at injection or insertion site

TRAINING:

Clinic staff who will initiate contraception must complete training using standing orders, prior to providing contraception. All training must be documented. Staff must demonstrate the following with 3 clients and clinician supervision:

- Accurate information regarding all contraceptive methods,
- Ability to assess client's health history and ask appropriate questions for any positive responses,
- Knowledge of age appropriate cancer screening, and
- Knowledge of age appropriate STD screening.

REFERENCES:

ACOG Committee Opinion #534, "Well-Woman Visit." August 2012, Reaffirmed 2014.
http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Gynecologic_Practice/Well-Woman_Visit

Centers for Disease Control & Prevention. "Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs." MMWR 2014;63.
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<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>

Implantable Contraceptives

DEFINITION:

The implantable contraceptive consists of a single, non-biodegradable, flexible plastic rod 4cm in length and 2mm in diameter. Nexplanon® contains the progestin hormone called etonogestrel and a small amount of barium sulfate so that the implant can be seen by X-ray. It is inserted just under the skin of the inner part of the upper arm. Nexplanon® is the only implantable contraceptive available in the United States and provides effective contraception for 3 years.

Implants can be offered to adolescents and can be inserted any time during the menstrual cycle as long as pregnancy may be reasonably excluded. A backup contraceptive method should be used for 7 days after insertion of a contraceptive implant, unless it is inserted within 5 days of initiating menses, immediately after childbirth or after abortion, or immediately upon switching from another hormonal contraceptive.

MECHANISM OF ACTION:

The implantable contraceptive works by suppressing ovulation and by thickening the cervical mucus which inhibits sperm transport and penetration. It also alters the endometrium which may contribute to its contraceptive effect.

DETERMINING MEDICAL ELIGIBILITY FOR USE OF CONTRACEPTIVES

The references listed below contain recommendations for the safe use of contraceptives by women with various characteristics and medical conditions. These references are intended to assist staff and providers in counseling clients about choosing a contraceptive method and are meant to be a source of clinical guidance. Initiation and continuation of a contraceptive method must always reflect the medical judgment of the health care provider based on the individual client's clinical circumstance. Staff should seek the guidance of their agency's health care provider if or when a determination of medical eligibility is required.

Package Inserts

- 1) The package inserts contain information on the following: Contraindications; Warnings and Precautions; Drug interactions; and use in Specific Populations.
- 2) If initiating or continuing a method, the agency's health care provider must provide guidance.

United States Medical Eligibility Criteria (USMEC)

The Centers for Disease Control and Prevention (CDC) developed the United States Medical Eligibility Criteria (USMEC) in 2010. An update to these guidelines was published in July 2016. The CDC adapted the Medical Eligibility Criteria as a national practice standard. It provides guidance on the safe use of contraceptive methods for clients with particular medical conditions or physical characteristics.

Guidance is divided into four categories:

- 1 = A condition for which there is no restriction for the use of the contraceptive method.
- 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method
- 4 = A condition that represents an unacceptable health risk if the contraceptive method is used

Medical consultant should determine which criteria are used. There may be some variations between the package inserts and the USMEC recommendations.

CONSENT:

Clients must sign prior to receiving services:

- General Consent for Service
- Consent for Procedure

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems.
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- During return visits update medical and surgical health history.

OBJECTIVE:

- Height/Weight/BMI
- Blood Pressure
- Physical examination as indicated, consistent with ACOG guidelines

LABORATORY:

- STD screening, as indicated
- Pregnancy test, as indicated

ASSESSMENT:

- Eligible candidate for implantable contraceptive start or continuation of method
- No desire for pregnancy within 12 months

PLAN:

- Prescribe and insert the implantable contraceptive per proper procedure/technique
- Document location of implantable contraceptive, lot number, expiration date
- Document in client chart and provide to the client: date when the implantable contraceptive must be removed. Instruct the client of potential risks if implant is not removed including pregnancy.
- Provide back-up method of contraception as indicated
- Authorize EC
- Return for age appropriate periodic assessment
- Follow Up: 3 months as indicated to assess satisfaction with method, bleeding patterns, check weight, and address any problems or concerns

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options if they are new or undecided about methods of contraception
- Information about their chosen method of contraception including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
- FDA-approved product information/ package insert
- The date the implantable contraceptive must be removed in writing
- Information about possible drug interactions
- Instruction to inform other providers of contraceptive method
- Information about warning signs with use of the implantable contraceptive and what to do if any of these symptoms occur including emergency plans and phone numbers
- Advise client to contact clinic if signs or symptoms of infection occur at the insertion site (tenderness or pain, redness, swelling, discharge)
- Provide information about use of back-up method
- Advise clients that implantable contraceptives do NOT provide STD/HIV protection
- Correct and consistent use of condoms is recommended for STD/HIV protection
- Efficacy in overweight clients has not been defined because those who weighed more than 130% of their ideal body weight were not studied in clinical trials. NEXPLANON® may be less effective in individuals who are very overweight
- Instruct client about health promotion and disease prevention
- All women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Instruct client about EC use and availability
- A review of common side effects that might be expected including bleeding changes that are unpredictable and may include prolonged bleeding, frequent bleeding, irregular bleeding, infrequent bleeding and amenorrhea

REFERRAL:

(Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

ACOG Practice Bulletin, #121, "Long Acting Reversible Contraception: Implants and Intrauterine Devices." July 2011, Reaffirmed 2015.

<http://www.acog.org/~media/Practice%20Bulletins/Committee%20on%20Practice%20Bulletins%20--%20Gynecology/Public/pb121.pdf?dmc=1>

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<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>

Intrauterine Copper T 380A (TCu 380A)

DEFINITION:

The Copper T 380A (TCu 380A), a copper-releasing intrauterine contraceptive device marketed under the brand name ParaGard has been available in the United States since 1988. The T shaped polyethylene device contains 380mm² of exposed copper with barium sulfate added to create x-ray visibility. The FDA approved duration of use for this IUD is ten years, although data indicate high effectiveness for twelve years.

IUDs can be offered to nulliparous women and adolescents and can be inserted any time during the menstrual cycle as long as pregnancy may be reasonably excluded. No backup contraceptive method is needed after inserting the copper IUD, regardless of when in the menstrual cycle it is inserted.

MECHANISM OF ACTION:

The primary method of action in intrauterine contraceptives (IUDs) is to prevent fertilization.

The TCu 380A causes an increase in copper ions, enzymes, prostaglandins, and white blood cells (macrophages) in uterine and tubal fluids; these impair sperm function and prevent fertilization.

DETERMINING MEDICAL ELIGIBILITY FOR USE OF CONTRACEPTIVES

The references listed below contain recommendations for the safe use of contraceptives by women with various characteristics and medical conditions. These references are intended to assist staff and providers in counseling clients about choosing a contraceptive method and are meant to be a source of clinical guidance. Initiation and continuation of a contraceptive method must always reflect the medical judgment of the health care provider based on the individual client's clinical circumstance. Staff should seek the guidance of their agency's health care provider if or when a determination of medical eligibility is required.

Package Inserts

- 1) The package inserts contain information on the following: Contraindications; Warnings and Precautions; Drug interactions; and use in Specific Populations.
- 2) If initiating or continuing a method, the agency's health care provider must provide guidance.

United States Medical Eligibility Criteria (USMEC)

The Centers for Disease Control and Prevention (CDC) developed the United States Medical Eligibility Criteria (USMEC) in 2010. An update to these guidelines was published in July 2016. <http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf>

The CDC adapted the Medical Eligibility Criteria as a national practice standard. It provides guidance on the safe use of contraceptive methods for clients with particular medical conditions or physical characteristics.

Guidance is divided into four categories:

- 1 = A condition for which there is no restriction for the use of the contraceptive method.
- 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.

- 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method
- 4 = A condition that represents an unacceptable health risk if the contraceptive method is used

Medical consultant should determine which criteria are used. There may be some variations between the package inserts and the USMEC recommendations.

CONSENT:

Clients must sign the following prior to receiving services

- General Consent for Service
- Consent for Procedure

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems.
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- During return visits update medical and surgical health history.

OBJECTIVE:

- Height/Weight/BMI
- Blood Pressure
- Physical examination as indicated, consistent with ACOG guidelines
- Normal pelvic exam (No purulent cervicitis or uterine anomaly)
- Uterine depth must sound from 6.0 to 9.0 cm

LABORATORY:

- STD screening, as indicated
- Pregnancy test, as indicated

ASSESSMENT:

- Eligible candidate for Copper T IUD or continuation of method.
- No desire for pregnancy within 12 months

PLAN:

- Prescribe and insert the IUD per proper procedure/technique
- Gonorrhea and Chlamydia screening can be performed at the time of IUD insertion, according to CDC guidelines. IUD insertion should not be delayed until test results are available. Treatment can easily be done, if necessary, after results are obtained, while the IUD is in place.
- Document uterine sound depth, lot number of IUD, expiration date and length of strings
- Document in client chart: date when the IUD must be removed
- Instruct client how to check IUD strings and advise client to self-check monthly
- Authorize EC
- Return for age appropriate periodic assessment
- Follow Up: After next menses or in 1-3 months for IUD check. Assess string length and possible expulsion of IUD. Assess satisfaction with method, bleeding patterns, check weight, and address any problems or concerns

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options if they are new or undecided about methods of contraception
- Information about their chosen method of contraception including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
- FDA-approved product information/ package insert
- Provide in writing, the date the IUD must be removed
- Discuss possible drug interactions
- Instruction to inform other providers of contraceptive method
- Instruction about about health promotion and disease prevention
- Counseling about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Information that the IUD does NOT provide STD/HIV protection, correct and consistent use of condoms as recommended for STD/HIV protection
- Instruct client about EC use and availability
- Review common side effects; especially heavier and longer periods and bleeding between periods which typically subsides after 2-3 months
- If client is on anticoagulation therapy, advise her of possible heavier bleeding
- Review potential complications including; possible uterine perforation, vaso-vagal response with insertion/removal, expulsion of device, risk of pregnancy, sepsis and increased risk of spontaneous abortion if pregnancy occurs
- Provide information about warning signs associated with use of Copper T IUD and what to do if any of these symptoms occur including emergency plans and phone numbers

Intrauterine Contraceptive Warning Signs

Abdominal or pelvic pain
Fever or chills which might suggest infection
Foul vaginal discharge
Missing or change in length of IUD strings
Severe or prolonged vaginal bleeding

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

ACOG Practice Bulletin, #121, “Long Acting Reversible Contraception: Implants and Intrauterine Devices.” July 2011, Reaffirmed 2015.

<http://www.acog.org/~media/Practice%20Bulletins/Committee%20on%20Practice%20Bulletins%20--%20Gynecology/Public/pb121.pdf?dmc=1>

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<https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

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<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>

Intrauterine Levonorgestrel-Releasing Systems

DEFINITION:

The two levonorgestrel-releasing intrauterine systems (LNG-IUS) marketed by Bayer under the name Mirena has been available in the United States since 2000 and Skyla since 2013. In 2015, Actavis Pharma and Medicines360 introduced Liletta.

- **Mirena** releases 20 mcg of levonorgestrel (synthetic progestin) every 24 hours (and drops to 10 mcg per day as it reaches expiration) from a polymer cylinder mounted on a T shaped frame (32 mm x 32 mm size) and placed into the uterus Mirena provides contraception for up to five years.
- **Liletta** releases 18.6 mcg/day initially and declines progressively to about 16.3 mcg/day at 1 year, 14.3 mcg/day at 2 years, and 12.7 mcg/day at three years after insertion. Liletta must be removed by the end of the third year.
- **Skyla** releases 14 mcg of levonorgestrel every 24 hours for 25 days, after that it drops to 5 mcg every day for the next three years. The T shaped frame (28 mm x 30 mm in size) and provides contraception for up to three years.

IUDs can be offered to nulliparous women and adolescents and can be inserted any time during the menstrual cycle as long as pregnancy may be reasonably excluded. A backup contraceptive method should be used for 7 days after insertion, unless it is inserted within 5 days of initiating menses, immediately after childbirth or after abortion, or immediately upon switching from another hormonal contraceptive.

MECHANISM OF ACTION:

The primary method of action of intrauterine contraceptives (IUDs) is to prevent fertilization.

The LNG-IUS has several different contraceptive actions; thickening of the cervical mucus, inhibition of sperm function and motility, endometrial thinning and suppression of ovulation may occur in some women.

DETERMINING MEDICAL ELIGIBILITY FOR USE OF CONTRACEPTIVES

The references listed below contain recommendations for the safe use of contraceptives by women with various characteristics and medical conditions. These references are intended to assist staff and providers in counseling clients about choosing a contraceptive method and are meant to be a source of clinical guidance. Initiation and continuation of a contraceptive method must always reflect the medical judgment of the health care provider based on the individual client's clinical circumstance. Staff should seek the guidance of their agency's health care provider if or when a determination of medical eligibility is required.

Package Inserts

- 1) The package inserts contain information on the following: Contraindications; Warnings and Precautions; Drug interactions; and use in Specific Populations.
- 2) If initiating or continuing a method, the agency's health care provider must provide guidance.

United States Medical Eligibility Criteria (USMEC)

The Centers for Disease Control and Prevention (CDC) developed the United States Medical Eligibility Criteria (USMEC) in 2010. An update to these guidelines was published in July 2016. <http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf>

The CDC adapted the Medical Eligibility Criteria as a national practice standard. It provides guidance on the safe use of contraceptive methods for clients with particular medical conditions or physical characteristics.

Guidance is divided into four categories:

- 1 = A condition for which there is no restriction for the use of the contraceptive method.
- 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method
- 4 = A condition that represents an unacceptable health risk if the contraceptive method is used

Medical consultant should determine which criteria are used. There may be some variations between the package inserts and the USMEC recommendations.

CONSENT:

Clients must sign the following prior to receiving services:

- General Consent for Service
- Consent for Procedure

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems.
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- During return visits update medical and surgical health history.

OBJECTIVE:

- Height/Weight/BMI
- Blood Pressure
- Physical examination as indicated, consistent with ACOG guidelines
- Normal pelvic exam (No purulent cervicitis or uterine anomaly)
- Uterine depth must sound from 6.0 to 10.0 cm for Mirena

LABORATORY:

- STD screening, as indicated
- Pregnancy test, as indicated

ASSESSMENT:

- Eligible candidate for levonorgestrel-releasing IUD or continuation of method
- No desire for pregnancy within 12 months

PLAN:

- Prescribe and insert levonorgestrel-releasing IUD per proper procedure/technique
- Gonorrhea and Chlamydia screening can be performed at the time of IUD insertion, according to CDC guidelines. IUD insertion should not be delayed until test results are available. Treatment can easily be done, if necessary, after results are obtained, while the IUD is in place.
- Document uterine sound depth, lot number of IUD, expiration date and length of strings
- Document in client chart: date when the IUD must be removed
- Instruct client how to check IUD strings and advise client to self-check monthly
- Provide back-up method of contraception as indicated
- Authorize EC
- Return for age appropriate periodic assessment
- Follow Up: after next menses or in 1-3 months for IUD check. Assess string length and possible expulsion of IUD. Assess satisfaction with method, bleeding patterns, check weight, and address any problems or concerns.

CLIENT EDUCATION

All education topics and the client's understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options if they are new or undecided about methods of contraception
- Information about their chosen method of contraception including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
- FDA-approved product information/ package insert
- Information about the date the IUD must be removed in writing
- Discuss possible drug interactions
- Instruction to inform other providers of contraceptive method
- Information about use of back-up method
- Instruction about health promotion and disease prevention
- Counseling about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Information that the IUD does NOT provide STD/HIV protection, correct and consistent use of condoms is recommended for STD/HIV protection
- Instruction about EC use and availability
- A review of common side effects; especially irregular bleeding or amenorrhea
- A review of potential complications including; possible uterine perforation, vaso-vagal response with insertion/removal, expulsion of device, risk of pregnancy, sepsis and increased risk of spontaneous abortion if pregnancy occurs
- Information about warning signs associated with use of the levonorgestrel-releasing IUD and what to do if any of these symptoms occur including emergency plans and phone numbers

Intrauterine Contraceptive Warning Signs

Abdominal or pelvic pain
Fever or chills which might suggest infection
Foul vaginal discharge
Missing or change in length of IUD strings
Severe or prolonged vaginal bleeding

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES

ACOG Practice Bulletin, #121, “Long Acting Reversible Contraception: Implants and Intrauterine Devices.” July 2011, Reaffirmed 2015.

<http://www.acog.org/~media/Practice%20Bulletins/Committee%20on%20Practice%20Bulletins%20--%20Gynecology/Public/pb121.pdf?dmc=1>

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<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>

Combined Oral Contraceptives

DEFINITION:

Combined oral contraceptives, commonly called “the pill,” are the most commonly used form of reversible birth control in the United States. This form of reversible birth control suppresses ovulation (the monthly release of an egg from the ovaries) by the combined action of the hormones estrogen and progestin.

MECHANISM OF ACTION:

Combined oral contraceptives lower the risk of becoming pregnant primarily by suppressing ovulation. Other possible mechanisms may include cervical mucus changes that inhibit sperm penetration and endometrial changes that reduce the likelihood of implantation.

DETERMINING MEDICAL ELIGIBILITY FOR USE OF CONTRACEPTIVES

The references listed below contain recommendations for the safe use of contraceptives by women with various characteristics and medical conditions. These references are intended to assist staff and providers in counseling clients about choosing a contraceptive method and are meant to be a source of clinical guidance. Initiation and continuation of a contraceptive method must always reflect the medical judgment of the health care provider based on the individual client’s clinical circumstance. Staff should seek the guidance of their agency’s health care provider if or when a determination of medical eligibility is required.

Package Inserts

- 3) The package inserts contain information on the following: Contraindications; Warnings and Precautions; Drug interactions; and use in Specific Populations.
- 4) If initiating or continuing a method, the agency’s health care provider must provide guidance.

United States Medical Eligibility Criteria (USMEC)

The Centers for Disease Control and Prevention (CDC) developed the United States Medical Eligibility Criteria (USMEC) in 2010. An update to these guidelines was published in July 2016. <http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf>

The CDC adapted the Medical Eligibility Criteria as a national practice standard. It provides guidance on the safe use of contraceptive methods for clients with particular medical conditions or physical characteristics.

Guidance is divided into four categories:

- 1 = A condition for which there is no restriction for the use of the contraceptive method.
- 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method
- 4 = A condition that represents an unacceptable health risk if the contraceptive method is used

Medical consultant should determine which criteria are used. There may be some variations between the package inserts and the USMEC recommendations.

CONSENT:

Clients must sign general consent for service prior to receiving services

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- During return visits update medical and surgical health history.

OBJECTIVE:

- Height/Weight/BMI
- Blood Pressure
- Physical examination as indicated, consistent with ACOG guidelines

LABORATORY:

- STD screening, as indicated
- Pregnancy test, as indicated

ASSESSMENT:

- Eligible candidate for combined oral contraceptive start or continuation of method

PLAN:

- Prescribe combined oral contraceptive method for up to one year
- Choose a pattern of use. Off-label extended use of hormonal contraception is intended for combined oral contraceptives
- Provide back-up method of contraception as indicated
- Authorize EC
- Follow Up: 3 months as indicated (should not be linked to prescription refills) to assess satisfaction and correct use of method, check weight and BP, and address any problems or concerns
- Return for age appropriate periodic assessment

CLIENT EDUCATION

All education topics and the client's understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options if they are new or undecided about methods of contraception
- Information about their chosen method of contraception including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
- FDA-approved product information/ package insert
- Information about how to use the method correctly
- A review common side effects and possible drug interactions
- Information provided about how to contact clinic with questions or concerns *before* stopping a method (unless one of the danger/warning signs listed below)
- Instruction to inform other providers of contraceptive method
- Information about managing missed pills and use of back-up method
- Instruction about health promotion and disease prevention
- Counseling about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Information that combined oral contraceptives do NOT provide STD/HIV protection, correct and consistent use of condoms is recommended for STD/HIV protection
- Instruction about EC use and availability
- Information about danger/warning signs with use of combined oral contraceptives and what to do if any of these symptoms occur including emergency plans and phone numbers

Hormonal Contraceptive Warning Signs (Acronym **ACHES**)

Abdominal Pain

Chest Pain

Headaches

Eye Problems

Severe Leg Pain

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63.

<https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

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During the Postpartum Period. MMWR 2011;60:878-883.

