CLINICAL MANUAL

APRIL 2022

Signature Page

CLINICAL MANUAL REVIEW
Signature Page

The Family Planning Clinical Manual must be reviewed and signed annually by Physicians, Nurse Practitioners, Certified Nurse Midwives, Physician Assistants, Registered Nurses, Medical Assistants and Clinic Assistants providing clinical services in the Title X Family Planning Programs. Signature pages must be available for review during clinical site visits. Agencies with multiple sites should keep a copy of the signature page at each site or in the agency's local online drive.

The April 2021 version of the Title X Family Planning Program Clinical Manual includes the most recent Title X regulations from May 2019. This recent version has been reviewed, discussed, and found appropriate for provision of care by the Nurse Practitioners, Certified Nurse Midwives, Physician Assistants, Registered Nurses, and Physicians listed below, for clients in the Title X Family Planning Program funded through Converge.
The local agency consulting Physician authorizes the use of the Title X Family Planning Clinical Manual for Nurse Practitioners, Certified Nurse Midwives, Physician Assistants, and Registered Nurses. Medical Assistants and Clinic Assistants providing clinical care will do so based on local agency policies and procedures that follow the appropriate Nursing and/or Physician delegation rules and regulations promulgated by the respective Colorado Department of Regulatory Agency Boards.

Add more lines as needed.

Printed Name	Consultant Physician Signature	Title	Date
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Federal Title X Program (March 2019)

Providing Quality Family Planning Services (QFP)
Recommendations of the CDC and U.S. Office of Populations Affairs
(April 2014, Updates March 2016 and December 2017)

Recommendations for Providing Quality Sexually Transmitted Disease
Clinical Services (January 2020)

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Section 1: Family Planning Health Care Services

A. Sexual health is a state of physical, emotional, mental, and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction, or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination, and violence. (World Health Organization, 2002)

B. Health care clinical service policies are based on the 2014 Providing Quality Family Planning Services, Recommendations of the CDC and the US Office of Population Affairs (QFP) (including 2015 and 2017 updates), and the Program Requirements for Title X Funded Family Planning Projects (2019). National guidelines and recommendations do not replace clinical judgment based on individual circumstances of the client. Access the QFP Mobile App. The Reproductive Health National Training Center (RHNTC) links to training options and job aids to assist in meeting FP requirements and recommendations are embedded throughout the clinical manual.

C. The QFP encourages using a client-centered approach to providing services. This begins with respecting the client's primary purpose for their visit, providing confidential services, offering a broad range of contraceptive methods, and delivering services in a culturally competent manner to meet the needs of all clients. Assessing the client's need for family planning services can be completed by utilizing the Reproductive Health National Training Center (RHNTC) Clinical Pathway of Family Planning Services Chart.

D. QFP core family planning services include: contraceptive services, pregnancy testing and counseling, helping clients achieve pregnancy, basic infertility services, preconception services, and sexually transmitted disease services. Family Planning staff must participate in QFP training.

E. Converge Health Care Services (Clinical) Requirements:

1. Signed Title X consent. **Federal requirement*
2. Comprehensive health history, including a medical and sexual health assessment. To ensure obtaining a comprehensive sexual health history and sexual health assessment, including behavioral practices, you may use the two resources below. The U.S. Selected Practice Recommendations (US SPR) and U.S. Medical Eligibility Criteria (US MEC) should be used to assist health care providers when they counsel clients about contraceptive methods of choice. Sexual health history taking resources are below. **Federal requirement*
    a. A Guide to Taking A Sexual History, Centers for Disease Control and Prevention (CDC)
    b. 5 "P's" of Sexual Health (RHNTC)
    c. Sexual History-Taking Toolkit (Cardea Services)
    d. Sexual Health and Your Patients: A Provider's Guide (National Coalition for Sexual Health)
3. Assess all clients for their reproductive life plan. The PATH approach to pregnancy intention screening is the preferred framework for assessing pregnancy intention. You may also use the pregnancy intention screening question, such as the One Key Question®, "Would you like to become pregnant in the next year?" or "Are you planning a pregnancy in the next year?" to make an initial assessment of a client's plans for pregnancy and contraceptive needs. You may also consider asking the question, "Do you have a sense of what is important to you about your method?" An overview of Pregnancy Intention Screening Questions can be found here. **Federal recommendation & Converge requirement*
4. Contraceptive services, including client-centered contraceptive counseling, a broad range of contraceptive methods, and specific education on contraceptive methods of choice. Optimally, a client should see a provider and receive their desired contraceptive method, if no contraindications, on the same day of their initial visit. Contraceptive method education must be provided as outlined in the respective contraceptive method sections of this manual. Dispensing of hormonal contraceptives may be provided by a Registered Nurse (RN) under physician signed standing orders for healthy, low risk clients (see Section 12- Pharmaceuticals). **Federal requirement*

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5. Physical exam **Federal requirement*
    a. American College of Obstetrics and Gynecology (ACOG) Well-Woman Visit, Committee Opinion No. 755, Oct. 2018, Reaffirmed in 2020
    b. ACOG Annual Women's Health Care and Well-Woman Recommendations
    c. Woman's Preventive Services Initiative (WPSI), Bright Futures and USPSTF Recommendations for Well-Woman Care Chart (2021) Available in Spanish.
    d. American Academy of Family Physician (AAFP) Men's Health Clinical Recommendations & Guidelines. A physical exam may be provided as indicated, but is not necessary in order to provide condoms.
    e. USPSTF "A" and "B" recommendations for preventive services should be referenced for additional guidance.
6. Pregnancy testing and prenatal care referral with positive pregnancy test result (nondirective pregnancy counseling is recommended and may include counseling on abortion, adoption and continuing the pregnancy). Referral for abortion is prohibited, except in cases of medical emergency, or in the case of rape or incest. **Federal requirement*
7. STI/HIV prevention and risk reduction counseling, and CT/GC screening and treatment for women 24 and younger (one screening annually at a minimum). CDC STD Treatment Guidelines (2021) and the STD QCS (2020) are reviewed in Section 15. **Federal requirement*. Colorado FPP requirement is to screening women 25 and under annually at a minimum. The screening rate goal for this priority population is 70%.
8. Breast and cervical cancer screenings, as appropriate and per national guidelines. **Federal requirement*
9. Adolescent counseling must include counseling on trusted adult engagement, resisting sexual coercion, reproductive life plan/pregnancy intention screening, and confidentiality. **Federal requirement*
10. Substance use disorder (SUD) screening. https://ncsacw.acf.hhs.gov/files/SAFERR_AppendixD.pdf *recommendation*
11. Referrals for conditions deemed medically necessary. Emergency care, HIV/AIDS care and treatment, infertility specialists, primary care, and chronic disease care providers must be included on the agency specific resource and referral list (see Section 23 for more details). **Federal requirement*
12. Intimate partner violence (IPV) screening using a validated screening tool. **Federal requirement*
13. Preconception counseling and basic infertility counseling, if applicable. **Federal requirement*
14. Clinical services operate under the direction of a physician that has experience providing family planning services. The Medical Director must approve Family Planning clinical protocols. **Federal requirement*

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F. Refer to the Reproductive Health National Training Center (RHNTC) family planning and family planning health services checklists for men and women regarding service recommendations. Recommended family planning services include nondirective pregnancy options counseling, sexually transmitted infection services for all clients, mental health screening and referral, and counseling on and administering immunizations (HPV/HBV/Tdap/MMR/influenza/varicella).