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<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>

Injectable Contraceptives

DEFINITION:

The most commonly used injectable contraceptive is depot-medroxyprogesterone acetate (DMPA) is available in two forms:

- **Intramuscular DMPA**—Both the 1 mL vial and the 1 mL prefilled syringe of DMPA should be shaken vigorously just before use to ensure that the dose being administered represents a uniform suspension; 150 mg of DMPA is administered by deep IM injection in the gluteal or deltoid muscle. This is given every 11-13 weeks.
- **Subcutaneous DMPA**—The pre-filled syringe (0.65 mL) of DMPA should be shaken vigorously just before use to create a uniform suspension; 104 mg of DMPA is administered by SC injection into the anterior thigh or abdomen. This is given every 11-13 weeks.

These methods are appropriate for those who cannot use or do not desire to use estrogen-containing contraceptives.

MECHANISM OF ACTION:

As with other progestin-only contraceptives, injectable depot-medroxyprogesterone acetate is believed to exert its effects via several mechanisms of action. It inhibits ovulation by suppressing both Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH) and by eliminating LH surges. It also thickens the cervical mucus to inhibit sperm transport and penetration, and alters the endometrium, making it atrophic and not receptive to implantation.

DETERMINING MEDICAL ELIGIBILITY FOR USE OF CONTRACEPTIVES

The references listed below contain recommendations for the safe use of contraceptives by women with various characteristics and medical conditions. These references are intended to assist staff and providers in counseling clients about choosing a contraceptive method and are meant to be a source of clinical guidance. Initiation and continuation of a contraceptive method must always reflect the medical judgment of the health care provider based on the individual client's clinical circumstance. Staff should seek the guidance of their agency's health care provider if or when a determination of medical eligibility is required.

Package Inserts

- 1) The package inserts contain information on the following: Contraindications; Warnings and Precautions; Drug interactions; and use in Specific Populations.
- 2) If initiating or continuing a method, the agency's health care provider must provide guidance.

United States Medical Eligibility Criteria (USMEC)

The Centers for Disease Control and Prevention (CDC) developed the United States Medical Eligibility Criteria (USMEC) in 2010. An update to these guidelines was published in July 2016. <http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf>

The CDC adapted the Medical Eligibility Criteria as a national practice standard. It provides guidance on the safe use of contraceptive methods for clients with particular medical conditions or physical characteristics.

Guidance is divided into four categories:

- 1 = A condition for which there is no restriction for the use of the contraceptive method.
- 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method
- 4 = A condition that represents an unacceptable health risk if the contraceptive method is used

Medical consultant should determine which criteria are used. There may be some variations between the package inserts and the USMEC recommendations.

BLACK BOX WARNING:

Food and Drug Administration. November 17, 2004:

Women who use Depo-Provera Contraceptive Injection (depot-medroxyprogesterone) may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible. It is unknown if use of Depo-Provera Contraceptive Injection during adolescence or early adulthood, a critical period of bone accretion, will reduce bone mass and increase the risk of osteoporotic fracture in later life. Depo-Provera Contraceptive Injection should be used as a long-term birth control method (e.g., longer than 2 years) only if other birth control methods are inadequate.

In 2005, the World Health Organization concluded that there should be no restriction on the use of DMPA in women aged 18-45 years, including no restriction on the duration of use. Among females younger than 18 years and women older than 45 years, the advantages of using DMPA generally outweigh the theoretic safety concerns regarding fracture risk.

ACOG) Committee Opinion #415, September 2008: “A possible adverse effect of depot medroxyprogesterone acetate (DMPA) contraceptive injections—bone mineral density (BMD) loss—should not prevent clinicians from either prescribing DMPA to appropriate patients or limiting its use to 2 consecutive years. Appropriate counseling with a discussion of current medical evidence should occur before the initiation of this medication and during prolonged use. Practitioners should not perform bone mineral density monitoring solely in response to DMPA use because any observed short-term loss in bone mineral density associated with DMPA use may be recovered and is unlikely to place a client at risk of fracture during use or in later years.”

June 2014 (ACOG Committee Opinion #602): “Although the use of DMPA is associated with loss of BMD, current longitudinal and cross-sectional evidence suggests that recovery of BMD occurs after discontinuation of DMPA. No high-quality data answer the important clinical question of whether DMPA affects fracture risk in adolescents or adults later in life. The effect of DMPA on BMD and potential fracture risk should not prevent practitioners from prescribing DMPA or continuing use beyond 2 years.

June 2014 (ACOG Committee Opinion #602) continued:

The potential health risks associated with the bone effects of DMPA must be balanced against the likelihood of pregnancy using other methods or no method, and the known negative health and social consequences associated with unintended pregnancy, particularly among adolescents. Health care providers should inform women and adolescents considering initiating DMPA or continuing to use the method about the benefits and the risks of DMPA should discuss the U.S. Food and Drug Administration “black box” warning and use clinical judgment to assess appropriateness of use.”

CONSENT:

Clients must sign a general consent for service prior to receiving services

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- During return visits update medical and surgical health history.

OBJECTIVE:

- Height/Weight/BMI
- Blood Pressure
- Physical examination as indicated, consistent with ACOG guidelines

LABORATORY:

- STD screening, as indicated
- Pregnancy test, as indicated

ASSESSMENT:

- Eligible candidate for injectable contraceptive start or continuation of method
- No desire for pregnancy within 12 months

PLAN:

- Prescribe injectable contraceptives for up to one year
- Provide back-up method of contraception
- Authorize EC
- Follow Up: 3 months as indicated (should not be linked to prescription refill) to assess satisfaction and correct use of method, check weight, and address any problems or concerns

- Return for age appropriate periodic assessment
- Instruct client that they must return to clinic every 12 (+/- 1 week) weeks for next injection and set reinjection schedule.

Reinjection Schedule:

- If the client returns for re-injection earlier than 12 weeks; may re-inject early when necessary
- If the client returns for re-injection up to 15 weeks and desires to continue the method; may re-inject without pregnancy evaluation
- If the client returns for re-injection after 15 weeks and desires to continue the method; a pregnancy test **must** be performed
 - Re-injection may be given if it is reasonably certain that the client is not pregnant. Advise the client to use a back-up method of contraception or abstain for 7 days. Consider EC if appropriate.
 - Provide options counseling for pregnancy if pregnancy test is positive

CLIENT EDUCATION

All education topics and the client’s understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options if they are new or undecided about methods of contraception
- Information about their chosen method of contraception including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
- FDA-approved product information/ package insert
- Information about how to use the method correctly
- A review common side effects and possible drug interactions
- Information about how to contact clinic with questions or concerns *before* stopping a method (unless one of the danger/warning signs listed below)
- Instruction to inform other providers of contraceptive method
- Information about managing missed pills and use of back-up method
- Instruction about health promotion and disease prevention
- Counseling about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Information that combined oral contraceptives do NOT provide STD/HIV protection, correct and consistent use of condoms is recommended for STD/HIV protection
- Instruction about EC use and availability
- Information about danger/warning signs with use of combined oral contraceptives and what to do if any of these symptoms occur including emergency plans and phone numbers

Hormonal Contraceptive Warning Signs (Acronym **ACHES**)

- A**bdominal Pain
- C**hest Pain
- H**eadaches
- E**ye Problems
- S**evere Leg Pain

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES

ACOG Committee Opinion #602: "Depot Medroxyprogesterone Acetate and Bone Effects." June 2014. <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Adolescent-Health-Care/Depot-Medroxyprogesterone-Acetate-and-Bone-Effects>

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Centers for Disease Control & Prevention. Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2015. MMWR 2016: Vol 65. <http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6509a3.pdf>

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Centers for Disease Control & Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2013: Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition. MMWR 2013;62:1-60. <http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>

Centers for Disease Control & Prevention. Update to CDC's U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: Revised Recommendations for the Use of Hormonal Contraception Among Women at High Risk for HIV Infection or Infected with HIV. MMWR 2012;61:449-452. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6124a4.htm>

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Progestin Only Contraceptives

DEFINITION:

Progestin only contraceptives, commonly called the “mini pill” or “POP’s,” are a form of oral contraceptive that is taken daily like combined oral contraceptives but contain only the hormone progestin and no estrogen. One pill is taken every day with no hormone free days. The amount of progestin in POP’s is lower than the amount in combined oral contraceptive pills containing the same components.

Progestin only contraceptive pills may be useful for women who experience estrogen-related side effects, who have contraindications to estrogen, or who are currently breastfeeding.

MECHANISM OF ACTION:

Progestin only contraceptives are thought to prevent pregnancy by suppressing ovulation in a variable proportion of cycles. Progestin only pills act primarily by thickening cervical mucus to inhibit sperm penetration, lowering the midcycle Luteinizing Hormone (LH) and Follicle Stimulating Hormone (FSH) peaks, slowing the movement of the ovum through the fallopian tubes and by altering the endometrium.

DETERMINING MEDICAL ELIGIBILITY FOR USE OF CONTRACEPTIVES

The references listed below contain recommendations for the safe use of contraceptives by women with various characteristics and medical conditions. These references are intended to assist staff and providers in counseling clients about choosing a contraceptive method and are meant to be a source of clinical guidance. Initiation and continuation of a contraceptive method must always reflect the medical judgment of the health care provider based on the individual client’s clinical circumstance. Staff should seek the guidance of their agency’s health care provider if or when a determination of medical eligibility is required.

Package Inserts

- 3) The package inserts contain information on the following: Contraindications; Warnings and Precautions; Drug interactions; and use in Specific Populations.
- 4) If initiating or continuing a method, the agency’s health care provider must provide guidance.

United States Medical Eligibility Criteria (USMEC)

The Centers for Disease Control and Prevention (CDC) developed the United States Medical Eligibility Criteria (USMEC) in 2010. An update to these guidelines was published in July 2016. <http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf>

The CDC adapted the Medical Eligibility Criteria as a national practice standard. It provides guidance on the safe use of contraceptive methods for clients with particular medical conditions or physical characteristics.

Guidance is divided into four categories:

- 1 = A condition for which there is no restriction for the use of the contraceptive method.
- 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method
- 4 = A condition that represents an unacceptable health risk if the contraceptive method is used

Medical consultant should determine which criteria are used. There may be some variations between the package inserts and the USMEC recommendations.

CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- During return visits update medical and surgical health history.

OBJECTIVE:

- Height/Weight/BMI
- Blood Pressure
- Physical examination as indicated, consistent with ACOG guidelines

LABORATORY:

- STD screening, as indicated
- Pregnancy test, as indicated

ASSESSMENT:

- Eligible candidate for progestin only contraceptive pill start or continuation of method

PLAN:

- Prescribe progestin only contraceptive pills for up to one year
- Provide back-up method of contraception as indicated
- Authorize EC
- Follow Up: 3 months as indicated (should not be linked to prescription refills) to assess satisfaction and correct use of method, check weight, and address any problems or concerns
- Return for age appropriate periodic assessment

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options if they are new or undecided about progestin only contraceptives
- Information about progestin only contraceptive pills including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
- FDA-approved product information/ package insert
- Information about how to use the method correctly
- Information about the importance of taking pills within 2-3 hours of the same time each day
- A review of common side effects and drug interactions
- Information how to contact the clinic with questions or concerns *before* stopping a method (unless one of the danger/warning signs listed below)
- Instruction to inform other providers of contraceptive method
- Information about managing missed pills and use of back-up method Instruct client about health promotion and disease prevention
- Counseling about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Information that progestin only contraceptive pills do NOT provide STD/HIV protection, correct and consistent use of condoms as recommended for STD/HIV protection
- Instruction about EC use and availability
- Information about danger warning signs with use of progestin only contraceptive pills and what to do if any of these symptoms occur including emergency plans and phone numbers.

Hormonal Contraceptive Warning Signs (Acronym **ACHES**)

Abdominal Pain
Chest Pain
Headaches
Eye Problems
Severe Leg Pain

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

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<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5904a1.htm>

Centers for Disease Control & Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2013: Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition. MMWR 2013:62:1-60.
<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>

Transdermal Patch

DEFINITION:

The transdermal contraceptive patch, Ortho Evra, delivers a continuous systemic dose of estrogen and progestin through the skin and subcutaneous tissue for absorption into the bloodstream. Each patch is applied for a period of 7 days; a new patch is applied each week to a different area of the body (buttocks, upper arm, lower abdomen or upper torso – excluding the breasts) and the old patch is discarded. Because of the method of delivery, the hormones bypass the gastrointestinal tract and are not lost during gastrointestinal upset.

MECHANISM OF ACTION:

The patch, like other combined hormonal contraceptives, works mainly by suppressing ovulation. Other likely mechanisms of action include thickening of the cervical mucus to prevent sperm penetration and endometrial changes that could affect implantation.

DETERMINING MEDICAL ELIGIBILITY FOR USE OF CONTRACEPTIVES

The references listed below contain recommendations for the safe use of contraceptives by women with various characteristics and medical conditions. These references are intended to assist staff and providers in counseling clients about choosing a contraceptive method and are meant to be a source of clinical guidance. Initiation and continuation of a contraceptive method must always reflect the medical judgment of the health care provider based on the individual client's clinical circumstance. Staff should seek the guidance of their agency's health care provider if or when a determination of medical eligibility is required.

Package Inserts

- 5) The package inserts contain information on the following: Contraindications; Warnings and Precautions; Drug interactions; and use in Specific Populations.
- 6) If initiating or continuing a method, the agency's health care provider must provide guidance.

United States Medical Eligibility Criteria (USMEC)

The Centers for Disease Control and Prevention (CDC) developed the United States Medical Eligibility Criteria (USMEC) in 2010. An update to these guidelines was published in July 2016. <http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf>

The CDC adapted the Medical Eligibility Criteria as a national practice standard. It provides guidance on the safe use of contraceptive methods for clients with particular medical conditions or physical characteristics.

Guidance is divided into four categories:

- 1 = A condition for which there is no restriction for the use of the contraceptive method.
- 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method
- 4 = A condition that represents an unacceptable health risk if the contraceptive method is used

Medical consultant should determine which criteria are used. There may be some variations between the package inserts and the USMEC recommendations.

WARNINGS:

Important Safety Information

Hormones from ORTHO EVRA[®] get into the bloodstream and are processed by the body differently than hormones from birth control pills. **You will be exposed to about 60% more estrogen if you use ORTHO EVRA[®] than if you use a typical birth control pill containing 35 micrograms of estrogen.** In general, increased estrogen may increase the risk of side effects. The risk of venous thromboembolic events (blood clots in the legs and/or the lungs) may be increased with ORTHO EVRA[®] use compared with use of birth control pills. Studies examined the risk of these serious blood clots in women who used either ORTHO EVRA[®] or birth control pills containing one of two progestins (levonorgestrel or norgestimate) and 30–35 micrograms of estrogen. Results of these studies ranged from an approximate doubling of risk of serious blood clots to no increase in risk in women using ORTHO EVRA[®] compared to women using birth control pills

Serious as well as minor side effects have been reported with the use of the patch. Serious risks, which can be life threatening, include blood clots, stroke and heart attacks and are increased with smoking cigarettes. Cigarette Smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use hormonal contraceptives should be strongly advised not to smoke.

CONSENT:

Clients must sign a general consent for service prior to receiving services

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- During return visits update medical and surgical health history.

OBJECTIVE:

- Height/Weight/BMI
- Blood Pressure
- Physical examination as indicated, consistent with ACOG guidelines

LABORATORY:

- STD screening as indicated
- Pregnancy test as indicated

ASSESSMENT:

- Eligible candidate for transdermal contraceptive method start or continuation of method
- Weight of 198 lbs. or less (90 kg.): Limited evidence suggests that heavier women (over 198 lbs.) may be at higher risk of pregnancy when using the transdermal contraceptive.

PLAN:

- Prescribe transdermal contraceptive method for up to one year
- Off-label extended use of hormonal contraception is not be used for the transdermal patch.
- Provide back-up method of contraception as indicated
- Authorize EC
- Follow Up: 3 months as indicated (should not be linked to prescription refills) to assess satisfaction and correct use of method, check weight and BP, and address any problems or concerns
- Return for age appropriate periodic assessment

CLIENT EDUCATION:

All education topics and the client’s understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options if they are new or undecided about transdermal contraceptive method
- Information about transdermal contraceptives including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
- FDA-approved product information/ package insert
- A review of common side effects and possible drug interactions
- Information about use of back-up method
- Instruction to inform other providers of contraceptive method
- Education about how to apply, remove and store the transdermal contraceptive patch:
 - Patch may be applied to buttocks, abdomen, upper torso (except the breasts), or on the outside of the upper arm. Avoid placing on areas of friction, such as bra straps. Only apply the patch to clean, dry skin, and never put it over skin that is irritated, sunburned, red, or infected. Make sure there are no creams, oils, powder, sunscreen or sweat on the skin – or the patch will not stick
 - After the patch is removed, fold in half so the adhesive sides seal in the medication. Discard the patch in the garbage; do not flush it into the toilet
 - Instruction about potential problems and corrective action such as: dislodged or detached patches, missed or forgotten patches, application-site reactions
 - Store patches in their protective pouches at room temperature

- Instruction about health promotion and disease prevention
- Counseling about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Information that transdermal contraceptives do NOT provide STD/HIV protection, correct and consistent use of condoms is recommended for STD/HIV protection
- Instruction about EC use and availability
- Information how to contact the clinic with questions or concerns *before* stopping a method (unless one of the danger/warning signs listed below)
- Information about danger/warning signs with use of transdermal contraceptives and what to do if any of these symptoms occur including emergency plans and phone numbers

Hormonal Contraceptive Warning Signs (Acronym **ACHES**)

Abdominal Pain

Chest Pain

Headaches

Eye Problems

Severe Leg Pain

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63.

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<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>

Vaginal Ring

DEFINITION:

A vaginal contraceptive ring, NuvaRing, was approved by the FDA in 2001. It is a soft, transparent, flexible ring and releases 120 mcg of etonogestrel (synthetic progestin), and 15 mcg of ethinyl estradiol (synthetic estrogen) daily. Each ring is designed to be placed vaginally once every 28 days; it is to be kept in place for 21 days and removed for a 7 day ring-free period to allow a withdrawal bleed. The vaginal route of delivery increases the bioavailability of hormones, thereby enabling the use of a lower total hormone dose, potentially reducing side effects. The ring can be used by women who cannot take a pill orally, and by women with abnormal intestinal absorption.

MECHANISM OF ACTION:

The vaginal contraceptive ring, works mainly by suppressing ovulation, similar to other combined hormonal contraceptives. Other likely mechanisms of action include thickening of the cervical mucus to prevent sperm penetration and endometrial changes that could affect implantation.

DETERMINING MEDICAL ELIGIBILITY FOR USE OF CONTRACEPTIVES

The references listed below contain recommendations for the safe use of contraceptives by women with various characteristics and medical conditions. These references are intended to assist staff and providers in counseling clients about choosing a contraceptive method and are meant to be a source of clinical guidance. Initiation and continuation of a contraceptive method must always reflect the medical judgment of the health care provider based on the individual client's clinical circumstance. Staff should seek the guidance of their agency's health care provider if or when a determination of medical eligibility is required.

Package Inserts

- 1) The package inserts contain information on the following: Contraindications; Warnings and Precautions; Drug interactions; and use in Specific Populations.
- 2) If initiating or continuing a method, the agency's health care provider must provide guidance.

United States Medical Eligibility Criteria (USMEC)

The Centers for Disease Control and Prevention (CDC) developed the United States Medical Eligibility Criteria (USMEC) in 2010. An update to these guidelines was published in July 2016. <http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf>

The CDC adapted the Medical Eligibility Criteria as a national practice standard. It provides guidance on the safe use of contraceptive methods for clients with particular medical conditions or physical characteristics.

Guidance is divided into four categories:

- 1 = A condition for which there is no restriction for the use of the contraceptive method.
- 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method
- 4 = A condition that represents an unacceptable health risk if the contraceptive method is used

Medical consultant should determine which criteria are used. There may be some variations between the package inserts and the USMEC recommendations.

WARNINGS:

Important Safety Information

The use of combination hormonal contraceptives is associated with increased risks of several serious side effects, including blood clots, which may lead to stroke or heart attack. NuvaRing® is not for women with a history of these conditions. The risk of getting blood clots may be greater with the type of progestin in NuvaRing® than with some other progestins in certain low-dose birth control pills. It is unknown if the risk of blood clots is different with NuvaRing® use than with the use of certain birth control pills

Cigarette Smoking increases the risk of serious cardiovascular side effects. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use combination hormonal contraceptives, including NuvaRing®, are strongly advised not to smoke.