G. Title X family planning services were established to assist individuals in determining the number and spacing of children through the provision of affordable voluntary family planning services. Clients may not be coerced to use contraception or to use any specific method of contraception. Client's acceptance of family planning services must not be a prerequisite to eligibility or receipt of other services or participation in other programs.

H. Delivery of services should not become a barrier to a client's ability to receive contraceptive services. Receiving contraceptive services and a contraceptive method, or achieving pregnancy services remains a priority in the FPP. If other family planning services cannot be delivered at the initial visit, follow-up visits should be scheduled as soon as possible (QFP pg. 7).

I. Services must be provided without imposing durational residency requirements or a requirement that the client be referred by a healthcare provider for services. Services must be provided without regard to religion, race, ethnicity, color, national origin, disability, sex, gender identity or expression, limited English proficiency, number of pregnancies, or marital status.

J. Services should include integration of male-focused family planning and reproductive health services. Research shows that they recognize unintended pregnancy and STIs/HIV as serious concerns and acknowledge that prevention is a joint responsibility with their partner(s). Contact the FPP Nurse Consultant for additional resources on providing services to male clients. Contact the Clinical Compliance Manager or the Medical Director for additional resources on providing services to male clients.

K. Most individuals will need no or few examinations or laboratory tests before starting a method of contraception. Unnecessary medical procedures and tests may create barriers to contraceptive access for some clients, especially adolescents. Exams and tests not routinely needed to start a healthy client on a contraceptive method include: pelvic exams, unless inserting an IUD or fitting a diaphragm; breast and cervical cancer screening; HIV screening; lipid, glucose, liver enzymes, and hemoglobin tests (QFP pg. 11).

L. Client education must include the following topics either in verbal or written form. Converge utilizes the client centered reproductive goals and counseling resource from RHNTC.

    1. Six Contraceptive method of choice education
        i. Managing side effects and problems with method
        j. User instructions for method
        k. Instructions on how to discontinue method
        l. Procedural instructions in case of an emergency
        m. Instruction to call or return to the clinic at any time to discuss side effects or other problems, if they want to change the method being used and when it is time to remove or replace the contraceptive method
        n. Non-barrier contraceptive methods do not protect against STIs and HIV
    2. Availability of emergency contraception
    3. Information needed to make informed decisions about family planning, including reproductive life plan
    4. Information about HIV and STI risks, infection prevention, actions to reduce transmission of HIV and STIs

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5. Health promotion/disease prevention information (i.e. nutrition, exercise and mental health issues)
6. Information about and a strong recommendation for the Human Papilloma Virus (HPV) vaccine for individuals up to 45 years old. In October 2018, the FDA approved expanded use of Gardasil 9 to include individuals 27 through 45 years old in order to prevent HPV-related diseases and cancers in a broader age range.
7. Immunization resources, including Hepatitis A and B vaccines information and recommendations
8. Primary care and social services referral resources and information
9. Consistent and correct condom use to prevent pregnancy and protect against STIs and HIV (CDC)
10. Sexuality and healthy relationships
11. Sexual dysfunction

M. Annual and re-visits for family planning and preventive services

1. Annual visits are provided for assessment of client's satisfaction or concerns with contraceptive method, preventive services such as blood pressure and body mass index screening, STI screening as indicated, and breast and cervical cancer screening, as indicated.
2. Lab tests as indicated or for subsequent doses of HPV vaccine.
3. U.S. Selected Practice Recommendations, 2016 (US SPR) do not generally recommend routine follow up visits related to the safe and effective use of a contraceptive method after the initiation of a contraceptive method for a healthy client. Exceptions would be a specific client who would benefit from a routine follow up visit, such as one with certain medical conditions or characteristics, those with multiple medical conditions and adolescents. The US SPR recommends and clients must be advised to return to the clinic any time to discuss side effects other problems or if they want to change their method.
4. At other routine visits, an assessment should be made:
    i. of the client's satisfaction and concerns with their method,
    ii. of any health status changes, including medications, that would change the appropriateness of their method (US MEC),
    iii. blood pressure (combined methods),
    iv. for clients with an IUD, consider performing an exam to check for the presence and length of IUD strings,
    v. consider assessing weight changes and counseling clients who are concerned about weight changes perceived to be associated with their contraceptive method.

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N. LGBTQ+ Individuals, Family Planning Services and iCare

1. Care for all individuals is provided using a client centered approach, delivered in a culturally competent manner to meet the needs of all clients. Individuals who identify as gay, lesbian, bisexual, transgender, queer or questioning (LGBTQ+) interested in and who receive family planning services related to determining the number and spacing of their children may be enrolled in Title X as any other client would be (i.e. consented, registered, provided with contraceptive counseling, etc.). However, if a client declines services related to family planning (contraceptive counseling, reproductive life plan discussion, preconception counseling and care, achieving pregnancy and basic infertility care) would not be enrolled in Title X because they are not receiving a qualifying procedure or counseling.

2. Alhers and Data Entry- For Alhers purposes, in order for a client to be considered a qualifying family planning client, a qualifying procedure or counseling that occurred during the client's visit must beentered into the Alhers data base.

3. Transgender clients' preferred gender identity should always be honored, and the pronouns and terminology that the client prefers should always be used. Clients' gender entry into Ahlers should be based on the clients' self-identified gender. If you have challenges coordinating the sex of a client and a method of contraceptive or qualifying procedure, please contact the Clinical Compliance Manger at Converge to make sure the client is identified correctly in the system. The Family Planning Annual Report (FPAR) reporting will use clients' self-identified gender.

4. LGBTQ+ Clients and Unintended Pregnancy- LGBTQ+ individuals can be at risk for unplanned pregnancy. The key is that obtaining family planning services is client directed – the client determines without coercion whether or not they are interested in receiving family planning services, regardless of gender identity or sexual orientation. STI testing by itself, without discussion of contraception and pregnancy prevention (or pregnancy planning) is not a Title X service. However, an STI visit may be a good way to introduce clients to family planning services.