CONSENT:

Clients must sign a general consent for service prior to receiving services

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems.
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- During return visits update medical and surgical health history.

OBJECTIVE:

- Height/Weight/BMI
- Blood Pressure
- Physical Examination as indicated, consistent with ACOG guidelines

LABORATORY:

- STD screening as indicated
- Pregnancy test as indicated

ASSESSMENT:

- Eligible candidate for vaginal contraceptive ring start or continuation of method

PLAN:

- Prescribe vaginal contraceptive ring for up to one year
- Choose a pattern of use. Off-label extended use of hormonal contraception is intended for combined oral contraceptives and may be considered for the vaginal ring.
- Provide back-up method of contraception as indicated
- Authorize EC
- Follow Up: 3 months as indicated (should not be linked to prescription refills) to assess satisfaction and correct use of method, check weight and BP, and address any problems or concerns
- Return for age appropriate periodic assessment

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options if they are new or undecided about combined vaginal contraceptive ring
- Information about vaginal contraceptive ring method including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
- A review of the common side effects and possible drug interactions
- FDA-approved product information/package insert
- Provide client education about how to insert, remove and store the vaginal contraceptive ring:
 - The vaginal contraceptive ring may accidentally slip out while removing a tampon, during intercourse, or having a bowel movement. If the vaginal contraceptive ring has been out of the vagina for less than 3 hours, no additional contraception or back-up method is required. The ring should be rinsed with warm water and reinserted as soon as possible
 - If the vaginal contraceptive ring has been out of the vagina for more than 3 hours, the ring should be rinsed with warm water, reinserted, and a back-up contraceptive method is necessary for 7 days
 - If the vaginal contraceptive ring has been left in place more than 3 weeks (but less than 4 weeks), it should be removed, and a new ring inserted after 1 week break without the ring.
 - If the vaginal contraceptive ring has been left in place for more than 4 weeks contraceptive effectiveness may have been compromised. Advise the client to consider a pregnancy test and EC if indicated, remove the ring, replace with a new ring, and use a back-up method of contraception until the new ring has been in place for at least 7 days
 - If the vaginal contraceptive ring has been broken, the ring should be discarded and replaced with a new vaginal contraceptive ring. No back-up method of contraception is needed
 - Discard the vaginal ring in the foil pouch and throw it in a trash container out of the reach of children and pets (do not flush it down the toilet)

- Store rings in their foil pouch at room temperature (for up to 4 months). Avoid direct sunlight or storing above 86°F (30°C)
- Advise client that they may perceive more vaginal discharge or wetness while using the vaginal contraceptive ring, but that this does not necessarily signify infection. Client should call for evaluation of vaginal infection if needed
- Advise client that the vaginal contraceptive ring should not be removed from vagina for intercourse. **If vaginal contraceptive ring is removed for more than 3 hours, a back-up method of contraceptive is necessary for 7 days**
- Information about how to contact clinic with questions or concerns *before* stopping a method (unless one of the danger/warning signs listed below)
- Instruction to inform providers of contraceptive method
- Counseling about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Information that vaginal contraceptive rings do NOT provide STD/HIV protection, correct and consistent use of condoms is recommended for STD/HIV protection
- Instruction about EC use and availability
- Information about danger warning signs with use of vaginal contraceptive ring and what to do if any of these symptoms occur including emergency plans and phone numbers

Hormonal Contraceptive Warning Signs (Acronym **ACHES**)

Abdominal Pain
 Chest Pain
 Headaches
 Eye Problems
 Severe Leg Pain

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

Centers for Disease Control & Prevention. Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2015. MMWR 2016: Vol 65. <http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6509a3.pdf>

Centers for Disease Control & Prevention. Update to CDC's U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: Revised Recommendations for the Use of Contraceptive Methods During the Postpartum Period. MMWR 2011;60:878-883. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6026a3.htm>

Centers for Disease Control & Prevention. U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: Adapted from the World Health Organization Medical Eligibility Criteria for Contraceptive Use, 4th edition. (US MEC). MMWR 2010:59 (No. RR-4).
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5904a1.htm>

Centers for Disease Control & Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2013: Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition. MMWR 2013:62:1-60.
<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>

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Diaphragm

DEFINITION:

The diaphragm is a shallow dome-shaped silicone cup designed to fit over the cervix and block the entry of sperm. It is inserted into the vagina before intercourse so the posterior rim rests in the posterior fornix and the anterior rim fits snugly behind the pubic bone. The diaphragm is a reusable contraceptive device meant for use with a spermicidal agent.

The diaphragm must be prescribed and fitted by a healthcare provider.

MECHANISM OF ACTION:

Vaginal barriers work by blocking sperm. Diaphragms usually combine two contraceptive mechanisms: a physical barrier to shield the cervix and a chemical spermicide to kill sperm.

Once in position, the diaphragm may provide effective contraceptive protection for up to six hours and may be used for repeated acts of intercourse with additional fresh spermicide inserted with an applicator without removing the diaphragm. After intercourse, the diaphragm must be left in place for at least six hours. It is not recommended to leave in place longer than 24 hours.

DETERMINING MEDICAL ELIGIBILITY FOR USE OF CONTRACEPTIVES

The references listed below contain recommendations for the safe use of contraceptives by women with various characteristics and medical conditions. These references are intended to assist staff and providers in counseling clients about choosing a contraceptive method and are meant to be a source of clinical guidance. Initiation and continuation of a contraceptive method must always reflect the medical judgment of the health care provider based on the individual client's clinical circumstance. Staff should seek the guidance of their agency's health care provider if or when a determination of medical eligibility is required.

Package Inserts

- 1) The package inserts contain information on the following: Contraindications; Warnings and Precautions; Drug interactions; and use in Specific Populations.
- 2) If initiating or continuing a method, the agency's health care provider must provide guidance.

United States Medical Eligibility Criteria (USMEC)

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The CDC adapted the Medical Eligibility Criteria as a national practice standard. It provides guidance on the safe use of contraceptive methods for clients with particular medical conditions or physical characteristics.

Guidance is divided into four categories:

- 1 = A condition for which there is no restriction for the use of the contraceptive method.
- 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method

- 4 = A condition that represents an unacceptable health risk if the contraceptive method is used

Medical consultant should determine which criteria are used. There may be some variations between the package inserts and the USMEC recommendations.

CONSENT:

Clients must sign a general consent for service prior to receiving services

SUBJECTIVE:

Should Include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- During return visits update medical and surgical health history.
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

Assess:

- Willingness to use method consistently and correctly
- Willingness to touch one's genitals

OBJECTIVE:

- Height/Weight/BMI
- Pelvic Exam: Evaluate for vaginal, cervical or uterine anomalies that would inhibit proper use, placement or retention of barrier method
- Physical Examination as indicated, consistent with ACOG guidelines
- Clinician to fit appropriate style and size of diaphragm
- Allow the client to practice insertion and removal. After client insertion, check to make sure that the cervix is covered and the client is comfortable using this method

LABORATORY:

- STD screening as indicated
- Pregnancy test, as indicated

ASSESSMENT:

- Eligible candidate for diaphragm start or continuation of method

PLAN:

- Prescribe diaphragm
- Authorize EC
- Return for diaphragm refitting after pregnancy, weight gain or loss >10 lbs., and as needed
- Return for age appropriate periodic assessment

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options if they are new or undecided about diaphragm or barrier contraceptives
- Information about diaphragm and barrier contraceptives including mechanism of action, efficacy, benefits/risks, side effects, advantages/disadvantages, warning signs, advantages and disadvantages, etc.
- FDA-approved product information/package insert
- Instruction on proper use of diaphragm including insertion, removal, cleaning and storage:
 - Examine diaphragm prior to use to assure it is intact with no cracks or holes. Do not use if cracked, brittle or if any holes or tears are identified
 - Diaphragm must be used consistently and correctly with every act of intercourse to be effective
 - Empty bladder and wash hands prior to insertion and removal to avoid introducing infective organisms into vagina
 - Instruct client on use of spermicide with diaphragm
 - For contraceptive effectiveness, the diaphragm should remain in place at least 6 hours after the last act of intercourse
 - Add another applicator of spermicidal gel if intercourse occurs more than 6 hours after insertion and prior to each successive act of intercourse
 - The diaphragm may remain in place for 24 hours
 - Wash diaphragm after each use. Plain soap is best; avoid deodorant soap or perfumed soap. Do not use talcum powder on the diaphragm or in its case
 - Use only water or water-based lubricants (ex. K-Y jelly) and spermicidal lubricants(ex. jellies, foam or suppositories) with diaphragm
 - Do NOT use oil-based lubricants (ex. Petroleum jelly, body lotions, massage oil, baby oil, and vegetable oil) with diaphragms because they may damage a diaphragm. Because vaginal medications (ex. for yeast infections) may contain oil-based ingredients that can damage diaphragms, advise client to remain abstinent until medication is completed and infection is cured
- Instruction about health promotion and disease prevention
- Counseling about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid

- Information that use of male condom with diaphragm provides additional protection for STD/HIV, correct and consistent use of condoms is recommended for STD/HIV protection
- Instruction about EC use and availability
- Information to call clinic with any questions about fit or placement

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

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Centers for Disease Control & Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2013: Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition. MMWR 2013:62:1-60. <http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>

Female Condom

DEFINITION:

The female condom is a soft, loose-fitting polyurethane sheath that lines the vagina with two polyurethane rings at either end. When properly inserted, the ring at the closed end of the sheath lies over the cervix and anchors the device in place while the outer ring forms the external, open end which remains outside the vagina and covers part of the labia. The sheath is coated with a silicone-based non-spermicidal lubricant. The *Reality Female Condom* is approved for over-the-counter sale without prescription and is intended for one-time use.

- Female and male condoms should not be used together; they can adhere to each other, causing slippage or displacement of one or both devices
- Oil-based products do not deteriorate the *Reality Female Condom*, it withstands storage better than latex, and is less likely to tear or break due to polyurethane being stronger than latex

MECHANISM OF ACTION:

The female condom lines the vagina entirely which provides a physical barrier to shield the

CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- During return visits update medical and surgical health history

Assess:

- Willingness of partners to use method consistently and correctly
- Willingness to touch one's genitals

OBJECTIVE:

- Physical examination is not necessary

LABORATORY:

- None necessary

ASSESSMENT:

- Eligible for barrier contraceptive method

PLAN:

- Provide female condoms, if available or OTC
- Authorize EC
- Recommend return for age appropriate periodic assessment

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptives options
- Information about EC use and availability
- Instruction about health promotion and disease prevention
- Counseling about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Information that correct and consistent use of condoms is recommended for STD/HIV protection
- Information about female condoms including:
 - Availability of female condoms OTC
 - Types of condoms available; Reality Female Condom
 - When to use condoms, and encourage consistent and correct use with each act of intercourse
 - How to use condoms: proper use, placement and storage
 - Encourage client/or partner(s) to practice correct placement, insertion and removal of female condom prior to intercourse
 - Use a new condom with each act of vaginal intercourse
 - How to negotiate/discuss condom use with their partner(s)
 - Male and female condoms should NOT be used together. They can adhere to each other causing slippage or displacement of one or both devices
 - Use of spermicide with female condom may increase contraceptive efficacy. Insert spermicide into vagina before condom or onto condom itself
 - Instruct client/partner(s) about what to do if condom slips or breaks
 - If available, may immediately insert spermicidal foam or gel into vagina

KEY INSTRUCTIONS FOR CONDOM USE

- Use a new condom for each act of intercourse
- Before any genital contact, place the condom inside the vagina
- Immediately after ejaculation, hold the rim of the condom, twist and remove from the vagina
- Throw away the used condom safely

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

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ACOG Committee Opinion #582. Addressing Health Risks of Noncoital Sexual Activity. December 2013. <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Adolescent-Health-Care/co582.pdf?dmc=1&ts=20160718T1611463170>

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Male Condom

DEFINITION:

The male condom is a sheath worn over the shaft of the penis and is one of the oldest known methods of contraception. Condoms are available in a wide variety of types, shapes and sizes. Male condoms made of latex or synthetic polyurethane are the most common and provide protection against both pregnancy and sexually transmitted infections.

Natural skin condoms made from the intestinal cecum of lambs, “natural skin” or “lambskin” condoms contain small pores that may permit the passages of viruses, including hepatitis B virus, herpes simplex virus, and HIV. Because of their porous qualities, natural skin condoms may not provide the same level of protection against STD’s as latex or synthetic condoms.

MECHANISM OF ACTION:

The male condom acts as a physical barrier by covering the penile glans and shaft. The condom prevents pregnancy by blocking the passage of semen; it also protects against sexually transmitted diseases by covering the major portals of entry and exit for many STD pathogens.

CONSENT:

Client must sign a general consent for service prior to receiving services

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- Assess willingness to use method consistently and correctly
- During return visits update medical and surgical health history

OBJECTIVE:

- Physical examination is not necessary

LABORATORY:

- None necessary

ASSESSMENT:

- Eligible for barrier contraceptive method

PLAN:

- Provide condoms
- Authorize EC
- Recommend return for age appropriate periodic assessment

CLIENT EDUCATION:

All education topics and the client’s understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options
- Information about EC use and availability
- Instruction about health promotion and disease prevention
- Information that correct and consistent use of condoms is recommended for STD/HIV protection
- Information about male condoms including:
 - Availability of male condoms OTC with various features; condoms with reservoir tips are recommended
 - Types of condoms available; polyurethane or vinyl condoms are available if latex allergy is present
 - When to use condoms, and encourage consistent and correct use with each act of intercourse
 - How to use condoms; proper use, placement and storage
 - Use a new condom with each act of anal, vaginal or oral intercourse
 - How to negotiate/discuss condom use with their partner(s)
 - Male and female condoms should NOT be used together. They can adhere to each other causing slippage or displacement of one or both devices
 - Use only water or water-based lubricants (ex. K-Y jelly, Astroglide) or spermicidal lubricants (ex. jellies or suppositories) with latex condoms
 - Do NOT use oil-based lubricants (ex. petroleum jelly, body lotions, massage oil, baby oil) with latex condoms because they reduce condom integrity. Oil-based products may be used with polyurethane condoms
 - Because vaginal medications (ex. for yeast infections) may contain oil-based ingredients that can damage latex condoms, advise client/partner(s) to remain abstinent or use synthetic condoms until medication is completed and infection is cured
 - Instruct client/partner(s) about what to do if condom slips or breaks
 - If available, may immediately insert spermicidal foam or gel into vagina

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63.
<https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

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ACOG Committee Opinion #582. Addressing Health Risks of Noncoital Sexual Activity. December 2013. <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Adolescent-Health-Care/co582.pdf?dmc=1&ts=20160718T1611463170>

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Emergency Contraception

Recent updates from Centers for Disease Control & Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2016. Page 34

<http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf>

DEFINITION:

Emergency contraception consists of methods that can be used by women after sexual intercourse to prevent pregnancy. Emergency contraception methods have varying ranges of effectiveness depending on the method and timing of administration. Four options are available in the United States: the Cu-IUD and three types of ECPs.

Intrauterine Device

Cu-IUD

Emergency Contraceptive Pills (ECPs)

- UPA in a single dose (30 mg)
- Levonorgestrel in a single dose (1.5 mg) or as a split dose (1 dose of 0.75 mg of levonorgestrel followed by a second dose of 0.75 mg of levonorgestrel 12 hours later)
- Combined estrogen and progestin in 2 doses (Yuzpe regimen: 1 dose of 100 μ g of ethinyl estradiol plus 0.50 mg of levonorgestrel followed by a second dose of 100 μ g of ethinyl estradiol plus 0.50 mg of levonorgestrel 12 hours later)

MECHANISM OF ACTION:

Emergency contraception is NOT an abortifacient

- Emergency contraception can prevent pregnancy during the 5 or more days between intercourse and implantation of a fertilized egg
- Emergency contraception does NOT interfere with an established pregnancy

No single mechanism of action has been established for emergency contraceptive pills; rather, the mode of action varies according to the day of the menstrual cycle on which intercourse occurs and when emergency contraception is administered. Emergency contraception has been shown to inhibit or delay an egg from being released from the ovary when taken prior to ovulation. Emergency contraception may also alter the receptiveness of the endometrium and inhibit implantation of a fertilized egg.

TIMING

Cu-IUD

The Cu-IUD can be inserted within 5 days of the first act of unprotected sexual intercourse as an emergency contraceptive.

In addition, when the day of ovulation can be estimated, the Cu-IUD can be inserted beyond 5 days after sexual intercourse, as long as insertion does not occur >5 days after ovulation.

INITIATION OF REGULAR CONTRACEPTION AFTER ECPS

Ulipristal Acetate (UPA)

Recommendations have been updated by the FDA regarding when to start regular contraception after UPA emergency contraceptive pills

(<http://www.fda.gov/safety/medwatch/safetyinformation/safety-relateddruglabelingchanges/ucm306971.htm>)

- Advise the client to start or resume hormonal contraception no sooner than 5 days after use of UPA, and provide or prescribe the regular contraceptive method as needed. For methods requiring a visit to a health care provider, such as depo-medroxyprogesterone acetate (DMPA), implants, and IUDs, starting the method at the time of UPA use may be considered; the risk that the regular contraceptive method might decrease the effectiveness of UPA must be weighed against the risk of not starting a regular hormonal contraceptive method.
- The client needs to abstain from sexual intercourse or use barrier contraception for the next 7 days after starting or resuming regular contraception or until her next menses, whichever comes first.
- Any non-hormonal contraceptive method can be started immediately after the use of UPA.
- Advise the client to have a pregnancy test if they do not have a withdrawal bleed within 3 weeks.

Levonorgestrel and Combined Estrogen and Progestin ECPs

Any regular contraceptive method can be started immediately after the use of levonorgestrel or combined estrogen and progestin ECPs.

The client needs to abstain from sexual intercourse or use barrier contraception for 7 days. Advise the client to have a pregnancy test if they do not have a withdrawal bleed within 3 weeks.

Comments and Evidence Summary

The resumption or initiation of regular hormonal contraception after ECP use involves consideration of the risk for pregnancy if ECPs fail and the risks for unintended pregnancy if contraception initiation is delayed until the subsequent menstrual cycle. A health care provider may provide or prescribe pills, the patch, or the ring for a client to start no sooner than 5 days after use of UPA. For methods requiring a visit to a health care provider, such as DMPA, implants, and IUDs, starting the method at the time of UPA use may be considered; the risk that the regular contraceptive method might decrease the effectiveness of UPA must be weighed against the risk of not starting a regular hormonal contraceptive method.

PREVENTION AND MANAGEMENT OF NAUSEA AND VOMITING WITH ECP USE

Levonorgestrel and UPA ECPs cause less nausea and vomiting than combined estrogen and progestin ECPs. Routine use of antiemetics before taking ECPs is not recommended. Pretreatment with antiemetics may be considered depending on availability and clinical judgment.

Vomiting within 3 hours of taking ECPs: Another dose of ECP should be taken as soon as possible. Use of an antiemetic should be considered.

Comments and Evidence Summary

Many women do not experience nausea or vomiting when taking ECPs, and predicting which women will experience nausea or vomiting is difficult. Although routine use of antiemetics before taking ECPs is not recommended, antiemetics are effective in some women and can be offered when appropriate. Health care providers who are deciding whether to offer antiemetics to women taking ECPs should consider the following: 1) women taking combined estrogen and progestin ECPs are more likely to experience nausea and vomiting than those who take levonorgestrel or UPA ECPs; 2) evidence indicates that antiemetics reduce the occurrence of nausea and vomiting in women taking combined estrogen and progestin ECPs; and 3) women who take antiemetics might experience other side effects from the antiemetics.

EMERGENCY CONTRACEPTIVE PILLS

ECPs should be taken as soon as possible within 5 days of unprotected sexual intercourse.

There are no medical contraindications for the use of combined or progestin-only Emergency Contraceptive Pills (ECPs). (The US Medical Eligibility Criteria for Contraceptive Use does not include ulipristal acetate) ECP use can be considered even for women who have medical conditions that make them poor candidates for combined oral contraceptives, such as vascular disease, migraine with aura, or severe liver disease. The use of ulipristal acetate or the progestin-only ECP is preferred to combined estrogen/progestin ECPs for these women. The reason ECPs should not be used in pregnancy is not because they are harmful, but because they are ineffective.