LGBTQ+ individuals experience challenges in accessing LGBTQ+ friendly care in their communities. Transgender individuals, in particular, experience discrimination and barriers to adequate health care services. Title X family planning clinics provide access to confidential, culturally sensitive health care services (including services to LGBTQ+ individuals) which include access to a broad range of contraceptive methods; breast and cervical cancer screening; STI and HIV testing and referral; and other prevention services. Referral option: UMMC's TEAM Clinic in the Center for Gender and Sexual Minority Health. 2550 Flowood Drive Flowood, MS 39232 601.984.2644 TEAMclinic@umc.edu

Appts by: umc.edu/teamintake

5. Resources

- ACOG Committee Opinion (#823), Health Care for Transgender and Gender Diverse Individuals, March 2021
- Birth Control Across the Gender Spectrum (Reproductive Health Access Project)
- The National Clinical Training Center For Family Planning (NCTCFP) provides an e-learning opportunity titled Providing Reproductive Life Planning for Non-Cisgender and Non-Heterosexual Women. The training focuses on recognizing barriers for sexual minorities in the FP settings, the perceptions of sexual minority groups regarding their clinical experiences in the FP setting, and consequences for LGBTQ+IA communities when they do not receive quality family planning services.
- The Center of Excellence for Transgender Health, University of California, San Francisco (UCSF) Department of Family and Community Medicine published Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People, June 2016 (2nd edition). An online course, "Acknowledging Gender and Sex", is also available on this website. This course focuses on training clinic staff and providers to create a welcoming environment

for transgender people.

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- The World Professional Association for Transgender Health Standards of Care (Version 7)
- The Substance Abuse and Mental Health Services Administration (SAMHSA)
- National LGBT Health Education Center: Fenway Institute
- Cardea Services: Introduction to Gender and Sexuality in a Health Care Setting: Providing Quality Care for Transgender and Gender Nonconforming Patients, Clinical Care for Transgender and Gender Nonconforming Patients, and Adolescent Care for Gender Nonconforming and Transgender Adolescents
- Mississippi resources include: The Women's Resource Center, Care Pregnancy Center, Pregnancy Resource Center, and Pregnancy Support Services

O. Protocol Policy

1. Services provided operate under clinical protocols that are in accordance with nationally recognized standards of care and the Program Requirements for Title X Funded Family Planning Projects.
2. Date and signature of the supervising physician and clinicians responsible for the service site are noted on protocols at time of each update or review.

P. Utilization of Telehealth in Family Planning

1. Telehealth in Family Planning rapidly expanded at the beginning of the COVID-19 pandemic. Telehealth visits, telephonically, video-based, and hybrid, are Title X Family Planning qualifying visit types. Family Planning telehealth visits must follow national and state telehealth rules and regulations (i.e. utilizing a HIPAA compliant video-based platform). Rules and regulations are constantly evolving at this time. Please reach out to a Converge member with any Family Planning telehealth question.
2. Resources to assist in providing high quality Family Planning telehealth services in Mississippi include:
    a. Mississippi Telehealth
        i. Twentyeight Health
        ii. National Family Planning Telehealth
        iii. National Family Planning and Reproductive Health Association (NFPRHA)
        iv. Reproductive Health National Training Center (RHNTC) Telehealth Resources
    b. National Telehealth
        i. CDC
        ii. National Consortium of Telehealth Resource Centers (NCTRC)
        iii. Center for Care Innovations (CCI) Telemedicine for Health Equity Toolkit
        iv American Medical Association (AMA) Digital Health Implementation Toolkit
        v. Rural Health Information (RHI) Hub Rural Telehealth Toolkit
        vi. American Academy of Family Physicians (AAFP): Telehealth Toolkit

Contraception services are a priority family planning service. Converge Title X Family Planning Program contraceptive protocols are based on the CDC and U.S. Office of Population Affairs 2014 publication Providing Quality Family Planning Services (QFP), the CDC U.S. Medical Criteria for Contraceptive Use, 2016 (US MEC) and updates and the CDC U.S. Selected Practice Recommendations, 2016 (US SPR). Summary Chart of U.S. Medical Eligibility Criteria forContraceptive Use (2016). Providers should sign up to receive email updates to these recommendations. Also available for download are an US MEC APP and US SPR eBook.

A. Method Selection

A broad range of contraceptive methods must be available to the client either in the clinic or by referral. A broad range of contraceptive methods includes, but is not limited to hormonal contraceptives, LARC, fertility awareness based methods, barrier methods, and abstinence)

Family planning contraceptive services should be offered with a **client-centered approach**. Clients must not be coerced to use contraception or to use any particular method of contraception.

The QFP offers recommendations for contraceptive counseling (QFP Appendix B, pgs. 36-38 and Appendix C, pgs. 45 - 46). The CDC's Effectiveness of Methods Chart may be helpful in counseling on the different methods. A check box or written statement should be used in the medical record to document that the client reported understanding the presented information about their chosen method.

The FPNTC offers contraceptive counseling education for Family Planning staff, including:

- An innovative tool for providing contraceptive counseling is the My Birth Control website. This tool was developed by Dr. Christine Dehlendorf and has been shown to improve patient experience of contraceptive counseling. https://clinic.mybirthcontrol.org/ The tool provides patients with an overview of birth control methods and considerations based on effectiveness, use of method, side effects, and ability to get pregnancy after discontinuing the method. The tool also prompts the patient to answer a series of questions regarding what is most important to them in a method, their prior experiences with birth control and their health history. After completing the questionnaire, a printout is provided to both the provider and patient with a few methods that best meet their needs and desires.

- Observational Contraceptive Counseling Checklist
- Quality Contraceptive Counseling and Education: A Client-Centered Conversation eLearning
- Birth Control Options Chart
- Same-Visit Contraception Implementation Checklist and Schedule Impact Calculator
- Contraceptive Change Access Package: QI tool to support improvement on NQF contraceptive care measures

The following are the US MEC Categories for contraceptive use to use when assessing the safety of a contraceptive method for clients with specific medical conditions or characteristics. The recommendations are intended to assist health care providers in decreasing barriers to choosing the contraceptive method best for each individual client.

Category 1: A condition for which there is no restriction for the use of the contraceptive method.

Category 2: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The method generally can be used but follow up may be required.

Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. Use of the method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account, and careful follow up is required. The provision of a method to a woman with a condition classified as Category 3 requires careful clinical judgment and access to clinical services.

Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

The recommendations address medical eligibility criteria for the initiation and continued use of all methods evaluated. The issue of continuation criteria is clinically relevant whenever a woman develops the condition while they are using the method. (US MEC 2016). The US MEC summary sheet (updated 2016) only contains a subset of the recommendations from the US MEC. For complete guidance, see:

B. Method Use

1. Providers should refer to the US SPR for information including how to initiate the chosen contraceptive method and how to address problems and side effects the client may experience with their method and instructions for incorrect method use.
2. Optimally, clients should be started on their method the day of their visit to the family planning clinic. Providers should be reasonably certain that a woman is not pregnant before starting them on a contraceptive method. In most cases a detailed history will provide the most accurate assessment of pregnancy risk for a woman who is starting a contraceptive method.
3. According to the US SPR, a provider can be reasonably certain that a woman is not pregnant if they have no symptoms or signs of pregnancy and meets one of the following criteria:
    a. Is less than or equal to 7 days after the start of normal menses
    b. Has not had sexual intercourse since the start of last normal menses
    c. Has been correctly and consistently using a reliable method of contraception
    d. Is less than or equal to 7 days after spontaneous or induced abortion
    e. Is within 4 weeks postpartum
    f. Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority ($\geq$85%) of feeds are breastfeeds), amenorrheic, and less than 6 months postpartum
4. If a woman meets one of these criteria (and therefore the health care provider can be reasonably certain that they are not pregnant), a urine pregnancy test might be considered in addition to these criteria (based on clinical judgment), bearing in mind the limitations of the accuracy of pregnancy testing. If a woman does not meet any of these criteria, then the provider cannot be reasonably certain that they are not pregnant, even with a negative pregnancy test. Routine pregnancy testing for every woman is not necessary.
5. Emergency contraception should be considered for females who have had unprotected intercourse in the last 5 days. See Emergency Contraception section for more information.

C. Method Education

1. Written method consents are no longer required. Clinics must continue the use of consents for contraceptive methods involving a procedure, i.e. implants and IUD methods.
2. Clients must continue to receive education regarding contraceptive alternatives and the safety, effectiveness, potential side effects and complications, and any problems/benefits concerning the use of a contraceptive method
    a. The FPP Sexual and Reproductive Health Resource Card (2017) connects clients to national websites that provide all of the essential information previously noted in the FP “Purple” Booklet.

b. When appropriate, or if indicated by client, staff will discuss all methods in detail.

c. While all methods may be covered at the initial visit, the majority of time should be spent on the method of choice.

d. Staff providing client education should be knowledgeable, objective, non-judgmental, and sensitive to the rights and differences of clients as individuals.

e. Staff must provide the client with a verbal detailed description of the client's selected method, demonstrate how to use the method, and give the client the appropriate, method-specific information including instructions for use. If a check off is used in the medical record to document that the client received specific method education, marking the check off indicates the following will have been included in the education. Information should include the following:

   1) Mechanism of Action
   2) Effectiveness
   3) Advantages and indications
   4) Possible side effects, complications and danger signs and symptoms
   5) Managing missed pills, patch, ring, DMPA as indicated
   6) Managing side effects and problems with method
   7) User instructions for method
   8) Instructions on how to discontinue method
   9) Procedural instructions in case of an emergency
   10) Instruction to call or return to the clinic at any time to discuss side effects or other problems, if they want to change the method being used and when it is time to remove or replace the contraceptive method
   11) The contraceptive method (other than barrier methods) does not protect against STI/HIV and a barrier method should also be used for dual protection.

A. Method selection

A broad range of contraceptive methods must be available to the client either in the clinic or by referral.

IUDs are considered highly effective contraceptive methods. Currently available in the U.S. are five IUDs, Paragard®, Liletta®, Mirena®, Kyleena®, and Skyla®. Paragard® is FDA approved for up to ten years, Liletta® is FDA approved for up to six years, Mirena® and Kyleena® are FDA approved for five years, and Skyla® is FDA approved for three years.

Prior to the pandemic, Converge allowed for off-label and extended use of LARC and the program plans to continue to support this effort post-pandemic. Agencies must have a policy with supporting evidence prior to initiating off-label and extended use contraceptives. An IUD is an example of a contraceptive method your agency may choose to use beyond FDA approved use. Your clinical team may also decide to extend use of DMPA and SubQ Depo. Here are two resources to help in the decision making process: RHAC resource & ACOG's Practice Bulletin.

US MEC Categories of medical eligibility criteria for contraceptive use to use when assessing the safety of a contraceptive method for clients with specific medical conditions or characteristics. Recommendations about the use of hormonal contraceptive methods (including depot medroxyprogesterone acetate) and intrauterine devices among women at high risk for HIV were updated in April 2020 in the MMWR and here.

Category 1: A condition for which there is no restriction for the use of the contraceptive method.

Category 2: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The method generally can be used but follow up may be required.

Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. Use of the method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account, and careful follow up is required. The provision of a method to a woman with a condition classified as Category 3 requires careful clinical judgment and access to clinical services.

Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

B. Objective Data

1. Comprehensive health history, physical exam and laboratory tests, if applicable.
2. Laboratory tests may include:
   a. Cervical cancer screening within the normal screening interval for the client (cervical cytology and HPV). Cervical intraepithelial neoplasia (CIN) is listed as a category 2 (a condition for which advantages of using the method generally outweigh theoretical or proven risk) for levonorgestrel-releasing IUDs and a category 1 (a condition for which there is no restriction for the use of the contraceptive method) for copper-containing IUD. An IUD should not be initiated for a client who has cervical cancer. Continuing an IUD for a client diagnosed with cervical cancer is a category 2. Currently, Paragard® is the only copper-containing IUD available in the U.S.
   b. GC and chlamydia tests according to national screening guidelines. If a person has not been screened for STDs according to national guidelines, screening should be performed immediately prior to insertion. If screening guidelines have been followed, most clients will not need additional STD screening at time of insertion and insertion should not be delayed. Clients with purulent cervicitis or chlamydial infection or gonorrhea should not undergo IUD insertion (US MEC)

C. Assessment and Plan

1. Client Education/Informed Consent

   a. Have the client read the FDA approved client brochure for the particular IUD that they are to have inserted.

   b. Provide anticipatory counseling and reinforce the effects of the IUD on the menstrual cycle.

   c. Client must sign an IUD procedure consent, witnessed by a provider, and a copy of the consent and IUD package insert must be provided to the client.

2. Pre-insertion Management

   a. Prophylactic antibiotics are generally not recommended for IUD insertion.

   b. Sub-bacterial endocarditis (SBE) prophylaxis prior to IUD insertion is not recommended (American Heart Association, JAMA 264: 2919, 1990: AMA Drug Evaluation 4:1, 1994). Routine administration of prophylactic antibiotics solely to prevent endocarditis is not recommended for clients undergoing genitourinary tract procedures. (American Heart Association, Circulation 2007;116:1736-1754) Routine antibiotic prophylaxis to prevent pelvic infection is not recommended before IUD insertion. (American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin No. 18**6**, Nov 2017, Reaffirmed 2021).

   c. For pre-insertion pain management, clients may be given a non-steroidal anti-inflammatory drug (NSAID) one hour prior to insertion. According to US SPR (2016), paracervical block with lidocaine may reduce patient pain during IUD insertion. Misoprostol is not recommended for routine use prior to IUD insertion. Misoprostol might be helpful clients with a recent failed insertion.

   d. Local anesthesia at the tenaculum site: options included 1) no anesthesia or 2) apply benzocaine 20% gel first at the tenaculum site then leave a gel-soaked cotton tipped applicator in the cervical canal for 1 minute before proceeding with the IUD insertion, or 3) inject 1 ml of local anesthetic lip into which the tenaculum will be placed (Zieman M., Hatcher RA. Managing Contraception. Tiger, Georgia: Bridging the Gap Foundation, 2015, p. 891)

3. Follow manufacturer's instructions, otherwise known as the package insertion for insertion instructions.

4. Insertion

   a. Follow manufacturer's instructions, otherwise known as the package insert for instructions.
   b. Document baseline pulse and blood pressure prior to insertion.

   c. Document pelvic exam done prior to insertion as to uterine position, size, cervix and discharge appearance and any abnormalities.

   d. Document IUD type, depth to which uterus is sounded, string length after insertion and trimming, and lot # and expiration date of the IUD.

5. Post-insertion of the IUD - Vasovagal observation
    a. See guidance under Section 21: Medical Emergencies
    b. Blood pressure and pulse should be taken and recorded.
    c. If vital signs indicate a vasovagal response, record BP and pulse frequently (every 5-15 minutes).
    d. Clients should not be allowed to leave the clinic until stable.
    e. Clients with persistent vasovagal symptoms should be evaluated for perforation, abdominal bleeding, etc.
    f. Usefulness of physical maneuvers for prevention of vasovagal syncope: https://www.ncbi.nlm.nih.gov/pubmed/16127191

6. Post-IUD Insertion Education
    a. Client should be instructed on the expiration period for the IUD
    b. Need for back up contraception, if indicated. Generally, the recommendation for back up contraception is a minimum of 7 days.
    c. Reinforce the signs and symptoms of possible IUD complications. Instruct the client to call the clinic for any of the following:
        1) Late or missed period if using ParaGard®; abnormal spotting or bleeding; signs or symptoms of pregnancy.
        2) Pelvic or lower abdominal pain; pain with intercourse
        3) Exposure to STIs; abnormal vaginal discharge
        4) Not feeling well – fever or chills
        5) Inability to locate IUD string, changes in string length
        6) Known partial or full expulsion
    d. Instruct the client to check for the string before intercourse, during their first menstrual cycle, and then after each menses
    e. Inform the client if they wish to discontinue the use of the IUD to make an appointment with their provider to have it removed. If they do not wish to become pregnant, they must start a new method on or before the day they have the IUD removed.
7. Follow-up Visits
    a. Scheduling follow-up visits is at the discretion of the provider and clients. Visits post IUD insertion are not required.
    b. Advise clients to return at any time to discuss side effects or other problems or if they want to change methods and/or have the IUD removed.
    c. At other routine visits, assess: client's satisfaction and any concerns with method, any changes in health status that would change the appropriateness of IUD use (category 3 or 4 US MEC), consider exam for IUD string check

d. Hemoglobin/Hematocrit if indicated

e. Review of IUD danger signs.

f. Reinforce the importance of an annual visit and preventive screening according to national screening guidelines.

D. Management of Complications/Side Effects

1. Client diagnosed with PID

a. Treat for PID as outlined in the CDC STD Treatment Guidelines. "If an IUD user receives a diagnosis of PID, the IUD does not need to be removed." Centers for Disease Control and Prevention (CDC), Sexually Transmitted Diseases Treatment Guidelines, 2021, MMWR; 64/No. RR-3, p. 82) however, close clinical follow up is required.

b. Inform the client to seek care immediately if symptoms do not improve or worsen. Reassess in 48 to 72 hours. If no improvement, consider IUD removal. Continue antibiotics and refer for care.

c. If the IUD is removed, contraceptive counseling is necessary.

1) If the client is mid-cycle, and has recently had intercourse, inform them of the risk of removing the IUD and a possible subsequent pregnancy. Offer ECP. If the client decides they do not want removal, documentation must exist of discussion of need for close clinical follow up.

2) If IUD is removed, be certain the client leaves the clinic with an alternative method of birth control.

2. Actinomyces on Pap test - SYMPTOMATIC OF PID

a. Clients must receive/be referred for intensive antibiotic therapy, along with the removal of the IUD, as this bacterium prefers to grow on foreign bodies. Physician consultation is required.

b. Clients must be counseled on the use of a different method of contraception.

3. Actinomyces on Pap test - ASYMPTOMATIC OF PID

Pelvic actinomycosis is a rare (<.001%) but serious condition. The relationship between actinomyces found on a Pap test in the asymptomatic IUD user and development of a pelvic actinomycosis infection is not clear.
Therefore, management of the asymptomatic IUD user with a Pap with actinomyces is not clearly established. There has only been one small, randomized controlled trial, and the results established no superior approach. "Although options for management have included oral antibiotics, removal of the IUD, or both, current recommendations for asymptomatic clients with an IUD and actinomyces found by cervical cytology screening focus on expectant management. Both the UK Faculty of Family Planning and the Standards and Guidelines of the Planned Parenthood Federation of America recommend continued IUD use and client education about the small risk of actinomycosis" (ACOG Practice Bulletin No. 186, November 2017, Reaffirmed 2021)). With this in mind, each agency's practitioners should discuss the management of actinomyces on Pap test in an asymptomatic IUD user with the medical consultant and determine the approach to be used.

a. Review the result with the cytologist/pathologist to confirm the diagnosis.

b. The IUD does not have to be removed, but the client should be informed and questioned about any

symptoms suggestive of PID. If they are asymptomatic, nothing more is required.

c. Treatment of asymptomatic actinomyces on Pap test is not required, as the actinomyces is a normal vaginal organism. Detecting its presence on Pap test represents colonization rather than infection in a client without pelvic tenderness. Review the signs and symptoms of PID with the client.

d. Since the importance of clearing the actinomyces colonization in the asymptomatic client is not established, there is no basis for recommending a repeat Pap to check for clearing of actinomyces.