DETERMINING MEDICAL ELIGIBILITY FOR USE OF CONTRACEPTIVES

The references listed below contain recommendations for the safe use of contraceptives by women with various characteristics and medical conditions. These references are intended to assist staff and providers in counseling clients about choosing a contraceptive method and are meant to be a source of clinical guidance. Initiation and continuation of a contraceptive method must always reflect the medical judgment of the health care provider based on the individual client's clinical circumstance. Staff should seek the guidance of their agency's health care provider if or when a determination of medical eligibility is required.

Package Inserts

- 3) The package inserts contain information on the following: Contraindications; Warnings and Precautions; Drug interactions; and use in Specific Populations.
- 4) If initiating or continuing a method, the agency's health care provider must provide guidance.

United States Medical Eligibility Criteria (USMEC)

The Centers for Disease Control and Prevention (CDC) developed the United States Medical Eligibility Criteria (USMEC) in 2010. An update to these guidelines was published in July 2016. <http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf>

The CDC adapted the Medical Eligibility Criteria as a national practice standard. It provides guidance on the safe use of contraceptive methods for clients with particular medical conditions or physical characteristics.

Guidance is divided into four categories:

- 1 = A condition for which there is no restriction for the use of the contraceptive method.
- 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method
- 4 = A condition that represents an unacceptable health risk if the contraceptive method is used

Medical consultant should determine which criteria are used. There may be some variations between the package inserts and the USMEC recommendations.

CONSENT:

Clients must sign the following prior to receiving services:

- General Consent for Service
- Consent for Procedure, if Copper-T inserted

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- During return visits update medical and surgical health history
- Family medical history
- History of unprotected or inadequately protected intercourse or contraceptive failure within the last 5 days
- Intercourse within past 120 hours (5 days) without contraceptive protection, independent of time in the menstrual cycle, although the longer the delay of initiating treatment, the lower the efficacy
- Contraceptive mishap
 - Barrier method dislodgment/breakage
 - Expulsion of IUD
 - Lapsed or incorrect use of any method
- Error in practicing “coitus interruptus” (withdrawal method) LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol, Tobacco and Other Drug Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

Copper T 380A IUD criteria:

- Intercourse within 120 hours without contraceptive protection or with contraceptive mishap
- LNMP
- No desire for pregnancy within 12 months
- Low risk of STD

OBJECTIVE:

Emergency Contraceptive Pills:

- Physical examination is not necessary

Copper T 380A IUD criteria:

- Normal pelvic exam (No purulent cervicitis or uterine anomaly)
- Uterine depth must sound from 6.0 to 9.0 cm

LABORATORY:

Emergency Contraceptive Pills

- Levonorgestrel: should not be withheld or delayed in order to pregnancy test
- Ulipristal Acetate: pregnancy test as indicated

Copper T 380A IUD

- STD screening as indicated
- Pregnancy test as indicated

ASSESSMENT:

- Eligible candidate for Emergency Contraceptive
- No desire for pregnancy within 12 months for Copper T 380A IUD

PLAN:

- Provide ECPs or prescription for ECPs, or insert IUD (see FPCI Medical Protocols “Intrauterine Contraceptives – Copper T”)
- Return for age appropriate periodic assessment and continued use of contraceptives

CLIENT EDUCATION:

All education topics and the client’s understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options if they are not using any contraceptive method
- Information about emergency contraceptives including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
- FDA-approved product information/ package insert
- Information about ECPs including how to use method (provide written instructions when possible) If Copper T used, see FPCI Medical Protocols “Intrauterine Contraceptives – Copper T”
- Instruction that emergency contraception is most effective in preventing pregnancy when taken as soon as possible after unprotected or inadequately protected intercourse
- A review of common side effects including nausea/vomiting and cramping
- Instruction regarding when to expect next menses

- Instruction to follow up for evaluation if menses have not returned in 3 weeks, if lower abdominal pain or persistent irregular bleeding
- Instruction that ECP's are for emergency use only and are not recommended for routine use because they are less effective than regular contraceptives
- Instruction that EC will not protect her from pregnancy resulting from unprotected intercourse in the days or weeks following treatment
- Recommendation that client use a barrier method or abstain from intercourse for 14 days or next menses, whichever comes first
- Recommendation that client use condoms, barrier method or initiation of contraceptive method to prevent pregnancy. Initiation of a reliable contraception may be started the day after ECP is complete
- Instruction about health promotion and disease prevention
- Counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Information that emergency contraception does NOT protect against STD/HIV - correct and consistent use of condoms is recommended for STD/HIV protection

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

Office of Population Research: "Emergency Contraception: Resource Overview."

<http://ec.princeton.edu/>

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<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5904a1.htm>

Centers for Disease Control & Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2013: Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition. MMWR 2013;62:1-60.

<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>

Spermicides

DEFINITION:

A spermicide is a substance that kills sperm. It is inserted vaginally prior to intercourse for contraceptive purposes. The most common active ingredient of spermicides is nonoxynol-9. Spermicides containing nonoxynol-9 are available over-the-counter as creams, film, foams, jellies, and suppositories.

MECHANISM OF ACTION:

A spermicide is a substance that kills sperm. As a contraceptive, spermicide may be used alone. However, when spermicides are combined with contraceptive barrier methods such as diaphragms, condoms, cervical caps, and sponges, combined methods are believed to result in lower pregnancy rates than either method alone.

DETERMINING MEDICAL ELIGIBILITY FOR USE OF CONTRACEPTIVES

The references listed below contain recommendations for the safe use of contraceptives by women with various characteristics and medical conditions. These references are intended to assist staff and providers in counseling clients about choosing a contraceptive method and are meant to be a source of clinical guidance. Initiation and continuation of a contraceptive method must always reflect the medical judgment of the health care provider based on the individual client's clinical circumstance. Staff should seek the guidance of their agency's health care provider if or when a determination of medical eligibility is required.

Package Inserts

- 1) The package inserts contain information on the following: Contraindications; Warnings and Precautions; Drug interactions; and use in Specific Populations.
- 2) If initiating or continuing a method, the agency's health care provider must provide guidance.

United States Medical Eligibility Criteria (USMEC)

The Centers for Disease Control and Prevention (CDC) developed the United States Medical Eligibility Criteria (USMEC) in 2010. An update to these guidelines was published in July 2016. <http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf>

The CDC adapted the Medical Eligibility Criteria as a national practice standard. It provides guidance on the safe use of contraceptive methods for clients with particular medical conditions or physical characteristics.

Guidance is divided into four categories:

- 1 = A condition for which there is no restriction for the use of the contraceptive method.
- 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method
- 4 = A condition that represents an unacceptable health risk if the contraceptive method is used

Medical consultant should determine which criteria are used. There may be some variations between the package inserts and the USMEC recommendations.

CONSENT:

Clients must sign a general consent for service prior to receiving services

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- During return visits update medical and surgical health history

Assess:

- Willingness of partners to use method consistently and correctly
- Willingness to touch one's genitals

OBJECTIVE:

- Physical examination is not necessary

LABORATORY:

- None necessary

ASSESSMENT:

- Eligible candidate for spermicide contraceptive method

PLAN:

- Provide spermicide, if available or OTC
- Authorize EC
- Return for age appropriate periodic assessment and other contraceptive choices

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options
- Information about spermicide including advantages/disadvantages and potential risks.
- A review of common side effects
- Information about vaginal spermicides (suppository, gel, cream, foam, sponge, and film) are available OTC

-
- Instruction on proper use of spermicide and care of supplies including:
 - Insert vaginal spermicide prior to intercourse
 - Reinsert vaginal spermicide with each act of intercourse, or if more than one hour passes from time of last spermicide insertion and intercourse
 - If symptoms of severe irritation of vulva, vagina, or partner's genitalia (burning, itching, or rash): stop using product and seek medical attention
- Instruction about health promotion and disease prevention
- Counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Information that nonoxynol 9 does not provide protection against STD/HIV - correct and consistent use of condoms is recommended for STD/HIV protection
- Instruction about EC use and availability

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63.

<http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

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<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5904a1.htm>

Centers for Disease Control & Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2013: Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition. MMWR 2013:62:1-60.

<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>

Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. *Contraceptive Technology*. 20th Revised Edition, 2011.

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Abstinence

DEFINITION:

The term “abstinence” has several meanings:

- Refraining from all sexual behavior
- Refraining from sexual behavior involving genital contact
- Refraining from penetrative sexual practices
- Primary abstainers have never had sexual intercourse with another person.
- Secondary abstainers are sexually experienced but for various reasons no longer engage in behaviors they consider as “having sex.” Individuals may voluntarily abstain: not be in a current relationship; unhappy with a relationship or have an estranged relationship; be fearful of a sexually transmitted infection; have the presence of preschoolers; have a geographical separation from their partner; have poor health, an illness or injury; or be pregnant or had a recent childbirth.

MECHANISM OF ACTION:

For the purpose of contraception, abstinence is defined as refraining from penile-vaginal intercourse. For the purpose of sexually transmitted infections, abstinence is defined as refraining from those acts that permit exposure to infectious lesions or secretions.

CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- During return visits update medical and surgical health history

OBJECTIVE:

- Physical examination is not necessary

LABORATORY:

- None necessary

ASSESSMENT:

- Eligible for abstinence contraception

PLAN:

- Provide instructions for abstinence
- Authorize EC
- Return for age appropriate periodic assessment

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented in their medical record. Family Planning clients must receive:

- Information about all types of contraceptive options
- Information about emergency contraceptives including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
- Education about the following:
 - They should make decisions about abstinence when they are clearheaded, sober, and not in the heat of the moment. They should decide with their partner about the right time to have sex
 - Discuss and decide with their partner, in advance what sexual activities they will and won't do
 - Avoid high-pressure sexual situations (drunk or high)
 - Always have condoms on hand if they change their minds
 - Learn more about their bodies and how to keep it healthy
 - Learn about contraception and safe sex
 - 100% abstinence, 100% of the time is 100% effective, against pregnancy and STDs
 - Abstinence is free and always available to everyone
 - Abstinence requires a high level of motivation
- Recommendation for the use of condoms, other barrier method or initiation of a contraceptive method to prevent pregnancy if/when they are no longer abstinent
- Instruction about health promotion and disease prevention
- Counseling about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Information that correct and consistent use of condoms is recommended for STD/HIV protection
- Instruction about EC use and availability

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

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Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. *Contraceptive Technology*. 20th Revised Edition, 2011.

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Natural Family Planning Fertility Awareness

DEFINITION:

Natural Family Planning (NFP) is also known as Fertility Awareness Based Method, which encompasses Standard Days, Calendar Rhythm, TwoDay, Billings Ovulation, and Symptothermal Method as possible methods to identify when ovulation might occur. These methods of “natural family planning” increase the users’ knowledge of their reproductive potential and enhance self-reliance. They can be used to avoid pregnancy, to achieve pregnancy, to detect pregnancy, or to detect impaired fertility.

NFP relies on identifying the “fertile window” in the menstrual cycle when intercourse is most likely to result in a pregnancy. To avoid pregnancy, couples either use another method or do not have sex during the fertile time. These methods involve keeping track of menstrual cycle days, observing, recording and interpreting the body’s fertility signs.

MECHANISM OF ACTION:

NFP uses one or more methods to identify the beginning and end of the fertile time in a menstrual cycle. In most cycles, ovulation occurs near the middle of the cycle and lasts about 6 days. Ovulation is expected to occur between cycle day 8-19 in cycles ranging from 26 and 32 days long (about 78% of cycles).

CONSENT:

Clients must sign a general consent for service prior to receiving services

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method
- During return visits update medical and surgical health history

LABORATORY:

- None necessary

OBJECTIVE:

- Physical examination is not necessary

ASSESSMENT:

- Eligible candidate for natural family planning

PLAN:

- Provide back-up method of contraception as indicated
- Authorize EC
- Return for age appropriate periodic assessment

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented in their medical record. Family Planning clients should receive:

- Information about all types of contraceptive options if they are new or undecided
- Information that to prevent pregnancy, use a barrier method or avoid sexual intercourse when ovulation or fertile times are identified
- Information about natural family planning methods including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, etc. client must know only the day of her menstrual cycle to consider herself potentially fertile on days 8-19. During these fertile days the couple either abstains or uses a barrier method.
- Information about these methods:
 - Calendar Rhythm Method: the client must have recorded the length of her previous 6-12 menstrual cycles in order to identify the longest and shortest of these cycles. Calculations are then made to identify the probable days of fertility during the current cycle. Subtract 18 from the number of days in the shortest cycle, and 11 from the number of days in the longest cycle. During these fertile days the couple either abstains or uses a barrier method.
 - TwoDay Method: If a client notices cervical secretions of any type YESTERDAY or TODAY, the client should consider themselves fertile TODAY.
 - Billings Ovulation Method: Changes in the characteristics of the cervical mucus is a signal of the beginning and end of the fertile time. When cervical mucus changes from thick cloudy or white and sticky to more abundant, clear, stretchy, wet and slippery indicates ovulation. Ovulation most likely occurs within 1 day before, during, or after the last day of abundant, clear, stretchy, slippery secretions.
 - Symptothermal Method: The temperature of the body at rest, called the basal body temperature, is lower in the first part of the cycle, rises to a higher level beginning around the time of ovulation and remains at that level for the rest of the cycle. The client should take her temperature when the client wakes up in the morning and record her temperature on a chart each day of her menstrual cycle to calculate her fertile time.
 - Natural Family Planning or Fertility Awareness may incorporate 1 or more of these methods to help predict when ovulation might occur.
- Information about the advantages and disadvantages of this method:
 - Advantages: NFP has no side effects; is safe; is affordable and available to all; may encourage the male partner's participation; increases the users' knowledge of their reproductive potential; and enhances self-reliance.

- **Disadvantages:** NFP offers no protection against STDs, must rely on the cooperation of the male partner, and is not suitable for all women to use. Conditions that make NFP difficult to use include recent childbirth, current breastfeeding, recent menarche, anovulatory cycling (PCOS) or obesity-related infrequent cycles, recent discontinuation of hormonal contraceptive methods and approaching menopause.
NFP is not recommended for women who have irregular menstrual cycles; are unable to interpret their fertility signs or the presence of secretions; have persistent reproductive tract infections or inter-menstrual bleeding that can hinder identification of secretions; are unable to abstain or use other methods during the fertile days; or are unmotivated to observe and record changes in their bodies.
- Instruction about health promotion and disease prevention
- Counseling about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Inform client that natural family planning methods do NOT provide STD/HIV protection- correct and consistent use of condoms is recommended for STD/HIV protection
- Instruction about EC use and availability

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

ACOG FAQ024 “Fertility Awareness-Based Methods of Family Planning.” April 2015
<http://www.acog.org/Patients/FAQs/Fertility-Awareness-Based-Methods-of-Family-Planning>

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Family Planning Clinical Protocols

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Well Woman Visits Age 13-20

DEFINITION:

Periodic assessments provide an excellent opportunity to counsel patients about preventive care. These assessments should include screening, evaluation and counseling, and immunizations based on age and risk factors. Positive behaviors, such as exercise, should be reinforced, and negative ones, such as smoking, should be discouraged. These guidelines specify routine assessments that should be available for nonpregnant women based on their age group and risk factors.

CONSENT:

Must be obtained prior to receiving services
Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems,
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

Should include:

- Height/Weight/BMI
- Blood Pressure
- Neck: adenopathy, thyroid
- Heart
- Lungs
- Skin
- Breasts, axillae (**ACOG: age >19 every 1-3 yrs.**)
- Pelvic examination **age 21 and over (13-20 yrs. of age when indicated by history)**
 - Vulva
 - Vagina
 - Cervix
 - Bimanual

LABORATORY:

- STD screening, as indicated
 - May include syphilis, and HIV
 - Should screen for gonorrhea, Chlamydia (GC/CT) when sexually active, under 25 years of age. Client may self-collected vaginal swab for GC/CT, clinician may perform a vaginal or cervical swab or patient may provide a urine sample
- Cervical cytology:
 - **Start at Age 21.** An adolescent with a history of normal cytology screening in the past should not be rescreened until age 21. HPV testing is not recommended at any time for adolescents and if inadvertently performed, a positive test result should not influence management.
- **If younger than 21 and client has had a history of an abnormal pap:** then continue the follow-up as previously established.

ASSESSMENT:

- Status of examination/evaluation

PLAN:

- Return annually
- Recommend other testing as indicated, services available elsewhere

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented.

Adolescent clients: must include information on parental involvement, confidentiality, sexual coercion, abstinence and safer sex practice options to reduce risks for STD/HIV and pregnancy. Information should be client centered, appropriate for the client's age, level of knowledge, language, and socio-cultural background and presented in an unbiased manner and may include:

- Sexuality and Reproductive Planning
 - Development
 - Contraceptive options for prevention of unintended pregnancy, including emergency contraception
 - Postponing sexual involvement
 - High-risk behaviors
 - Sexually transmitted disease prevention
 - Partner risk assessment
 - Barrier protection
 - Preconception health services
- Fitness and Nutrition
 - Exercise
 - Dietary/nutrition
 - Folic acid supplementation
- Calcium intake, Vitamin D, Folic Acid 0.4 to 0.8 mg daily

- Psychosocial
 - Interpersonal/family relationships
 - Intimate partner violence
 - Sexual assault prevention
 - Depressive symptoms, suicide
 - Sexual orientation and gender identity
 - Personal goal development
 - Behavioral/learning disorders
 - Abuse/neglect
 - School satisfaction
 - Lifestyle/stress
 - Sleep disorders
 - Peer relationships

- Cardiovascular Risk Factors
 - Family history
 - Hypertension
 - Dyslipidemia
 - Obesity
 - Diabetes mellitus
 - Lifestyle

- Health/Risk Behaviors
 - Hygiene including dental
 - Injury prevention
 - Skin exposure to ultraviolet rays
 - Tobacco, alcohol, other drug use

- Immunizations
 - Recommended Immunizations (**not Title X funded**):
<http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-schedule-easy-read.pdf>
 - Review immunization status for all clients. Offer vaccinations or provide referrals to community providers for age appropriate immunizations, as needed. **Vaccinations are not a Title X funded or required service.**
 - HPV (one series, females age 11-26)
 - Diphtheria and reduced tetanus toxoids and acellular pertussis vaccine (one-time dose of Tdap for Td booster; then boost with Td every 10 years (once between ages 11-18) Women should get one dTdap vaccine during every pregnancy to protect the baby.
 - Hepatitis B vaccine (one series, if not previously immunized)
 - Hepatitis A vaccine (one series, if at risk, discuss with healthcare provider)
 - Influenza vaccine annually
 - Measles, mumps, rubella vaccine (not previously immunized))
 - Meningococcal vaccine (MenACWY or MPSV4 and MenB) recommended if certain risk factors due to health, job or lifestyle).
 - Pneumococcal vaccine-one dose each, PCV13 and PPSV23, depending on age and health condition
 - Varicella vaccine (one series, not previously immunized)

Changes in the 2016 Adult Immunization Schedule reflect ACIP recommendations summarized: [Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older — United States, 2016](http://www.cdc.gov/mmwr/volumes/65/wr/mm6504a5er.htm)(<http://www.cdc.gov/mmwr/volumes/65/wr/mm6504a5er.htm>).

Primary changes to the immunization schedule include:

- Interval change for 13-valent pneumococcal conjugate vaccine (PCV13) followed by 23-valent pneumococcal polysaccharide vaccine (PPSV23) from "6 to 12 months" to "at least 1 year" for immunocompetent adults aged ≥65 year who do not have immunocompromising conditions, anatomical or functional asplenia, cerebrospinal fluid leak, or cochlear implants ([MMWR 2015;64\[34\]:944–947](#)). The interval for adults aged ≥19 years with any of these conditions is at least 8 weeks.
- Serogroup B meningococcal (MenB) vaccine series should be administered to persons aged ≥10 years who are at increased risk for serogroup B meningococcal disease ([MMWR 2015;64\[22\]:608–612](#)).
- Men B vaccine series may be administered to adolescents and young adults aged 16 through 23 years (preferred age is 16 through 18 years) to provide short-term protection against most strains of serogroup B meningococcal disease ([MMWR 2015;64\[41\]:1171–1176](#)).
- Nine-valent human papillomavirus (HPV) vaccine (9vHPV) has been added to the schedule and can be used for routine vaccination of females and males against HPV ([MMWR 2015;64\[11\]:300–304](#)).

REFERRAL:

(Referred services are not Title X funded)

- As indicated by history, physical examination or lab findings

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<http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-schedule-easy-read.pdf>

Centers for Disease Control & Prevention. Sexually Transmitted Diseases Treatment Guidelines. MMWR June 2015:64. <http://www.cdc.gov/mmwr/pdf/rr/rr6403.pdf>

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Well Woman Visits Age 21 and Above

DEFINITION:

Periodic assessments provide an excellent opportunity to counsel patients about preventive care. These assessments should include screening, evaluation and counseling, and immunizations based on age and risk factors. Positive behaviors, such as exercise, should be reinforced, and negative ones, such as smoking, should be discouraged. These guidelines specify routine assessments that should be available for non-pregnant women based on their age group and risk factors.

INFORMED CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- DES exposure in utero (if born between 1940-1970)
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

Should include:

- Height/Weight/BMI
- Blood Pressure
- Neck: adenopathy, thyroid
- Heart
- Lungs
- Breasts, axillae (**ACOG: age >19 every 1-3 yrs., age 40+ yearly**)
- Abdomen
- Pelvic examination (every 1-3 yrs., age 40+ yearly)
 - Vulva
 - Vagina
 - Cervix
 - Bimanual
 - Recto-vaginal, as indicated
- Skin

LABORATORY:

- STD screening, as indicated
 - May include syphilis, and HIV
 - Should include gonorrhea, Chlamydia (GC/CT) screening, if sexually active and under 25 years of age or younger; or if over 25 years of age and with risk factors or symptoms
- Cervical cytology:

Cervical cytology screening should be done regardless of HPV vaccine status, following age-specific recommendations (same as unvaccinated women)

 - **Women younger than 21 years:** No screening
 - **Women Age 21-29:** Cytology (reflex HPV for ASCUS) alone every 3 years. HPV co-testing should not be performed in women younger than 30 years, and should only be used to determine if a colposcopy is needed in women with an ASCUS cytology result (“reflex testing”)
 - **Women Age 30-65:**
 - Human Papillomavirus and cytology co-testing every 5 years (preferred)
 - Cytology alone every 3 years (acceptable)
 - Screening by HPV testing alone is not recommended
 - **Women Age over 65 years:**
 - No screening is necessary after adequate negative prior screening results
 - Women with a history of CIN 2, CIN 3 or adenocarcinoma in situ should continue routine age-based screening for at least 20 years
 - **Women with total hysterectomy:**

No screening is necessary, if she is without a cervix and without a history of CIN 2, CIN 3, adenocarcinoma in situ, or cancer in the past 20 years
 - **Women with risk factors requiring more frequent cervical cytology screening:**
 - Women infected with HIV (screen twice in the first year after diagnosis, even if younger than age 21, and annually thereafter)
 - Women who are immunocompromised (received solid organ transplants). Annual cytology screening starting at age 21 is reasonable. Test characteristics for HPV testing have not been determined.
 - Women who were exposed to diethylstilbestrol in utero (annual screening)
 - Women previously treated for CIN 2, CIN 3, or cancer. Women should continue to undergo routine age-based screening for 20 years after the initial post-treatment surveillance period.
- Recommended (**not Title X funded**), with suggested locations to obtain services:
 - Mammogram (every 1-2 years, starting at **age 40**, yearly at **age 50**)
 - Fasting glucose test (every 3 years **after age 45**, yearly if history of gestational diabetes)
 - Screen for diabetes if asymptomatic sustained blood pressure >135/80 mm Hg (either treated or untreated)
 - Thyroid-stimulating hormone (every 5 years, starting at **age 50**)
 - Lipid profile (every 5 years, starting at **age 20, as indicated**)
 - Screening for fecal occult blood, client collected (yearly starting at **age 50**, if not undergoing colonoscopy every 10 yrs.)

- Preferred: Colonoscopy screening (every 10 years, starting at **age 50**, African Americans should begin screening at **age 45**) Screening should start earlier if high risk. High-Risk Factors: First-degree relative younger than age 60 or 2 or more first-degree relatives of any age with colorectal cancer or adenomatous polyps; family history of familial adenomatous polyposis or hereditary nonpolyposis colon cancer; history of colorectal cancer, adenomatous polyps, inflammatory bowel disease, chronic ulcerative colitis, or Crohn's disease.

ASSESSMENT:

- Status of examination

PLAN:

- Return annually
- Recommend other testing as indicated

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented in their medical chart.

Information should be client centered, appropriate for the client's age, level of knowledge, language, and socio-cultural background and presented in an unbiased manner and may include:

- Sexuality and Reproductive Planning
 - Contraceptive options for prevention of unintended pregnancy, including emergency contraception
 - High-risk behaviors
 - Sexually transmitted disease prevention
 - Partner risk assessment
 - Barrier protection
 - Preconception health services
 - Sexual function
- Fitness and Nutrition
 - Exercise
 - Dietary/nutrition
 - Folic acid supplementation
 - Calcium intake, Vitamin D, Folic Acid 0.4 to 0.8 mg daily
- Psychosocial
 - Interpersonal/family relationships
 - Intimate partner violence
 - Sexual assault prevention
 - Depressive symptoms, suicide
 - Sexual orientation and gender identity
 - Abuse/neglect
 - School/work satisfaction
 - Peer relationships
 - Lifestyle/stress
 - Sleep disorders
 - Retirement planning
- Cardiovascular Risk Factors
 - Family history
 - Hypertension
 - Dyslipidemia
 - Obesity

- Diabetes mellitus
- Lifestyle
- Health/Risk Behaviors
 - Breast self-awareness
 - Hygiene including dental
 - Injury prevention
 - Skin exposure to ultraviolet rays
 - Tobacco, alcohol, other drug use
 - Aspirin prophylaxis (ages 55-79)
 - Hormone therapy
- Immunizations
 - Recommended (**not Title X funded**):
<http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-schedule-easy-read.pdf>

Review immunization status for all clients. Offer vaccinations or provide referrals to community providers for age appropriate immunizations, as needed. **Vaccinations are not a Title X funded or required service.**

- HPV (one series, females age 11-26)
- Diphtheria and reduced tetanus toxoids and acellular pertussis vaccine (one-time dose of Tdap for Td booster; then boost with Td every 10 years (once between ages 11-18) Women should get one dTdap vaccine during every pregnancy to protect the baby.
- Hepatitis B vaccine (one series, if not previously immunized)
- Hepatitis A vaccine (one series, if at risk, discuss with healthcare provider)
- Influenza vaccine annually
- Measles, mumps, rubella vaccine (not previously immunized))
- Meningococcal vaccine (MenACWY or MPSV4 and MenB) recommended if certain risk factors due to health, job or lifestyle).
- Pneumococcal vaccine-one dose each, PCV13 and PPSV23, depending on age and health condition
- Varicella vaccine (one series, not previously immunized)

Changes in the 2016 Adult Immunization Schedule reflect ACIP recommendations summarized: [Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older — United States, 2016](http://www.cdc.gov/mmwr/volumes/65/wr/mm6504a5er.htm)(<http://www.cdc.gov/mmwr/volumes/65/wr/mm6504a5er.htm>).

Primary changes to the immunization schedule include:

- Interval change for 13-valent pneumococcal conjugate vaccine (PCV13) followed by 23-valent pneumococcal polysaccharide vaccine (PPSV23) from "6 to 12 months" to "at least 1 year" for immunocompetent adults aged ≥65 year who do not have immunocompromising conditions, anatomical or functional asplenia, cerebrospinal fluid leak, or cochlear implants ([MMWR 2015;64\[34\]:944–947](http://www.cdc.gov/mmwr/volumes/64/wr/mm6434a1.htm)). The interval for adults aged ≥19 years with any of these conditions is at least 8 weeks.
- Serogroup B meningococcal (MenB) vaccine series should be administered to persons aged ≥10 years who are at increased risk for serogroup B meningococcal disease ([MMWR 2015;64\[22\]:608–612](http://www.cdc.gov/mmwr/volumes/64/wr/mm6422a1.htm)).

- Men B vaccine series may be administered to adolescents and young adults aged 16 through 23 years (preferred age is 16 through 18 years) to provide short-term protection against most strains of serogroup B meningococcal disease ([MMWR 2015;64\[41\]:1171–1176](#)).
- Nine-valent human papillomavirus (HPV) vaccine (9vHPV) has been added to the schedule and can be used for routine vaccination of females and males against HPV ([MMWR 2015;64\[11\]:300–304](#)).

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

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Well Man Visits

DEFINITION:

Periodic assessments provide an excellent opportunity to counsel patients about preventive care. These assessments should include screening, evaluation and counseling, and immunizations based on age and risk factors. Positive behaviors, such as exercise, should be reinforced, and negative ones, such as smoking, should be discouraged. These guidelines specify routine assessments that should be available for men based on their age group and risk factors.

CONSENT:

Clients must sign a general consent for service prior to receiving services

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- DES exposure in utero (if born between 1940-1970)
- Family medical history
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

Should include:

- Height/Weight/BMI
- Blood Pressure
- Neck: adenopathy, thyroid
- Heart
- Lungs
- Breasts (**age 19 and over**)
- Abdomen and inguinal area
- Genital examination
 - Penis
 - Testicles
 - Prostate, as indicated
- Skin

LABORATORY:

- STD screening, as indicated (refer to 2015 Sexually Transmitted Disease Treatment Guidelines (<http://www.cdc.gov/std/tg2015/specialpops.htm#msm>))
 - May include syphilis, and HIV
 - Gonococcal infection, in particular, is concentrated in specific geographic locations and communities. Subgroups of men having sex with men (MSM) are at high risk for gonorrhea infection and should be screened at sites of exposure (see [MSM \(<http://www.cdc.gov/std/tg2015/specialpops.htm#msm>\)](http://www.cdc.gov/std/tg2015/specialpops.htm#msm)). Screening for gonorrhea in men and older women who are at low risk for infection is not recommended
 - For MSM who've had sex in the last year, screen at least annually:
 - HIV if status of client or his sex partner is unknown or he has had more than one sex partner since the last HIV test
 - Syphilis
 - Urine GC/CT NAAT, for men reporting "insertive" sex
 - Rectal swab GC/CT NAAT, for men reporting receptive anal sex
 - Pharyngeal swab GC NAAT, for men reporting receptive oral sex
- Recommended (**not Title X funded**), with suggested locations to obtain services:
 - Lipid profile (every 5 years, starting at **age 20, as indicated**)
 - Screen for diabetes if asymptomatic sustained blood pressure >135/80 mm Hg (either treated or untreated) and every 3 years starting at age 45 as indicated
 - Screening for fecal occult blood, client collected (yearly starting at **age 50**, if not undergoing colonoscopy every 10 years)
 - Colonoscopy screening (every 10 years, starting at **age 50**, African Americans should begin screening at **age 45**) Screening should start earlier if high risk. High-Risk Factors: First-degree relative younger than age 60 or 2 or more first-degree relatives of any age with colorectal cancer or adenomatous polyps; family history of familial adenomatous polyposis or hereditary nonpolyposis colon cancer; history of colorectal cancer, adenomatous polyps, inflammatory bowel disease, chronic ulcerative colitis, or Crohn's disease

ASSESSMENT:

- Status of examination

PLAN:

- Return annually
- Recommend other testing as indicated

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented

Information should be client centered, appropriate for the client's age, level of knowledge, language, and socio-cultural background and presented in an unbiased manner and may include:

- Sexuality and Reproductive Planning
 - Contraceptive options for prevention of unintended pregnancy, including emergency contraception
 - High-risk behaviors
 - Sexually transmitted disease prevention

- Partner risk assessment
 - Barrier protection
- Preconception health services
- Sexual function
- Fitness and Nutrition
 - Exercise
 - Dietary/nutrition
 - Folic acid supplementation
 - Calcium intake, Vitamin D
- Psychosocial
 - Interpersonal/family relationships
 - Intimate partner violence
 - Sexual assault prevention
 - Depressive symptoms, suicide
 - Sexual orientation and gender identity
 - Abuse/neglect
 - School/work satisfaction
 - Peer relationships
 - Lifestyle/stress
 - Sleep disorders
 - Retirement planning
- Cardiovascular Risk Factors
 - Family history
 - Hypertension
 - Dyslipidemia
 - Obesity
 - Diabetes mellitus
 - Lifestyle
- Health/Risk Behaviors
 - Breast self-awareness
 - Testicular self-awareness
 - Hygiene including dental
 - Injury prevention
 - Skin exposure to ultraviolet rays
 - Tobacco, alcohol, other drug use
 - Aspirin prophylaxis (ages 55-79)
- Immunizations
 - Recommended Immunizations (**not Title X funded**):
<http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-schedule-easy-read.pdf>

Review immunization status for all clients. Offer vaccinations or provide referrals to community providers for age appropriate immunizations, as needed. **Vaccinations are not a Title X funded or required service.**

- HPV (one series, men age 13-21). Vaccination is also recommended through age 26 years for men who have sex with men and for immunocompromised persons (including those with HIV infection) if not vaccinated previously.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a3.htm>
- Diphtheria and reduced tetanus toxoids and acellular pertussis vaccine (one-time dose of Tdap for Td booster; then boost with Td every 10 years (once between ages 11-18)
- Hepatitis B vaccine (one series, if not previously immunized)

- Hepatitis A vaccine (one series, if at risk, discuss with healthcare provider)
- Influenza vaccine annually
- Measles, mumps, rubella vaccine (not previously immunized)
- Meningococcal vaccine (MenACWY or MPSV4 and MenB) recommended if certain risk factors due to health, job or lifestyle).
- Pneumococcal vaccine-one dose each, PCV13 and PPSV23, depending on age and health condition
- Varicella vaccine (one series, not previously immunized)

Changes in the 2016 Adult Immunization Schedule reflect ACIP recommendations summarized: [Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older — United States, 2016](http://www.cdc.gov/mmwr/volumes/65/wr/mm6504a5er.htm)(<http://www.cdc.gov/mmwr/volumes/65/wr/mm6504a5er.htm>).

Primary changes to the immunization schedule include:

- Interval change for 13-valent pneumococcal conjugate vaccine (PCV13) followed by 23-valent pneumococcal polysaccharide vaccine (PPSV23) from "6 to 12 months" to "at least 1 year" for immunocompetent adults aged ≥65 year who do not have immunocompromising conditions, anatomical or functional asplenia, cerebrospinal fluid leak, or cochlear implants ([MMWR 2015;64\[34\]:944–947](#)). The interval for adults aged ≥19 years with any of these conditions is at least 8 weeks.
- Serogroup B meningococcal (MenB) vaccine series should be administered to persons aged ≥10 years who are at increased risk for serogroup B meningococcal disease ([MMWR 2015;64\[22\]:608–612](#)).
- Men B vaccine series may be administered to adolescents and young adults aged 16 through 23 years (preferred age is 16 through 18 years) to provide short-term protection against most strains of serogroup B meningococcal disease ([MMWR 2015;64\[41\]:1171–1176](#)).
- Nine-valent human papillomavirus (HPV) vaccine (9vHPV) has been added to the schedule and can be used for routine vaccination of females and males against HPV ([MMWR 2015;64\[11\]:300–304](#)).

REFERRAL (Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

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Preconception Health Services

DEFINITION:

Preconception health services are beneficial because of their effect on pregnancy and birth outcomes and their role in improving the health of women and men. Preconception describes any time a woman of reproductive potential is not pregnant, but is at risk of becoming pregnant, or any man who is at risk for impregnating his female partner.

Preconception health services for women aim to identify and modify biomedical, behavioral, and social risks to a woman's health or pregnancy outcomes through prevention and management. It promotes the health of women of reproductive age before conception, and thereby helps to reduce pregnancy-related adverse outcomes, such as low birth weight, premature birth, and infant mortality. These services contribute to the improvement of women's health and well-being, regardless of her childbearing intentions.

Recommendations for improving the preconception health of men have been identified, although the evidence is less than that for women. This includes preconception health services that address men as partners in family planning (preventing and achieving pregnancy), their direct contributions to infant health (genetics), and their role in improving the health of women (reduced STD transmission). These services are important for improving the health of men regardless of their pregnancy intention.

All women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid.

REPRODUCTIVE LIFE PLAN

A discussion of a reproductive life plan should be included in preconception health services for both women and men. ACOG recommendations include:

- Each patient visit as an important teachable moment to assess each client's short- and long-term reproductive plans so this is an important opportunity to utilize.
- Engage each patient in supportive, respectful conversation about her pregnancy intentions and provide preconception or contraceptive counseling based on the client's desires and preferences.
- Discuss the range of contraceptive methods and the perceived barriers to contraception, and engage in shared decision making to optimize contraceptive choices with clients who desire to avoid pregnancy

Questions to assess the client's reproductive life plan could be:

- Would you like to become pregnant in the next 12 months?
- Do you have any children now?
- Do you want to have (more) children?
- When would you like to have children?
- How many (more) children would you like to have and when?

MEDICAL HISTORY

Female client's history should include:

- Reproductive history
- History of poor birth outcomes (pre-term, cesarean, miscarriage, stillbirth)
- Environmental exposures, hazards and toxins (smoking, alcohol, and other drugs)
- Medications known to be teratogenic
- Genetic conditions
- Family history

Male client's history should include

- Past medical, and surgical history that might impair his reproductive health (genetic conditions, reproductive failures, obesity, diabetes, varicocele)
- Family history
- Environmental exposures, hazards and toxins (smoking, alcohol, and other drugs)

INTIMATE PARTNER VIOLENCE

Screen all women of childbearing age for intimate partner violence and provide or refer women who screen positive to intervention services. Interventions may include counseling, safety planning, home visits, information cards, and community resources.

ALCOHOL, TOBACCO AND OTHER DRUG USE

All clients should be screened for alcohol, tobacco and other drug use. Recommend behavioral counseling interventions as indicated. Adults who use tobacco products should be provided or referred for tobacco cessation interventions and pharmacotherapy.

IMMUNIZATIONS

<http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-schedule-easy-read.pdf>

Review immunization status for all clients. Offer vaccinations or provide referrals to community providers for age appropriate immunizations, as needed. **Vaccinations are not a Title X funded or required service.**

- HPV (one series, females age 11-26)
- Diphtheria and reduced tetanus toxoids and acellular pertussis vaccine (one-time dose of Tdap for Td booster; then boost with Td every 10 years (once between ages 11-18) Women should get one dTdap vaccine during every pregnancy to protect the baby.
- Hepatitis B vaccine (one series, if not previously immunized)
- Hepatitis A vaccine (one series, if at risk, discuss with healthcare provider)
- Influenza vaccine annually
- Measles, mumps, rubella vaccine (not previously immunized)
- Meningococcal vaccine (MenACWY or MPSV4 and MenB) recommended if certain risk factors due to health, job or lifestyle).
- Pneumococcal vaccine-one dose each, PCV13 and PPSV23, depending on age and health condition
- Varicella vaccine (one series, not previously immunized)

Changes in the 2016 Adult Immunization Schedule reflect ACIP recommendations summarized: [Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older — United States, 2016](http://www.cdc.gov/mmwr/volumes/65/wr/mm6504a5er.htm)(<http://www.cdc.gov/mmwr/volumes/65/wr/mm6504a5er.htm>).

Primary changes to the immunization schedule include:

- Interval change for 13-valent pneumococcal conjugate vaccine (PCV13) followed by 23-valent pneumococcal polysaccharide vaccine (PPSV23) from "6 to 12 months" to "at least 1 year" for immunocompetent adults aged ≥ 65 year who do not have immunocompromising conditions, anatomical or functional asplenia, cerebrospinal fluid leak, or cochlear implants ([MMWR 2015;64\[34\]:944–947](#)). The interval for adults aged ≥ 19 years with any of these conditions is at least 8 weeks.
- Serogroup B meningococcal (MenB) vaccine series should be administered to persons aged ≥ 10 years who are at increased risk for serogroup B meningococcal disease ([MMWR 2015;64\[22\]:608–612](#)).
- Men B vaccine series may be administered to adolescents and young adults aged 16 through 23 years (preferred age is 16 through 18 years) to provide short-term protection against most strains of serogroup B meningococcal disease ([MMWR 2015;64\[41\]:1171–1176](#)).
- Nine-valent human papillomavirus (HPV) vaccine (9vHPV) has been added to the schedule and can be used for routine vaccination of females and males against HPV ([MMWR 2015;64\[11\]:300–304](#)).