4. Spotting, Bleeding
   a. Rule out pregnancy, infection or partial expulsion and manage appropriately.
   b. If client complains of excess bleeding within the first three months after insertion,
      1) Reassure that it is likely to get better in subsequent cycles,
      2) Check HCT or HGB and give iron supplement, if indicated,
      3) For Copper IUD: US SPR recommends short term NSAIDs for 5-7 days.
      4) Rule out other pathology related to vaginal bleeding.
5. Cramping or Pain – varying degrees of discomfort may be felt at the time of insertion and may be followed by cramping pain over the next 10-15 minutes.
   a. Pain with sounding of the uterus during insertion
      1) Go slowly, consider smaller sound
      2) If severe, check alignment of uterine cavity on bimanual exam, and consider using a paracervical block before proceeding.
   b. Pain at the time of insertion persists, with signs of abdominal tenderness
      1) If the string is present, treat as pelvic infection
      2) If the string is absent, consider the possibility of perforation, migration, expulsion or pregnancy and refer to the emergency room.
      3) If severe: rule out perforation, pregnancy or infection. Check blood pressure and pulse. Consider removing the IUD if indicated.
      4) If mild: prescribe a mild analgesic such as Ibuprofen.

6. Severe post-insertion reaction, such as syncope
   a. If placement is questionable, remove the IUD. An IUD can be re-inserted now or at a later date.
   b. If the IUD is properly placed, and pulse <60 beats/min, consider the use of ammonium capsules (smelling salts). If symptoms persist, consider atropine 0.5 mg IV. IV fluids may be helpful.
   c. Call 911 for emergency services
   d. Remove the IUD if necessary

e. See 2020 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science and bradycardia algorithm for guidance.

7. Partial expulsion of IUD
   a. Without signs of infection, remove IUD and another IUD may be inserted if the provider is reasonably certain the woman is not pregnant and a urine pregnancy test is negative.
   b. With PID or question of PID, treat with antibiotics and remove the partially expelled IUD. Provide alternative contraception. Another IUD may be inserted after 3 cycles.
   c. Consider ECP
8. Pregnancy with IUD in situ- A woman pregnant with an IUD in place must be evaluated promptly to confirm an intrauterine pregnancy and to exclude an ectopic pregnancy.
   a. Do highly sensitive pregnancy test and pelvic exam
   b. If the client is pregnant and the IUD string is visible, the IUD should be removed, regardless of plans to continue or terminate the pregnancy.
      1) Counsel the client that an ectopic pregnancy, SAB, or sepsis is a possibility and review signs and symptoms of each.
      2) Refer the client for health care services.
      3) If the client chooses to keep the IUD, advise them to seek care promptly and especially with heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.
   c. If the client is pregnant and the string not visible, explain the risks of ectopic pregnancy, SAB and sepsis with an IUD in situ during pregnancy.
      1) Review the warning signs of infection, SAB and ectopic pregnancy, including where to seek emergency care.
      2) Refer to physician immediately for follow-up.
   d. Ectopic pregnancy- IUD significantly reduces a woman's risk of an ectopic pregnancy, because the IUD prevents all types of pregnancies. Should a pregnancy occur with an IUD in place, the ratio of ectopic to intrauterine pregnancies might be increased (Contraceptive Technology, 21st Edition, p. 163 and 168-169).
9. Absent IUD Strings
   a. If menses have not been missed and there is no abdominal pain:
      1) After ruling out pregnancy, attempt to determine if the IUD is in the uterus by gently exploring the cervix for the strings.
      2) If the strings are located, bring them to their appropriate place.
      3) If the strings are not found, the clinician may elect to discuss and provide an alternative method of contraception with the client and have them return with the next menses to check again for the string OR obtain a pelvic ultrasound to determine if the IUD is in the uterus.

a) If the IUD is seen on ultrasound, clarify the location to R/O perforation. If the IUD is in the uterus, nothing else needs to be done.

b) If the IUD is not located by pelvic ultrasound, order an abdominal X-ray to differentiate IUD expulsion from translocation into the abdominal cavity. Translocated intraperitoneal IUD should be removed as promptly as possible, as copper-bearing IUDs are known to cause dense adhesions.

b. If menses have been missed and/or there are signs and symptoms of infection:

1) Rule out pregnancy

2) See management of pregnancy with IUD in situ or PID with IUD.

E. IUD Removal

1. Subjective Data
   a. LMP and previous menstrual period
   b. Medical history update
   c. History of recent intercourse, if client not menstruating
   d. Reason for IUD removal
2. Objective Data
   a. Physical exam/pelvic exam as indicated.
   b. Laboratory as indicated.
3. Assessment and Plan
   a. Client requesting change in contraceptive method
      1) Counsel regarding other methods of birth control. Hormonal methods may be initiated before the IUD is removed.
      2) Remove IUD. If the client is not menstruating, counsel on risks of pregnancy. Consider ECP.
      3) Provide an interim method of birth control, as indicated.
      4) If pregnancy is desired, preconception counseling, including the benefits of folic acid, should be provided.
   b. If the client is requesting reinsertion of IUD, the reinsertion may be completed at the same visit.
   c. Client symptomatic of PID – refer to Item D. above.
4. Please contact the Reproductive Health National Training Center (RHNTC) for LARC education and training opportunities.

Section 4: Tier 1 Method - Contraceptive Implants

A. Method selection

A broad range of contraceptive methods must be available to the client either in the clinic or by referral.

Contraceptive implants are a Tier 1 and a very effective contraceptive method.

US MEC Categories of medical eligibility criteria for contraceptive use to use when assessing the safety of a contraceptive method for clients with specific medical conditions or characteristics.

Category 1: A condition for which there is no restriction for the use of the contraceptive method.

Category 2: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The method generally can be used but follow up may be required.

Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. Use of the method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account, and careful follow up is required. The provision of a method to a woman with a condition classified as Category 3 requires careful clinical judgment and access to clinical services.

Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

B. Initial Objective Data

1. Comprehensive health history, physical exam and laboratory tests, if applicable.

C. Assessment/Plan

1. Client Education/Informed Consent

   a. Client must sign the contraceptive implant insertion consent, witnessed by a provider.

   b. Inform client that unscheduled bleeding and spotting are common and expected with the implant. The frequency of unscheduled bleeding is highest in the first few months of use, and then usually begins to diminish. It may also increase or remain the same.

   c. Inform client that implant offers no protection against sexually transmitted infections; advised client to use condoms if they have concerns about potential exposure. Document this discussion in the client record.

   d. Certain medications may make implants less effective, specifically those that induce CYP3A4 enzymes resulting in increased clearance of sex hormones in the liver. These drugs likely involve the CYP3A4 pathways and reduce effectiveness. Some examples include: phenytoin, carbamazepine, oxcarbazepine, phenylbutazone, barbiturates, bosentan, felbamate, and the herbal remedy St. John's Wort, rifampin/rifampicin, efavirenz, lumacaftor, and griseofulvin (see package insert for complete list). Women in long-term treatment with these drugs should consider another method of birth control

   e. Antiretroviral (ARV) drugs have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. Limited data suggest potential drug interactions between many ARV drugs (particularly some NNRTIs and ritonavir-boosted protease inhibitors) and hormonal contraceptives.