DEPRESSION

Screen all clients for depression and refer for counseling as indicated. Emotional health and development are essential when considering when to start or expand a family. A healthy body and mind are important.

Ask this question: Do you often feel sad, anxious, overwhelmed or worried for longer than two weeks? If so, what sorts of things make you feel that way?

HEIGHT, WEIGHT, AND BODY MASS INDEX

Screen all clients for obesity and refer for intensive counseling and behavioral interventions to promote sustained weight loss, as indicated.

BLOOD PRESSURE

Screen all clients for hypertension. Clients with blood pressure less than 120/80 mmHg may be screened every 2 years; and every year if clients have pre-hypertension of 120-139/80-89 mmHg.

DIABETES

Asymptomatic female and male clients who have sustained blood pressure (either treated or untreated) $>135/80$ mmHg should be screened for type 2 diabetes.

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ACOG Committee Opinion, #313. "The Importance of Preconception Care in the Continuum of Women's Health Care." September 2005, Reaffirmed 2015.

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ACOG Committee Opinion #661, “Integrating Immunizations into Practice.” April 2016. <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Integrating-Immunizations-Into-Practice>

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Centers for Disease Control and Prevention. Recommendations to improve preconception health and health care — United States: a report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care. MMWR 2006;55. <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5506a1.htm>

Basic Infertility Services

DEFINITION:

Infertility is defined as a couple unable to conceive after 12 months or longer of regular unprotected intercourse. Primary infertility is when a couple has never conceived. Secondary infertility is when the couple has previously conceived, but now are unable to conceive with 12 months of unprotected intercourse. On average 80-85% of those couples trying to conceive, do become pregnant within 12 months, and 5-10% more couples will conceive in the second year.

Conditions that require earlier assessment, at 6 months, are those women over age 35, women with a history of oligo-amenorrhea, those with known or suspected uterine or tubal disease or endometriosis, or those with a partner known to be subfertile; and immediate evaluation and treatment for women over age 40.

Basic Infertility Services

Sub-recipients must provide basic infertility services to women and men who request such services. Basic infertility services for women and men include initial infertility interview, education, medical history, sexual health assessment and physical examination, and appropriate referral. An established referral system must be in place. Evaluation of both partners should begin at the same time.

Achieving Pregnancy

To help clients who wish to become pregnant, providers should ask the client (or couple) how long she or they have been trying to get pregnant and when she/they hope to become pregnant. If the client's situation does not meet the standard definition of infertility, then she/they may be counseled about how to maximize fertility. Key points to educate clients:

- Peak days and signs of fertility and ovulation, characterized by slippery, stretchy cervical mucus and other signs of ovulation
- If regular menstrual cycles, she should be advised to have vaginal intercourse every 1-2 days beginning soon after the menstrual period ends to increase her pregnancy likelihood
- Discuss methods or devices to determine or predict ovulation timing (over-the-counter-ovulation kits, cycle beads, digital telephone applications)
- Fertility rates are lower among very thin or obese women, and those who consume high levels of caffeine (more than 5 cups/day)
- Discourage smoking, consuming alcohol, using recreational drugs, and using commercially available vaginal lubricants

INFORMED CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include for women:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual history, current medications (complementary and alternative), allergies, and health problems, lifestyle exposures, childhood disorders, results of cervical cancer screening, and family history of reproductive failure
- Reproductive health history: methods of contraception, coital frequency and timing in menstrual cycle, duration of infertility

- Previous pregnancies, outcomes, and associated complications
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Stress
- Detailed menstrual history (age at menarche, cycle length, characteristics, dysmenorrhea), STDs and PID, fertility with other partners
- Duration of unprotected intercourse
- Previous infertility evaluation and treatment, level of fertility awareness
- Assess abuse or neglect

Should include for men:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual history, current medications, allergies, and health problems, lifestyle exposures
- Reproductive health history: methods of contraception, coital frequency and timing, duration of infertility and prior fertility, gonadal toxin exposure (including heat)
- Family medical history
- Female partner's history of PID, STDs, and problems with sexual dysfunction
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression

OBJECTIVE:

For women:

- Height/Weight/BMI
- Blood Pressure
- Thyroid
- Breast
- Pelvic examination
 - Tenderness
 - Organ enlargement or mass
 - Vaginal or cervical abnormality
 - Secretions or discharge
 - Uterine size, shape, position, and mobility
 - Adnexal mass or tenderness
 - Cul-de-sac mass, tenderness or nodularity
- Skin (acne, hirsutism)

For men:

- Height/Weight/BMI
- Blood Pressure
- Genital examination
 - Penis, location of the urethral meatus
 - Palpation of the testes and measurement of their size
 - Presence and consistency of both the vas deferens and epididymis
 - Presence of a varicocele
 - Secondary sex characteristics
 - Digital rectal exam

LABORATORY:

May include:

- CBC, as indicated
- Chlamydia and gonorrhea

ASSESSMENT:

- Inability to conceive after 12 months of unprotected intercourse
- Inability to conceive after 6 months of unprotected intercourse, over age 35
- Inability to conceive, history of oligo-amenorrhea, uterine or tubal disease or endometriosis, or partner known to be subfertile
- Inability to conceive with unprotected intercourse, over age 40

PLAN:

- Discuss fertility and coital timing
- Refer to OB/GYN or infertility specialist for further infertility evaluation (**not Title X funded**)

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented

Information should be client centered, appropriate for the client's age, level of knowledge, language, and socio-cultural background and presented in an unbiased manner

- Preconception services and additional counseling:
 - Ovulation prediction and coital timing
 - Male infertility factors
 - Encourage healthy lifestyle habits in preparation for a healthy pregnancy
 - Avoid alcohol, tobacco, and STD exposure
 - Start folic acid supplementation (0.4-0.8 mg daily) or prenatal vitamins
 - Medicines currently taking (prescription and over the counter)
 - Check immunization status of Rubella, Hepatitis B, Tdap, Varicella, influenza

REFERRAL (Referred services are not Title X funded)

- Refer to OB/GYN physician or infertility specialist for further infertility evaluation

Other possible evaluations or referral for (not Title X funded):

- Serum progesterone
- FSH/LH
- TSH
- Prolactin
- Semen analysis

- Endometrial biopsy
- Transvaginal ultrasound
- Hysterosalpingogram
- Diagnostic laparoscopy

REFERENCES:

ACOG Committee Opinion #589, “Female Age-Related Fertility Decline.” March 2014 (Reaffirmed 2016) <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Female-Age-Related-Fertility-Decline>

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Marcell A. Preventive Male Sexual and Reproductive Health Care: Recommendations for Clinical Practice. Male Training Center for Family Planning & Reproductive Health, 2014. http://www.maletrainingcenter.org/wp-content/uploads/2014/09/MTC_White_Paper_2014_V2.pdf

Pregnancy Testing & Options Counseling

DEFINITION:

An essential family planning service is providing immediate scheduling for pregnancy testing. With early diagnosis, a woman planning to continue her pregnancy can begin healthy habits (if not already doing so) and prenatal medical care during the most vulnerable stages of early fetal development. A woman considering adoption or abortion will have time for adequate counseling and decision making. Early pregnancy diagnosis helps ensure that ectopic pregnancy can be detected early, which reduces the risk of life-threatening complications and increases the likelihood that the affected fallopian tube can be preserved.

Pregnancy testing is one of the most common reasons for a visit to a family planning facility. It is important to use this opportunity as an entry point for providing education and counseling about family planning, such as a discussion of preconception health/reproductive life plan, medical history and coexisting conditions.

INFORMED CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- Current contraceptive method
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

- If negative pregnancy test, no examination needed
- If positive pregnancy test, and unknown LNMP dates, offer a pelvic examination for length of gestation exam and to assess for adnexal tenderness as indicated

LABORATORY:

- High Sensitivity Pregnancy test

ASSESSMENT:

- Negative or Positive Pregnancy

PLAN:

Negative Pregnancy Test

- Assess why client felt the need for a pregnancy test
- Offer contraceptive method, if none is being used
- Prescribe contraceptive method, if client desires, for up to one year
 - Encourage Quick Start Method
- If a contraceptive method is being used, assess if it is being used correctly. Consider changing types of methods or scheduling an appointment with a clinician
- Recommend STD screening using client self-collected vaginal swabs if age 16-25 and asymptomatic
- If bleeding irregularities or amenorrhea, schedule an appointment with the clinician for evaluation
- Women who are not pregnant, but are trying to conceive should be offered services to help achieve pregnancy, as well as preconception health and STD screening services

Positive Pregnancy Test

- Assess if this is a planned pregnancy
- Estimate gestational age if possible (a pelvic exam might be needed)
- Provide appropriate counseling for this pregnancy:
 - Parenting
 - Adoption or Foster Care
 - Termination
- Refer to appropriate providers for follow-up care
- Clients continuing the pregnancy
 - Provide initial prenatal counseling

CLIENT EDUCATION:

All education topics and the client’s understanding of this education must be thoroughly documented

Negative Pregnancy Test

- If contraceptive services are accepted
 - Clients must receive:
 - Information about all types of contraceptive options if they are new or undecided about combined oral contraceptives
 - Information about the chosen contraceptive method including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
 - FDA-approved product information/package insert
 - How to use the method correctly
 - Review common side effects
 - Advise client to contact clinic with questions or concerns *before* stopping a method (unless one of the danger/warning signs listed below)
 - Discuss possible drug interactions
 - Inform other providers of contraceptive method
 - Provide information about danger/warning signs and what to do if any of these symptoms occur including emergency plans and phone numbers

- Contraceptive counseling should explore why she sought a pregnancy test and whether she has difficulties using her current method, if she's using a method
- Provide information about prenatal vitamins, folic acid 0.4 to 0.8 mg daily, proper nutrition, exercise, avoidance of tobacco, alcohol and drugs, recommended pre-pregnancy vaccinations, and healthy lifestyle habits which are important to establish, in case of an unintended conception
- If the client is trying to conceive:
 - Offer services to help achieve pregnancy, as well as preconception health and STD screening services
 - All women planning a pregnancy should be encouraged to take a daily supplement containing 0.4 to 0.8 mg of folic acid
 - If client meets infertility criteria, refer for infertility services

Positive Pregnancy Test

- Give information in a factual, neutral and nondirective fashion:
 - Continue the pregnancy and parent the child
 - Provide information about prenatal care, prenatal vitamins, folic acid 0.8 mg to 1.0 mg daily, proper nutrition, exercise, avoidance of tobacco, alcohol and drugs
 - Review current medications
 - Discourage smoking, alcohol, other drugs, fish with high levels of mercury
 - Offer STD/HIV screening and vaccinations if prenatal care is delayed
 - Continue the pregnancy and considering/planning adoption or fostering
 - Provide information about prenatal care, prenatal vitamins, folic acid 0.8 mg to 1.0 mg daily, proper nutrition, exercise, avoidance of tobacco, alcohol and drugs
 - Provide information about adoption services
 - Terminate the pregnancy
 - Provide information about medical and surgical options
 - If unsure of decision, provide information about all options, reinforce she may return to discuss all information, if still undecided
 - Do not give information about specific options, if the client declines it

REFERRAL (Referred services are not Title X funded)

- To continue the pregnancy, refer to OB for services
 - If preexisting health conditions exist that potentiate prenatal risks, refer for immediate evaluation by OB/GYN physician
- To seek adoption or fostering, refer to available site for services
- To terminate the pregnancy, inform client of available sites for services
- If unsure of decision, refer for counseling services

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

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Estrogen Exposed Offspring

DEFINITION:

As part of the medical history, clients born in the US between 1940 and 1971 (until early 1980s born outside the US) should be asked if their mothers took estrogens during pregnancy to prevent miscarriage. The children (both male and female) of women who received DES or similar hormones during pregnancy may have abnormalities of their reproductive systems or other fertility related risks. Clients prenatally exposed to exogenous estrogens should receive information and special screening either on-site or by referral.

INFORMED CONSENT:

Client must sign a general consent for service prior to receiving services

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- DES exposure in utero (if born between 1940-1980)
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

Females:

- Pelvic examination
 - Vulva
 - Vagina
 - Cervix
 - Bimanual
 - Palpation of cervix and upper vaginal walls

Males:

- Genital examination- Testicles

LABORATORY:

Females:

- Colposcopy at initial pelvic/Pap examination
- Cervical cytology
 - Screen **annually**

Males: none

ASSESSMENT:

- Intrauterine DES exposure

PLAN:

- Discuss clinical findings
- Make appropriate referrals
- Encourage annual return visits, explain importance

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented in their medical record. Education should include the following:

- Contraceptive management may be complicated:
 - IUDs are controversial, due to common structural uterine abnormalities
 - Diaphragms and cervical caps may be difficult to fit, due to common cervical abnormalities
 - Some experts are reluctant to prescribe hormonal contraception, due to unknown safety factors
- Pregnancy complications are possible:
 - Slight increased risk of infertility
 - Possible increased risk of adverse pregnancy outcome
 - Increased risk of first and second trimester spontaneous abortion
 - Increased risk of ectopic pregnancy
 - Increased risk of preterm delivery
- Sons exposed in utero:
 - Are three times more likely to have genital structural abnormalities
 - Epididymal cysts
 - Undescended testes (increased risk of testicular cancer)
 - Small testes (increased risk of testicular cancer)
 - Sperm and semen abnormalities, but not infertility or sexual dysfunction
 - Encourage testicular self-examination
- All women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid

REFERRAL:

(Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

REFERENCES:

ACOG Practice Bulletin #131, "Screening for Cervical Cancer." November 2012, Reaffirmed 2015. <http://www.acog.org/Resources-And-Publications/Practice-Bulletins-List>

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Sexual Assault

DEFINITION:

Sexual assault encompasses a continuum of sexual activity that ranges from sexual coercion to contact abuse to rape and is a crime of violence and aggression. Perpetrators may be female or male, and includes oral, vaginal, and anal penetration, as well as penetration with an object. Vulnerable victims who are incapable of demonstrating consent include those who are intoxicated or otherwise mentally or physically unable to give consent; in these circumstances physical force is not required to meet the definition of rape. Sexual assault and rape are often used interchangeably, and include acquaintance and date rape, statutory rape, child sexual abuse and incest.

Acute traumatic injuries resulting from a sexual assault may be relatively minor, including scratches, bruises, and welts. Some women do sustain fractures, lacerations, head and facial trauma, bullet wounds, or even death. Adult woman rape victims who are at particular risk for injury include those whose perpetrator is a current or former intimate partner, those whose rape occurs in the victim's or perpetrator's home; situations in which the rape is completed or the victim is threatened by a perpetrator with a gun, knife, or other weapon; or when the perpetrator is using alcohol or drugs at the time of the assault.

Consider requesting assistance or referring the client to ensure appropriate evidence collection, if called on to perform a sexual assault examination, and if the staff have little or no experience with the collection. Improper evidence collection, including incorrect handling of samples, contamination, and breaking the chain of custody virtually eliminates the option to prosecute the case. If the victim communicates with the health care provider's office or clinic prior to evaluation, she should be encouraged to immediately go to the medical facility without bathing, changing her clothes, douching, rinsing out her mouth, eating or drinking. Many jurisdictions use a 72-120 hour cutoff time for evidence collection in a sexual assault case.

Acquisition of a sexually-transmitted infection is a concern, including the acquisition of HIV, as the status of the assailant is often unknown or unavailable. Multiple characteristics increase the risk of HIV transmission, including genital or rectal trauma leading to bleeding, multiple traumatic sites involving lacerations or deep abrasions, and the presence of preexisting genital infection or ulcers in the victim.

INFORMED CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse (assault and prior to assault)
- Nutrition assessment and physical activity

- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

- Detailed examination of the entire body (any injuries should be thoroughly described, drawn or photographed)

LABORATORY:

- STD screening: GT/CT, Syphilis, HIV, as indicated
- Wet mount, as indicated
- Pregnancy test, as indicated

ASSESSMENT:

- Sexual Assault
- Possible STD exposure
- Contraceptive need

PLAN:

- Refer for Hepatitis B screening
- Refer for post-exposure hepatitis B vaccination
- Offer prophylactic treatment for chlamydia, gonorrhea, and trichomonas as described in the current CDC Treatment Guidelines
- Evaluate risks and benefits of non-occupational post-exposure prophylaxis for HIV. Refer to Infectious Disease specialty, with understanding that prophylaxis must be initiated within 72 hours of the assault and continued for 28 days, as indicated (**not Title X funded**)
- Offer Emergency Contraception, as indicated
- Discuss contraceptive method, proper use, as indicated
- Refer/recommend to local police department, as indicated
- Refer/recommend to local advocacy services, as indicated

Follow-up

- Test for STDs in 1-2 months
- Test for HIV in 6 weeks, 3 and 6 months
- Contraceptive needs

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented in their medical record. Educational information should include:

- Information about medication being prescribed
- Review common side effects
- Advise client to contact clinic with questions or concerns *before* stopping a medication
- Discuss possible drug interactions and inform other providers of current medication
- Provide information about danger/warning signs with use

- Instruct client that the use of latex condoms is the best way to reduce the risk of infection
- Recommend follow-up in 3 months for testing
- Instruct client about Emergency Contraception use and availability
- All women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid

REFERRAL (Referred services are not Title X funded)

- As indicated by history, physical examination, or lab findings
- As indicated, if treatment fails to resolve infection

REFERENCES:

ACOG Committee Opinion #592, "Sexual Assault." April 2014.

http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Health_Care_for_Underserved_Women/Sexual_Assault

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Family Planning Clinical Protocols

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Chlamydia

STD services should be offered in accordance with the 2015 CDC's STD Treatment Guidelines (a copy and link included with this manual). It is important to annually test young sexually active females for chlamydia and at-risk sexually active females for gonorrhea because of the risk of tubal infertility in women, if left untreated. Syphilis, HIV/AIDS, and hepatitis C testing should be conducted as recommended. Human papillomavirus (HPV) and hepatitis B vaccinations are important parts of STD services and preconception care.

The guidelines also state that individuals with chlamydia and HIV infections should receive the same treatment regimen as those who do not have the HIV infection.

Hepatitis, Sexually Transmitted Diseases and HIV Counseling

All clients must receive thorough and accurate counseling on Hepatitis, STDs and HIV. Counseling refers to an individualized dialogue with a client in whom there is discussion of personal risks for these infections, and steps to be taken by the individual to reduce risk, if necessary. Persons found to have behaviors which currently put them at risk for STDs must be given advice regarding risk, whether or not clinical evaluation is indicated. All sub-recipients must offer, at a minimum, education about Hepatitis, HIV infection and AIDS, information on risks and infection prevention, and referral services. On an optional basis, clinics may provide HIV risk assessment, counseling and testing by specially trained staff. When the sub-recipient does not offer these optional services, they must provide the client with a list of health care providers who can perform these services.

DEFINITION:

Caused by *Chlamydia trachomatis*, this infection is the leading cause of preventable infertility and ectopic pregnancy. Chlamydia is the most common reportable sexually transmitted infectious disease in the US. Widespread screening is necessary, because many Chlamydia infections are asymptomatic and chronic. The CDC recommends annual screening for all sexually active women age 25 and younger. Women and men 25 and older should be screened when there is an increased risk, such as new or multiple partners or prevalence is high.

CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint,
- Client may report possible exposure to partner with Chlamydia
- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations

- Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

- Pelvic examination with bimanual exam
- May visualize vaginal mucopurulent discharge
- May visualize abundance of WBCs on saline wet mount

LABORATORY:

- STD screening of anatomic site of exposure (MSM: NAAT urine testing is preferred for men who have had insertive intercourse during the preceding year; NAAT rectal testing is preferred for men who have had receptive intercourse during the preceding year. Testing for pharyngeal chlamydia infection is not recommended)
- Wet mount, as indicated
- Pregnancy test, as indicated

ASSESSMENT:

- Suspected or proven Chlamydia
- Contraceptive need

PLAN:

- **Notify state or local Department of Public Health of positive test result**
- **See current CDC Treatment Guidelines for treatment and follow-up**
- Discuss contraceptive method, proper use and if method is right for client
- Clients diagnosed with one STD should be offered testing for other STDs (CT/GC, Syphilis, HIV, and Hep C)

Follow-up

- A test of cure is NOT recommended for clients who have uncomplicated Chlamydia and have been treated with any of the recommended or alternative regimens. All clients with Chlamydia should be encouraged to be retested 3 months after treatment. If clients do not seek retesting in 3 months, providers should retest whenever they seek medical care in the following 12 months, regardless of client's belief of partner treatment.

For pregnancy, therapy noncompliance, persistent symptoms despite therapy or a suspicion of reinfection, a test of cure can be done no earlier than 3 weeks after therapy, if using NAAT testing, because of the continued presence of nonviable organisms leading to a false-positive result.

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented

- Clients must receive: Information about medication being prescribed
- Review common side effects
- Advise client to contact clinic with questions or concerns *before* stopping a medication
- Discuss possible drug interactions and inform other providers of current medication
- Provide information about danger/warning signs with use
- Instruct client that partner must be treated, and to avoid sex until 7 days after completed treatment
- Instruct client that the use of latex condoms is the best way to reduce the risk of infection
- Recommend follow-up in 3 months for retesting

- Public Health notification
- Instruct client about Emergency Contraception use and availability
- All women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid

Partner Treatment

- Sex partners of patients with *Chlamydia* should be treated. Patients should be instructed to abstain from sexual intercourse for 7 days after they and their sexual partners have completed treatment and have a resolution of symptoms

An alternative approach to assuring treatment of partners is expedited partner therapy (EPT). In the state of Kansas, partner treatment is potentially allowable: <http://www.cdc.gov/std/ept/legal/>

- EPT is the delivery of medications or prescriptions by persons infected with an STD to their sex partners without clinical assessment of the partners. Clinicians (e.g., physicians, nurse practitioners, physician assistants, pharmacists, public health workers) provide patients with sufficient medications directly or via prescription for the patients and their partners. After evaluating multiple studies involving EPT, [CDC concluded that EPT is a “useful option” to further partner treatment, particularly for male partners of women with chlamydia or gonorrhea](http://www.cdc.gov/std/treatment/eptfinalreport2006.pdf) (<http://www.cdc.gov/std/treatment/eptfinalreport2006.pdf>).

REFERRAL:

(Referred services are not Title X funded)

- As indicated by history, physical examination, or lab findings
- As indicated, if treatment fails to resolve infection

REFERENCES:

ACOG Committee Opinion #641, “Human Papillomavirus Vaccination.” September 2015. <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Adolescent-Health-Care/Human-Papillomavirus-Vaccination>
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Centers for Disease Control & Prevention. Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2015. MMWR 2016: Vol 65. <http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6509a3.pdf>

Centers for Disease Control & Prevention. 2015 Sexually Transmitted Diseases Treatment Guidelines. MMWR June 2015:64 <http://www.cdc.gov/mmwr/pdf/rr/rr6403.pdf>

Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. *Contraceptive Technology*. 20th Revised Edition, 2011.

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Condyloma Acuminata

DEFINITION:

Condyloma Acuminata (genital warts) are typically asymptomatic flat, papular, or pedunculated growths on the genital mucosa. Diagnosis of genital warts is made by visual inspection. If the diagnosis is uncertain, if the lesions do not respond to standard therapy, if the warts worsen during therapy, or are pigmented, indurated, fixed, bleeding, or ulcerated, a biopsy is needed.

Removal of visible genital warts is the goal of treatment. Untreated genital warts may resolve on their own, remain the same, or increase in size and number. Treatment of genital warts may reduce HPV infectivity, but not eliminate it.

Since there is no data regarding re-infection and infectivity, examination of sex partners is not required. Examination would assess the presence of genital warts and other sexually transmitted infections. Female sex partners of patients who have warts should be encouraged to get routine cervical cytology screening, as is recommended for all women over 21 years of age.

CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or updated personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

- Genital examination

LABORATORY:

- STD screening, as indicated
- Wet mount, as indicated
- Pregnancy test, as indicated

ASSESSMENT:

- Condyloma Acuminata
- Contraceptive need

PLAN:

- **See current CDC Treatment Guidelines for treatment and follow-up**
- Discuss contraceptive method, proper use and if method is right for client

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented

- Clients must receive: Information about medication being prescribed
- Review common side effects
- Instruct client to return to the clinic for evaluation if symptoms persist or fail to resolve
- Advise client to contact clinic with questions or concerns *before* stopping a medication
- Discuss possible drug interactions and inform other providers of current medication
- Discuss possible causes and prevention behaviors
- Provide information about danger/warning signs with use
- All women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Instruct client about Emergency Contraception use and availability

REFERRAL:

(Referred services are not Title X funded)

- As indicated by history, physical examination
- As indicated, if treatments fail to resolve condyloma

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

Centers for Disease Control & Prevention. Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2015. MMWR 2016: Vol 65. <http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6509a3.pdf>

Centers for Disease Control & Prevention. 2015 Sexually Transmitted Diseases Treatment Guidelines. MMWR June 2015:64 <http://www.cdc.gov/mmwr/pdf/rr/rr6403.pdf>

Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. *Contraceptive Technology*. 20th Revised Edition, 2011.

Gonorrhea

STD services should be offered in accordance with the 2015 CDC's STD Treatment Guidelines. It is important to annually test young sexually active females aged <25 years and at-risk, sexually active females for gonorrhea because of the risk of tubal infertility in women, if left untreated.

Subgroups of MSM are at high risk of gonorrhea infection and should be screened at sites of exposure. Screening in men and older women who are at low risk of infection is not recommended by the CDC.

Syphilis, HIV/AIDS, and hepatitis C testing should be conducted as recommended. Human papillomavirus (HPV) and hepatitis B vaccinations are important parts of STD services and preconception care.

Hepatitis, Sexually Transmitted Diseases and HIV Counseling

All clients must receive thorough and accurate counseling on Hepatitis, STDs and HIV. Counseling refers to an individualized dialogue with a client in whom there is discussion of personal risks for these infections, and steps to be taken by the individual to reduce risk, if necessary. Persons found to have behaviors which currently put them at risk for STDs must be given advice regarding risk, whether or not clinical evaluation is indicated.

All sub-recipients must offer, at a minimum, education about Hepatitis, HIV infection and AIDS, information on risks and infection prevention, and referral services. On an optional basis, clinics may provide HIV risk assessment, counseling and testing by specially trained staff. When the sub-recipient does not offer these optional services, they must provide the client with a list of health care providers who can perform these services.

DEFINITION:

Neisseria gonorrhoea is the second most commonly reported bacterial sexually transmitted infection. Men will seek evaluation for urethral symptoms, but most often women are asymptomatic. No recognizable symptoms may be present until complications, such as PID, have occurred. Tubal scarring leading to infertility or ectopic pregnancy can result from symptomatic and asymptomatic PID cases. Because of this, annual screening is recommended for all sexually active females 24 years and younger. Subgroups of MSM are at high risk for gonorrhea infection and should be screened at sites of exposure.

Co-infections with Chlamydia are frequently seen with patients infected with gonorrhea, so routine treatment for uncomplicated genital Chlamydia is recommended when gonorrhea is diagnosed. Combination therapy using two antimicrobials with different mechanisms of action to improve treatment efficacy is the theoretical basis for adding azithromycin for the treatment of gonorrhea.

INFORMED CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history

- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

- Women: If pelvic examination is done, may visualize cervical mucopurulent discharge and/or an abundance of WBCs on saline wet mount. Cervical motion tenderness or adnexal tenderness on bimanual examination may be present when there is infection of the upper genital tract (pelvic inflammatory disease).

LABORATORY:

- STD screening of anatomic site of exposure (MSM: NAAT urine testing is preferred for men who have had insertive intercourse during the preceding year; NAAT rectal and pharyngeal testing is preferred for men who have had receptive intercourse during the preceding year)
- Wet mount, as indicated
- Pregnancy testing, as indicated

ASSESSMENT:

- Suspected or proven gonorrhea
- Contraceptive need

PLAN:

- **Notify state or local Department of Public Health of positive test result**
- **See current CDC Treatment Guidelines for treatment and follow-up**
- Discuss contraceptive method, proper use and if method is right for client
- Clients diagnosed with one STD should be offered testing for other STDs (CT/GC, Syphilis, HIV, and Hep C)

Gonorrhea's Building Antibiotic Resistance

The CDC recently reported Gonorrhea may be developing resistance to the antibiotics that can cure it. CDC's report highlights that prevention of Gonorrhea transmission remains the best strategy for reducing Gonorrhea incidence and morbidity. MMWR Surveill Summ 2016;65 (No. SS-7):1–19. <http://www.cdc.gov/mmwr/volumes/65/ss/ss6507a1.htm>.

PARTNER TREATMENT

Sex partners of patients with *gonorrhea* should be treated. Every effort should be made to ensure that the patient's sex partners from the preceding 60 days are evaluated and treated for gonorrhea with a recommended regimen. Patients should be instructed to abstain from sexual intercourse for 7 days after they and their sexual partners have completed treatment and after they have a resolution of symptoms.

An alternative approach to assuring treatment of partners is expedited partner therapy (EPT). In the state of Kansas, partner treatment is potentially allowable: <http://www.cdc.gov/std/ept/legal/>

EPT is the delivery of medications or prescriptions by persons infected with an STD to their sex partners without clinical assessment of the partners. Clinicians (e.g., physicians, nurse practitioners, physician assistants, pharmacists, public health workers) provide patients with sufficient medications directly or via prescription for the patients and their partners. After evaluating multiple studies involving EPT, CDC concluded that EPT is a “useful option” to further partner treatment, particularly for male partners of women with chlamydia or gonorrhea <http://www.cdc.gov/std/treatment/eptfinalreport2006.pdf>

FOLLOW-UP

A test-of-cure is NOT recommended for clients who have uncomplicated urogenital or rectal gonorrhea and have been treated with the recommended or alternative regimens, however, any person with pharyngeal gonorrhea who is treated with an alternative regimen should return 14 days after treatment for a test-of-cure using either culture or NAAT. All clients with gonorrhea should be encouraged to be retested 3 months after treatment. If clients do not seek retesting in 3 months, providers should retest whenever they seek medical care in the following 12 months, regardless of client's belief of partner treatment.

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented

- Clients must receive: Information about medication being prescribed
- Review common side effects
- Advise client to contact clinic with questions or concerns *before* stopping a medication
- Discuss possible drug interactions and inform other providers of current medication
- Provide information about danger/warning signs with use
- Instruct client that partner must be treated, avoid sex until 7 days after completed treatment
- Instruct client that the use of latex condoms is the best way to reduce the risk of infection
- Recommend follow-up in 3 months for retesting
- Public Health notification
- All women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Instruct client about Emergency Contraception use and availability

REFERRAL:

(Referred services are not Title X funded)

- As indicated by history, physical examination, or lab findings
- As indicated, if treatments fail to resolve infection

REFERENCES:

ACOG Committee Opinion, #632, “Expedited Partner Therapy in the Management of Gonorrhea and Chlamydial Infection.” June 2015. <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Gynecologic-Practice/co632.pdf?la=en>

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63.<https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

Centers for Disease Control & Prevention. Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2015. MMWR 2016: Vol 65. <http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6509a3.pdf>

Centers for Disease Control & Prevention. 2015 Sexually Transmitted Diseases Treatment Guidelines. MMWR June 2015:64 <http://www.cdc.gov/mmwr/pdf/rr/rr6403.pdf>
Centers for Disease Control & Prevention. Legal Status of Expedited Partner Therapy (EPT). Last update March 2016. <http://www.cdc.gov/std/ept/legal/>

Centers for Disease Control. Update to CDC's sexually transmitted diseases treatment guidelines, 2010: oral cephalosporins no longer a recommended treatment for gonococcal infections. MMWR 2012:61 (31). <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6131a3.htm>

Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. *Contraceptive Technology*. 20th Revised Edition, 2011.

Kirkcaldy RD, Harvey A, Papp JR, et al. *Neisseria gonorrhoeae* Antimicrobial Susceptibility Surveillance — The Gonococcal Isolate Surveillance Project, 27 Sites, United States, 2014. MMWR Surveill Summ 2016;65(No. SS-7):1–19.
<http://www.cdc.gov/mmwr/volumes/65/ss/ss6507a1.htm>

Herpes Simplex Virus

DEFINITION:

HSV-1 and HSV-2 are the two types of herpes virus identified. Genital herpes is a chronic, life-long viral infection. The majority of cases of recurrent genital herpes are caused by HSV-2 although HSV-1 might become more common as a cause of first episode genital herpes. At least 50 million people in the United States have genital HSV infection, but the majority of people with HSV-2 have not been diagnosed with genital herpes. Many of these persons have mild or unrecognized infections that shed virus intermittently in the genital tract. The majority of genital herpes infections are transmitted by others who are unaware that they have the infection or who are asymptomatic when transmission occurs.

DIAGNOSTIC CONSIDERATIONS:

Clinical diagnosis of HSV is both insensitive (sensitivity of 80-98%) and nonspecific. The typical ulcerative lesion or multiple painful vesicles are not present in all infected people. HSV-1 accounts for up to 50% of first episode cases of genital herpes, and recurrences and subclinical shedding are less frequent than in HSV-2 infections. For clients who seek medical evaluation for genital ulcers, a cell culture to isolate the HSV is the preferred virology test.

Type-specific HSV serology (IgG) assays might be helpful in the following situations:

- 1). Atypical symptoms of recurrent genital symptoms, with negative HSV cultures;
- 2). A clinical diagnosis of genital herpes without laboratory confirmation; and
- 3). A partner with genital herpes. *Screening for HSV-1 or HSV-2 in the general population is not indicated, and is not recommended by the CDC.*

Suppressive therapy reduces the frequency of genital herpes recurrences and decreases the risk of genital HSV-2 transmission to a susceptible partner.

INFORMED CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

- Genital examination

LABORATORY:

- STD Screening, as indicated
- HSV lesion culture (preferred virology test) **(not Title X funded) OR**
- HSV lesion polymerase chain reaction test **(not Title X funded) OR**
- HSV type specific serology (IgG) test **(not Title X funded)**

ASSESSMENT:

- Genital lesions, possible/probable/proven herpes simplex virus
- Contraceptive needs

PLAN:**(Testing and Treatment is Not Title X funded funded)**

- **See current CDC Treatment Guidelines for treatment and follow-up**
- Discuss contraceptive method, proper use and if method is right for client
- Clients diagnosed with one STD should be offered testing for other STDs (CT/GC, Syphilis, HIV, and Hep C)

CLIENT EDUCATION:**All education topics and the client's understanding of this education must be thoroughly documented**

- Clients must receive: Information about medication being prescribed
 - Review common side effects
 - Advise client to contact clinic with questions or concerns *before* stopping a medication
 - Discuss possible drug interactions and inform other providers of current medication
 - Provide information about danger/warning signs with use
- Provide counseling about HSV infections:
 - Potential recurrent episodes, asymptomatic viral shedding, risk of transmission
 - Possible treatment options, especially suppressive therapy to reduce asymptomatic viral shedding
 - Discussing with current sexual partner and future partners before initiating a sexual relationship
 - Remain abstinent when lesions or prodromal symptoms are present
- Instruct client that the use of latex condoms is the best way to reduce the risk of infection
 - Active infections during pregnancy, use of suppressive therapy in last month of pregnancy
 - Self care, keeping lesions clean and dry
 - Topical therapy with antiviral drugs is discouraged, due to their minimal clinical benefit
- All women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Instruct client about Emergency Contraception use and availability

REFERRAL:**(Referred services are not Title X funded)**

- As indicated by history, physical examination, or lab findings
- As indicated, if treatments fail, if infection severe or wide-spread

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

Centers for Disease Control & Prevention. Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2015. MMWR 2016: Vol 65. <http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6509a3.pdf>

Centers for Disease Control & Prevention. 2015 Sexually Transmitted Diseases Treatment Guidelines. MMWR June 2015:64 <http://www.cdc.gov/mmwr/pdf/rr/rr6403.pdf>

Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. *Contraceptive Technology*. 20th Revised Edition, 2011.

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Human Immunodeficiency Virus

STD services should be offered in accordance with the 2015 CDC's STD Treatment Guidelines. It is important to annually test young sexually active females for chlamydia and at-risk sexually active females for gonorrhea because of the risk of tubal infertility in women, if left untreated. Syphilis, HIV/AIDS, and hepatitis C testing should be conducted as recommended. Human papillomavirus (HPV) and hepatitis B vaccinations are important parts of STD services and preconception care.

Hepatitis, Sexually Transmitted Diseases and HIV Counseling

All clients must receive thorough and accurate counseling on Hepatitis, STDs and HIV. Counseling refers to an individualized dialogue with a client in whom there is discussion of personal risks for these infections, and steps to be taken by the individual to reduce risk, if necessary. Persons found to have behaviors which currently put them at risk for STDs must be given advice regarding risk, whether or not clinical evaluation is indicated. All sub-recipients must offer, at a minimum, education about Hepatitis, HIV infection and AIDS, information on risks and infection prevention, and referral services. On an optional basis, clinics may provide HIV risk assessment, counseling and testing by specially trained staff. When the sub-recipient does not offer these optional services, they must provide the client with a list of health care providers who can perform these services.

DEFINITION:

Human Immunodeficiency Virus is a virus that can lead to acquired immunodeficiency syndrome, or AIDS. It spreads through contact with body fluids and affects cells of the immune system, the CD4 cells, or T cells. Over time, HIV can destroy so many of these cells that the body can't fight off infections and disease. When this happens, HIV infection leads to AIDS. Unlike other viruses, the human body cannot get rid of HIV. In the United States, HIV is spread mainly by having sex with or sharing drug injection equipment with someone who is infected with HIV. HIV cannot be spread by casual contact such as hugging or shaking hands. One in five people with HIV are unaware of their infection. The CDC recommends testing everyone between the ages of 13 - 64 (USPSTF recommends age 15 - 65) at least once in their life and that high-risk groups get tested more often. CDC has recently reported that gay and bisexual men may benefit from getting an HIV test more often, perhaps every 3-6 months. Younger adolescents and older adults who are at increased risk should be screened. All pregnant women should be screened for HIV with their routine prenatal tests.

INFORMED CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

A separate written consent solely for the purpose of HIV testing **is not** required. State laws (IA Code 139A.35) dictate that minors must give written consent for HIV testing and treatment services, and they understand that their legal guardian will be notified if the test is confirmed as positive, **“however a testing facility which is precluded by federal statute, regulation, or centers for disease control and prevention guidelines from informing the legal guardian is exempt from the notification requirement.** The minor shall give written consent to these procedures and to receive the services, screening, or treatment. Such consent is not subject to later disaffirmance by reason of minority.”

Delegates can perform HIV preliminary or rapid testing within each clinic site or may recommend another agency. Contracts with an outside laboratory for confirmatory blood testing after a positive screening test should be in place.

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
 - All clients who seek screening for other STDs and have risk factors
 - All clients who seek treatment for other STDs should be offered screening for HIV
 - All clients who report or are suspected to have behavioral risks for HIV should be offered HIV screening
- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

- Exam, as indicated

LABORATORY:

- HIV screening **OR**
- HIV positive screening test, needs confirmatory HIV test

Opt-Out Testing in Kansas

In 2006, the CDC released its Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>)

These recommendations advise providers in healthcare settings to:

- Adopt a policy of routine HIV testing for everyone between the ages of **13-64** and all **pregnant women**
- Use *opt-out screening* for HIV—meaning that HIV tests will be done routinely unless a patient explicitly refuses to take an HIV test
- Eliminate the requirements for pretest counseling, *informed consent*, and post-test counseling

“Opt-out testing” does not mean that you **MUST** take an HIV test. **In general, you have the right to refuse an HIV test.** (Exceptions include blood and organ donors, military applicants and active duty personnel, Federal and state prison inmates under certain circumstances, newborns in some states, and immigrants.) See also: The center for HIV Law and Policy. <http://www.hivlawandpolicy.org/states/kansas>

The CDC believes that opt-out screening for HIV:

- Will help more people find out if they have HIV
- Will help those infected with HIV find out earlier, when treatment works best
- Can further decrease the number of babies born with HIV

- Can reduce stigma associated with HIV testing
- Will enable those who are infected to take steps to protect the health of their partners

Kansas Services Sites for STI testing are listed on the KDHE website:

Guide to STI Service in Kansas. Then go to menu on left side of page. Prevention/Counseling and Testing/STI Test Sites (underlined link in blue near bottom of page provides list by county).

http://www.kdheks.gov/sti_hiv/sti_services.htm

ASSESSMENT:

- HIV screening
- Positive HIV screening, HIV confirmatory test
- STD positive test results
- High risk behaviors or possible exposure to HIV
 - Injection drug users and their partners
 - Sex workers
 - Sex partners of HIV-infected persons
 - Men who have sex with men (MSM)
 - Client or their partner has had more than one sex partner since their most recent HIV test
- Contraceptive need

PLAN:

Although HIV results may be delivered over the phone, it is recommended that results be provided in person.

Delivering negative rapid/preliminary results:

- Explain the meaning of negative test results (absence of HIV antibodies)
- Explain the limitations of the test and the “testing window” and the importance of re-testing high risk individuals
- Instruct prevention measures, risk reduction and negotiating risk reduction

Delivering positive rapid/preliminary results:

You may want to notify your Kansas Disease Prevention Specialist of the positive preliminary result. This is not mandatory at this point.

Explain and emphasize:

- The meaning of the positive preliminary results
- The need for confirmatory testing, draw specimen at that time if possible
- The test screens for HIV antibodies, not the virus itself
- The need for confirmatory test to rule out a false positive result
- HIV is a treatable, manageable chronic illness
- Medical treatment is available to limit harmful activity of HIV and the conversion to AIDS
- Many people live long productive lives on antiretroviral therapy
- The importance of practicing safe sex and needle use
- Identify and discuss the client's concerns
- Assess how client is coping with the result
- Assess for risk of suicide and homicide given positive test result
- Assist client to create a 24 hour plan, having a support person, or immediate mental health/counseling referral if necessary
- Make a follow-up appointment to deliver HIV confirmatory results

Delivering positive confirmatory results:**Notify state or local Department of Public Health of positive result**

When delivering positive test results, you may want to involve your local or state Disease Prevention Specialist (DPS) to assist with delivering results and offering other referral information.

Emphasize:

- A positive result does NOT indicate an AIDS diagnosis or a “death sentence”
- HIV is a treatable, manageable chronic illness
- Medical treatment is available to limit harmful activity of HIV and the conversion to AIDS
- Many people live long productive lives on antiretroviral therapy
- The importance of practicing safe sex and needle use to avoid transmitting the virus to others
- Identify and discuss the client’s concerns
- Discuss partner notification options
- Assess how client is coping with the result
- Assess for risk of suicide and homicide given positive test result
- Make the referral appointment with an HIV disease specialty care provider

Once a referral is made, follow up is imperative to make sure the client was seen for HIV medical care, treatment and follow up testing. Assistance with scheduling appointments, transportation, child care or other personal concerns should be addressed. Information from the client’s referred provider regarding the client’s evaluation and treatment is expected and should be documented in the client’s medical record. Follow up must be done to make sure the client has had every opportunity to receive medical care for a positive HIV result.

Staff members who deliver HIV test results must have a comprehensive directory of providers, agencies and programs to which clients are referred. In addition to referring clients to primary and specialty HIV medical care, they also may need referrals to the following types of services:

- HIV information lines
- HIV Drug Assistance Programs (HDAP)
- HIV counseling and testing sites
- HIV/AIDS service organizations
- State and city HIV/AIDS programs
- HIV partner services (Partner Counseling and Referral Services)
- Substance abuse treatment programs
- Mental health services
- Domestic violence services
- Clients diagnosed with one STD should be offered testing for other STDs (CT/GC, Syphilis)
- Hepatitis screening and treatment programs
- TB testing services
- Emergency assistance programs (food, shelter)
- Other services (e.g. health insurance, legal services, housing and employment programs)
- Discuss contraceptive methods, proper use and methods that are right for a client with HIV

Partner Notification

- Sexual Partners
- People who have shared equipment for injected drugs

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented

Instruct the client:

- Limit the number of sexual partners
- Never share needles
- Always use condoms correctly and consistently
- Avoid lubricants containing nonoxynol-9 (they can irritate the lining of the vagina or anus and increase the risk of getting HIV)
- Encourage the partner to be tested and treated if HIV positive
- Antiretroviral therapy (ART) reduces the amount of virus (viral load) in the blood and body fluids. ART can dramatically improve health and extend life, but there are also prevention benefits to treatment: clients who have an undetectable viral load are much less likely to infect others through sex or sharing needles. However, the risk of spreading infection is still not zero, which means they should still use other prevention methods, such as condoms
- If clients are taking ART, stress the importance of following their health care provider's advice, staying in care and always taking their medicine as directed
- Partners may benefit from [pre-exposure prophylaxis](#) (PrEP), daily medicine to prevent HIV for people at ongoing risk, or [post-exposure prophylaxis](#) (PEP), a 4-week course of medicine to prevent HIV after possible exposure during a single event
- Public Health notification
- All women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid

REFERRAL:

(Referred services are not Title X funded)

- As indicated by history, physical examination, or lab findings

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ACOG Committee Opinion, #536, "Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome and Women of Color." September 2012. <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Human-Immunodeficiency-Virus-and-Acquired-Immunodeficiency-Syndrome-and-Women-of-Color>

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ACOG Practice Bulletin, #117, "Gynecologic Care for Women with Human Immunodeficiency Virus." December 2010, Reaffirmed 2015. <http://www.acog.org/~media/Practice%20Bulletins/Committee%20on%20Practice%20Bulletins%20--%20Gynecology/Public/pb117.pdf?dmc=1>

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Centers for Disease Control & Prevention Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>)

Pediculosis Pubis (Pubic Lice)

DEFINITION:

Also known as “crabs”, Pediculosis is a parasite infection about the size of a pinhead that must have a host to live. Thousands of types of lice exist, some of which are head and body lice. Pubic lice are visible to the naked eye and are attached to the coarse hair follicles found in the pubic area, beard, chest or armpits. Pubic lice are characteristically different than head or body lice. Pubic lice have three pairs of legs on either side of the rounded body. The female lifespan is about 3 weeks, where she produces about 3 eggs per day. The eggs or “nits” attach to the base of the pubic hair shaft for approximately six to eight days before hatching.

Pubic lice are transmitted by close, intimate, physical contact, and from contaminated belongings such as towels, sheets or clothing. Lice do not jump or fly, and cats, dogs and other pets do not spread human lice from one person to another. The main symptoms of pubic lice are itching and burning of the pubic area, and many report the itching is worse at night. Intense or prolonged scratching may lead to skin breakdown and a secondary bacterial infection.

INFORMED CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

- Inspection of skin and coarse hair follicles of pubis, chest, axillae, beard
- Visible parasites and/or nits on hair follicles

LABORATORY:

- STD screening, as indicated

ASSESSMENT:

- Pediculosis Pubis
- Contraceptive need

PLAN:**(Not Title X funded)**

- **See current CDC guidelines for treatment and follow-up**
- Discuss contraceptive method, proper use and if method is right for client

CLIENT EDUCATION:**All education topics and the client's understanding of this education must be thoroughly documented**

- Clients must receive: Information about medication being prescribed
- Review common side effects
- Advise client to contact clinic with questions or concerns *before* stopping a medication
- Discuss possible drug interactions and inform other providers of current medication
- Provide information about danger/warning signs with use
- Instruct client that partner must be treated
- Instruct client that all linen, pillows, towels, clothing must be cleaned thoroughly, but fumigation of living areas is not necessary
- All women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Instruct client about Emergency Contraception use and availability

REFERRAL:**(Referred services are not Title X funded)**

- As indicated by history, physical examination, or lab findings
- As indicated, if treatment fails to resolve infection

REFERENCES:

Centers for Disease Control & Prevention. Parasites-Lice- Pubic "Crab" Lice: Treatment. September 2015. <http://www.cdc.gov/parasites/lice/pubic/treatment.html>

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Syphilis

STD services should be offered in accordance with the 2015 CDC's STD Treatment Guidelines. It is important to annually test young sexually active females for chlamydia and at-risk sexually active females for gonorrhea because of the risk of tubal infertility in women, if left untreated.

Syphilis, HIV/AIDS, and hepatitis C testing should be conducted as recommended. Human papillomavirus (HPV) and hepatitis B vaccinations are important parts of STD services and preconception care.

Hepatitis, Sexually Transmitted Diseases and HIV Counseling

All clients must receive thorough and accurate counseling on Hepatitis, STDs and HIV. Counseling refers to an individualized dialogue with a client in whom there is discussion of personal risks for these infections, and steps to be taken by the individual to reduce risk, if necessary. Persons found to have behaviors which currently put them at risk for STDs must be given advice regarding risk, whether or not clinical evaluation is indicated.

All sub-recipients must offer, at a minimum, education about Hepatitis, HIV infection and AIDS, information on risks and infection prevention, and referral services. On an optional basis, clinics may provide HIV risk assessment, counseling and testing by specially trained staff. When the sub-recipient does not offer these optional services, they must provide the client with a list of health care providers who can perform these services.

DEFINITION:

Syphilis is a systemic disease caused by *T. pallidum*. Primary infections may present as an ulcer or chancre at the infection site, whereas, secondary infections may include skin rash, mucocutaneous lesions, and lymphadenopathy, and tertiary infections may include cardiac, ophthalmic, or auditory abnormalities, or gummatous lesions. Latent infections are those without clinical signs and are detected by serologic testing.

DIAGNOSTIC CONSIDERATIONS:

A presumptive diagnosis is possible with two types of serology tests: nontreponemal (VDRL and RPR) and treponemal (fluorescent treponemal antibody absorbed and *T. pallidum* particle agglutination). Only one type of serologic test is insufficient for diagnosis as false-positive nontreponemal test results may be caused by various medical conditions unrelated to syphilis.

Antibody titers with a nontreponemal test can correlate disease activity with quantitative results. A fourfold change in titer is needed to demonstrate a clinically significant difference between two nontreponemal test results that were obtained using the same serologic test. The same test method and same laboratory should be used for sequential serologic testing.

INFORMED CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems

- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

- Exam, as indicated

LABORATORY:

- Syphilis Screening test (VDRL, RPR, IgG, TP-PA, FTA or EIA/CLIA, depending on the lab used)
- STD screening, as indicated
- HIV screening, if not already done
- Pregnancy testing, as indicated

ASSESSMENT:

- Suspect or proven syphilis
- Contraceptive need

PLAN:

- **Notify state or local Department of Public Health of positive test result**
- **See current CDC Treatment Guidelines for treatment and follow-up**
- **Refer if any neurologic symptoms, HIV positive or PCN allergy, and for follow-up of treatment for positive results (Not a Title X funded service)**
- Discuss contraceptive method, proper use and if method is right for client
- Clients diagnosed with one STD should be offered testing for other STDs (CT/GC, Syphilis, HIV, and Hep C)

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented

- Clients must receive: Information about medication being prescribed
- Provide counseling about syphilis infection
 - Proper follow-up at 6 and 12 months for nontreponemal test titers
- Review common side effects
- Advise client to contact clinic with questions or concerns *before* stopping a medication
- Discuss possible drug interactions and inform other providers of current medication
- Provide information about danger/warning signs with use
- Instruct client that the use of latex condoms is the best way to reduce the risk of infection
- Instruct client that exposed partners within, and more than the last 90 days must be tested and treated
- Public Health notification
- All women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid

- Instruct client about Emergency Contraception use and availability

REFERRAL:

(Referred services are not Title X funded)

- As indicated by history, physical examination, or lab findings
- As indicated, if treatment fail to resolve infection

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

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Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart F, Kowal D, Policar M. *Contraceptive Technology*. 20th Revised Edition, 2011.

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Urinary Tract Infection

DEFINITION:

Cystitis and urethritis (infections of the bladder and urethra) are usually caused by *Escherichia coli*, commonly found in the gastrointestinal tract. Sexual intercourse may lead to cystitis. All women are susceptible to cystitis because of their anatomy — specifically, the close proximity of the urethra to the anus and the short distance from the urethral opening to the bladder. In addition, because of the female urethra's proximity to the vagina, sexually transmitted infections (STDs), such as herpes, gonorrhea and Chlamydia, also are possible causes of urethritis.

DIAGNOSTIC CONSIDERATIONS:

Symptoms may include: a strong, persistent urge to urinate; a burning sensation when urinating; passing frequent, small amounts of urine; urine that appears cloudy, bright pink or cola colored; strong, foul-smelling urine; pelvic pain, in women; or rectal pain, in men. Untreated urinary tract infections can lead to acute or chronic pyelonephritis, which could permanently damage kidneys.

INFORMED CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

- Examination, as indicated
- Urine dipstick (high pH or protein; positive nitrites, leukocytes or blood)
- Assess for flank pain
- Assess for fever

LABORATORY:

- Urine dipstick
- STD screening, as indicated
- Wet mount, as indicated
- Pregnancy test, as indicated
- Urine culture, as indicated

ASSESSMENT:

- Urinary Tract Infection or Cystitis
- Contraceptive need

PLAN:

Considerations in selecting an agent for treatment of acute cystitis include efficacy, risk of adverse effects, resistance rates, cost, and drug availability. The treatment options below and suggested treatment durations (ACOG 2014) for acute uncomplicated cystitis are the same for any adult woman with acute uncomplicated cystitis, regardless of age:

- Trimethoprim-sulfamethoxazole (TMP-SMX) one double strength tablet [160/800 mg] twice daily for 3 days).
- Ciprofloxacin (250 mg orally twice daily for 3 days)
- Levofloxacin (250 mg orally once daily for 3 days)
- Norfloxacin (400 mg, twice daily for 3 days)
- Gatifloxacin (200 mg once daily for 3 days)
- Nitrofurantoin macrocrystals (50-100 mg four times daily for 7 days)
- Nitrofurantoin monohydrate macrocrystals (100 mg twice a day for 7 days)
- Foxfomycin trometamine (3g dose (powder) single dose

Although fluoroquinolones (ciprofloxacin, levofloxacin, ofloxacin in 3-day regimens) are very effective for treatment of acute cystitis, increased resistance is mitigating the usefulness of the fluoroquinolone class. In addition, in the United States, the FDA has stated that risks of systemic fluoroquinolone antibacterial drugs outweigh their benefits for uncomplicated UTI.

<http://www.fda.gov/Drugs/DrugSafety/ucm500143.htm>

For more information see <http://www.acog.org/Resources-And-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Treatment-of-Urinary-Tract-Infections-in-Nonpregnant-Women>

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented

- Clients must receive: Information about medication being prescribed
- Emphasize antibiotic course completion importance
- Review common side effects
- Advise client to contact clinic with questions or concerns *before* stopping a medication
- Discuss possible drug interactions and inform other providers
- Provide information about danger/warning signs
- Instruct importance of increasing water intake
- Instruct on proper hygiene, and frequency of emptying bladder especially after coitus
- All women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Instruct client about Emergency Contraception use and availability

REFERRAL:

(Referred services are not Title X funded)

- As indicated by history, physical examination, or lab findings
- As indicated, if treatment fail to resolve infection

REFERENCES:

ACOG Practice Bulletin, #91. "Treatment of Urinary Tract Infections in Nonpregnant Women" March 2008, Reaffirmed 2014. <http://www.acog.org/Resources-And-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Treatment-of-Urinary-Tract-Infections-in-Nonpregnant-Women>

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Centers for Disease Control & Prevention. "Get Smart: Know when Antibiotics Work –Urinary Tract Infections." April 2015. <http://www.cdc.gov/getsmart/community/for-patients/common-illnesses/uti.html>

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Vaginal Discharge

DEFINITION:

Women will most likely have a vaginal infection at some point in their lives, characterized by vaginal discharge, itching, or odor. A careful history, examination and laboratory testing are essential, since the medical history alone has been shown to be inaccurate for diagnosing vaginitis. The three infections most frequently associated with vaginal discharge are bacterial vaginosis, trichomoniasis, and candidiasis.

DIAGNOSTIC CONSIDERATIONS:

Various diagnostic methods and laboratory tests are available to identify the causes of vaginitis. In the office, samples of vaginal discharge can be used to determine vaginal pH, amine or “whiff” test, and the use of the potassium hydroxide (KOH) and saline test for microscopic examination. In reproductive-aged women, vaginal secretions normally have a pH of 3.8 to 4.5. Vaginal pH higher than 4.5 is common with BV or Trichomoniasis. Because pH testing is not specific, the discharge must be examined microscopically using 0.9% normal saline (NS) and 10% potassium hydroxide (KOH). The NS solution might yield motile trichomonads or clue cells. The KOH solution typically will identify yeast or pseudohyphae of *Candida*. The absence of trichomonads or pseudohyphae in KOH samples does not rule out these infections, however, because the sensitivity of microscopy is about 50% compared with NAAT (Trichomoniasis) or culture (yeast). Alternative clinical laboratory testing can be used to diagnose vaginitis when pH paper, KOH, and microscopy are not available.

Bacterial vaginosis (BV): Several species of vaginal bacteria replace normal lactobacillus species, which may cause excessive, malodorous vaginal discharge. The cause of microbial alteration is not fully understood. BV is associated with having multiple male or female sex partners, a new sex partner, douching, and a lack of vaginal lactobacilli. It is unclear whether BV is acquired from a sexually transmitted pathogen. It is not beneficial to treat male sex partners to prevent the recurrence. Clinical criteria require three of the following symptoms or signs for positive diagnosis: homogeneous, thin, white discharge that smoothly coats the vaginal walls; clue cells on microscopic examination; pH of vaginal fluid >4.5; or a fishy odor of vaginal discharge before or after addition of 10% KOH.

Trichomoniasis is a common sexually transmitted disease caused by a motile protozoan with an undulating membrane and four flagella. Symptoms may include excessive, frothy, yellow-green vaginal discharge with erythema, edema, and pruritus of the external genitalia. This may be accompanied by dysuria and dyspareunia in women, although, some women are asymptomatic. Men may develop urethritis, epididymitis, or prostatitis, but the majority of males are asymptomatic. Diagnosis can be made several ways for women: NAAT testing, wet-mount microscopy, RNA detecting assay, culture, and point of care tests for antigen-detection or DNA hybridization. Culture specimens are used for men from a urethral swab, urine sediment and/or semen. Retesting is recommended for all sexually active women within 3 months following initial treatment.

Candida: *C. albicans* is the usual species causing vaginal candidiasis; these are dimorphic fungi that grow as budding oval yeast cells and as chains of cells called hyphae. Symptoms may include thick white vaginal discharge and erythema, edema, and pruritus of the external genitalia, dyspareunia, or external dysuria. Diagnosis can be made in women who have signs and symptoms of vaginitis when either a wet prep or Gram stain of vaginal discharge demonstrates budding yeasts, hyphae or pseudohyphae; or a culture or other test yields a positive result for a yeast species.

Cervicitis: The presence of white blood cells (WBCs) without evidence of trichomonads or yeast in saline solution is suggestive of cervicitis.

INFORMED CONSENT:

Must be obtained prior to receiving services

- Clients must sign: General Consent for Service

SUBJECTIVE:

Should include:

- Reason for visit or chief complaint
- Complete or update personal medical and surgical history, including sexual and reproductive health history, current medications (complementary and alternative), allergies, and health problems
- Family medical history
- LNMP and last unprotected intercourse
- Nutrition assessment and physical activity
- Preconception health services
 - Reproductive Life Plan
 - Intimate Partner Violence
 - Alcohol and Other Drug Use
 - Tobacco Use
 - Immunizations
 - Depression
- Assess abuse or neglect
- Current contraceptive method

OBJECTIVE:

- Pelvic examination

LABORATORY:

- Wet Mount, Gram Stain or Vaginal Culture, as indicated
- KOH whiff test, as indicated
- Vaginal pH, as indicated
- STD screening, as indicated
- Pregnancy testing, as indicated

ASSESSMENT:

- Bacterial Vaginosis, Candidiasis, or Trichomoniasis
- Contraceptive need

PLAN:

- See current CDC Treatment Guidelines for treatment and follow-up
- Discuss contraceptive method, proper use and if method is right for client

CLIENT EDUCATION:

All education topics and the client's understanding of this education must be thoroughly documented

- Clients must receive: Information about medication being prescribed
- Review common side effects
- Advise client to contact clinic with questions or concerns *before* stopping a medication
- Discuss possible drug interactions and inform other providers of current medication
- Provide information about danger/warning signs with use

- All women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid
- Instruct client about Emergency Contraception use and availability

REFERRAL:

(Referred services are not Title X funded)

- As indicated by history, physical examination, or lab findings
- As indicated, if treatments fail to resolve infection

REFERENCES:

Centers for Disease Control & Prevention. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014;63. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

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