These interactions may alter the safety and effectiveness of both the hormonal contraceptive and the ARV drug. Thus, if a woman on ARV treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms is recommended to both prevent HIV transmission and compensate for any possible reduction in the effectiveness of the hormonal contraceptive.

f. Inform the client that if they wish to discontinue the implant, they should make an appointment at the clinic for removal. If they do not wish to become pregnant, they must start using another method on the day of removal.

g. Insertion of implants - follow package insert instructions, including verifying the presence of the implant in the client arm, immediately after insertion by palpation. The client should also be able to palpate the implant.

E. Follow-Up

1. The client may return for an insertion site check if they have concerns about the implant insertion site.
2. Clients should be advised to call the clinic for an appointment for any of the following:
   a. Arm pain; pus or bleeding at the insertion site; expulsion of the rod;
   b. Heavy vaginal bleeding that is unusual for this client;
   c. Concern that they might be pregnant, including delayed menstrual cycles after a long interval of regular cycles;
   d. Onset or worsening of migraine headaches, repeated very painful headaches or blurred vision;
   e. Severe lower abdominal pain (rule out ectopic pregnancy).
3. Management of Post-Insertion Side Effects/ Complications
   a. Arm pain, pus, or bleeding at insertion site
      1. Management
         a) Advise the client to apply ice packs to the area for bruising, swelling, bleeding; moist heat for signs of infection.
         b) Advise to take Ibuprofen or other non-steroidal anti-inflammatory medication to relieve the discomfort.
         c) In case of infection of the insertion site, consultation with medical back up may be indicated to select a therapeutic treatment drug.
      2. Follow-up
         a) Consider contacting the client within 48-72 hours to confirm improvement.
      3. Education
         a) Instruct client to keep the wound site clean and dry for 24 hours.
         b) Inform the client that there might be irritation of a superficial nerve from the implants; paresthesia or paresthesia-like events may occur.
         c) Expulsion or migration of implants might be possible.

b. The implant appears to be coming out

Assessment/management - If the implant is protruding from the incision site, the implant should be removed, and a new implant inserted at a different site.

c. Heavy or prolonged vaginal bleeding

1. Assessment

a) Review client history, including sexual history, other symptoms, and contact to STIs.

b) Physical examination and appropriate lab work should be done to rule out pregnancy, STIs or underlying gynecologic problems.

2. Management – if no underlying gynecologic problem

a) Any low-dose combination birth control pill for one or more cycles, if no contraindications to estrogen, or

b) NSAIDS for short term treatment (5-7) days.

d. Amenorrhea from the time of implant insertion, or after a pattern of regular periods

1. Assessment

a) Evaluate for pregnancy

2. Management

a) If pregnancy test is positive:

1) Remove implant if client wishes to continue the pregnancy.

2) Refer for immediate follow-up if ectopic pregnancy is suspected.

3) Leave the implant in if the client plans an abortion.

b) If the pregnancy test is negative:

1) Discuss amenorrhea with clients and reassure that amenorrhea is a normal side effect of implant use.

2) Implant may be removed if the client desires.

e. Headache

1. Assessment

a) Review headache history.

b) Take blood pressure.

2. Management

a) Refer to physician for further evaluation, if indicated.

b) If a client develops migraine headaches with aura or other neurological symptoms while using the implant, the theoretical or proven risk of continuing the implant usually outweigh the advantages of using the method. The implant should be removed.

f. Development of ischemic heart disease or stroke while using implant - The theoretical or proven risk of continuing the implant usually outweigh the advantages of using the method. Implant should be removed.

F. For Clients Desiring Removal

1. Subjective

   If the client desires removal before three years, investigate the user's reasons for desiring removal. If, after counseling, the client still desires removal, the procedure should be scheduled.

2. Client Education

   a. Inform the client that removal may take more time and may be more difficult than the insertion.

   b. This information should be included in a removal consent, which must be signed by the client and witnessed by a provider.

   c. The client should be counseled on alternative contraceptive methods, and if they do not desire a pregnancy at this time, a method should be provided, as appropriate.

3. Removal of implants – follow manufacturer's removal instructions. The exact location of the implant in the arm should be verified by palpation before the removal procedure.

   https://www.merckconnect.com/ nexplanon/overview. html

4. Non-palpable/deep implants – follow manufacturer's instructions. The implant should always be located before removal. Nexplanon® is radiopaque and can be located using CT scan, 2-dimensional x-ray, ultrasound, and MRI. The manufacturer recommends the following routes of localization:
   a. Confirm the presence of the implant using 2-dimensional x-ray

   b. Use ultrasound to localize the implant and guide removal

5. Follow-Up

   a. The client may return for a removal site check if they have concerns about the implant removal site

   b. Clients should be encouraged to return for an annual visit.

G. Please contact the Converge Clincal Compliance Manager for LARC education and training opportunities.

A. Method selection

A broad range of contraceptive methods must be available to the client either in the clinic or by referral.

Depot medroxyprogesterone acetate (DMPA) is marketed as Depo Provera®.

Agencies must have a policy with supporting evidence prior to initiating any off-label and extended use contraceptives. Depo SubQ is an example of a contraceptive method your agency may choose to use beyond FDA approved use. Your clinical team may also decide to extend use of LARC methods. Below are two resources to help in the decision-making process.

US MEC Categories of medical eligibility criteria for contraceptive use to use when assessing the safety of a contraceptive method for clients with specific medical conditions or characteristics. Recommendations about the use of hormonal contraceptive methods (including depot medroxyprogesterone acetate) and intrauterine devices among women at high risk for HIV were updated in April 2020 in the MMWR and here.

Category 1: A condition for which there is no restriction for the use of the contraceptive method.

Category 2: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The method generally can be used but follow up may be required.

Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. Use of the method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account, and careful follow up is required. The provision of a method to a woman with a condition classified as Category 3 requires careful clinical judgment and access to clinical services.

Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

B. Initial Objective Data

1. Comprehensive health history, physical exam and laboratory tests, if applicable.

C. DMPA Assessment and Plan

1. Client Education/Informed Consent

   a. DMPA offers no protection against STIs/HIV.

   b. Likelihood of irregular spotting for up to the first nine months, and of the likelihood of amenorrhea after the first year.

   c. Fertility can return immediately after missing the next timed injection, or be delayed up to 12 months. They should discuss any future fertility plans with their provider.

   d. If a client wishes to discontinue the use of this method for any reason, they should not get a reinjection at 12 weeks. They will have to wait for any side effects to wear off. If they do not wish to become pregnant, a new method must be started before the next shot would be due.

   e. Review information regarding loss of bone mineral density with the client, information from the studies showing reversal of the bone loss and information regarding measures for bone strength such as calcium and vitamin D intake and weight-bearing exercise.

f. Aminoglutethimide can decrease the effectiveness of DMPA. The drug is usually used to suppress adrenal function in selected cases of Cushing's disease (Contraceptive Technology 21st Edition, pg. 199).

g. The CDC released updated recommendations in April 2020 about the use of depot medroxyprogesterone acetate among women at high risk for HIV. These recommendations can be accessed at MMWR and here.

h. Some studies indicate that clients using DMPA are at risk for weight gain. Clients should be advised that their appetite may increase, and to be aware of changes in caloric intake to avoid this effect. https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6637a6.pdf

2. Administering the injection of DMPA

a. See the US SPR for timing of initiation of DMPA, need for back up contraception, reinjection, and information on addressing bleeding irregularities during DMPA use. Per FDA, prescribing information, DMPA should be administered every 3 months or 13 weeks. Per US SPR (2016), a repeat DMPA injection can be given up to two weeks late (15 weeks from the last injection or 105 days) without requiring additional contraceptive protection.

b. Rarely, an anaphylactic or anaphylactoid reaction may occur immediately following DMPA injection. Manage as per agency's Medical Emergencies protocol. Some clinics encourage clients to remain in the clinic for 20 minutes after an injection. (Contraceptive Technology, 2^{1st} Revised Edition, p. 203). To prevent severe allergic reactions, ask clients if they have experienced significant itching or redness at the site of previous DMPA injections and do not repeat DMPA if allergic reaction is suspected.

c. DMPA 150 mg/ml in a deep IM injection. Do not massage the injection site.

d. DMPA SQ 104 Provera in a subcutaneous injection. Do not massage the injection site.

e. Counseling on self-administration of SubQ Depo increased during the early months of the COVID pandemic. Several resources have been developed over the past year to assist family planning providers in determining best practices for counseling on self-administration of SubQ Depo.

A. Method selection

A broad range of contraceptive methods must be available to the client either in the clinic or by referral.

Oral contraceptives, the contraceptive ring, and contraceptive patch are Tier 2 contraceptives and are moderately effective.

US MEC Categories of medical eligibility criteria for contraceptive use to use when assessing the safety of a contraceptive method for clients with specific medical conditions or characteristics.

Category 1: A condition for which there is no restriction for the use of the contraceptive method.

Category 2: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The method generally can be used but follow up may be required.

Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. Use of the method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account, and careful follow up is required. The provision of a method to a woman with a condition classified as Category 3 requires careful clinical judgment and access to clinical services.

Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

B. Management of Clients with Special Considerations Requiring Further Evaluation

1. An adverse cardiovascular risk profile or multiple risk factors for arterial cardiovascular disease is classified as Category 3/4, a condition for which the theoretical or proven risks usually outweigh the advantages of using the method or represent an unacceptable health risk if the method is used. (US MEC).

   If a woman has two or more risk factors, the case must be evaluated by, and use of oral contraceptives approved by a physician. Risk factors include the following: age ≥35; smoking cigarettes; high cholesterol levels; diabetes; hypertension.

2. Diabetes mellitus

   a. Combined hormonal contraceptive use in clients with diabetes must be individualized. As risk factors increase in number or severity, it may become less appropriate to prescribe combined hormonal contraceptives

   b. Consider involving the primary care provider managing the client's diabetes if combined contraceptives are initiated.

3. High Blood Pressure

   a. Severe hypertension of systolic ≥160 or diastolic ≥100 and hypertension with vascular disease are Category 4 risk conditions. These individuals should not use combined hormonal contraceptives. Hypertension that is adequately controlled and hypertension of systolic 140-159 or diastolic 90-99 are Category 3. These individuals generally should not use combined hormonal contraceptives. Blood pressure should be evaluated before initiating combined hormonal contraceptives.

   b. An elevated blood pressure (BP) with a systolic of 140-160 or a diastolic of 90-100 on three separate visits or any BP >160/100 are reasons to discontinue oral contraception and refer the patient for medical evaluation. Begin the client on a progestin-only or non-hormonal method of contraception immediately.

   c. AHA and ASA issued new high blood pressure guidelines in November 2017. These guidelines lower the definition of hypertension to 130/80 from 140/90.

4. Headaches

   a. Management of non-migrainous headaches (classification category 2) that start or worsen after the initiation of combined hormonal methods is up to the discretion of the provider and client. "Classification depends on accurate diagnosis of those severe headaches that are migrainous and those headaches that are not. Any new headache or marked changes in headaches should be evaluated. Classification is for clients without any other risk factors for stroke. Risk for stroke increases with age, hypertension and smoking." and may include any of the following:

      1) Referral for headache evaluation;

      2) Change in pill prescription including very low dose COCs (20 ug), or progestin only methods;

      3) Change in birth control method;

      4) For headaches during the hormone free interval, instruct the client to skip the week of placebo pills or hormone free interval and immediately start a new cycle.

   b. Common Migraine Headaches (without focal neurologic symptoms [aura, visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities]) (without aura, age < 35 yrs. – classification category 2 for initiation and category 3 for continuation of combined hormonal methods)

      1) A trial of a combined hormonal method may be provided for clients with a history of migraine headaches without focal neurological symptoms. The client must be advised to report any increase in the frequency and severity of such headaches. The initiation of an estrogen containing method to clients ≥ 35 years old with a history of migraine headaches without focal neurological symptoms is a category 3, a condition for which the theoretical or proven risks usually outweigh the advantages.

      2) If migraines worsen in frequency or severity, or if focal neurological symptoms or signs (aura, visual changes, scotoma, flashing lights, dysphasia, and numbness of face/extremities) occur, combined hormonal methods must be discontinued. Clients who develop focal neurological symptoms or signs should be referred promptly for neurologic evaluation. If a woman ≥ 35 years old develops migraine headaches without aura or other neurological symptoms, combined hormonal methods must be discontinued.

   c. Migraine headache with aura at any age is classified as a Category 4 for combined methods and represents an unacceptable health risk.

5. Age: For individuals 40 and older the use of combined hormonal contraceptives (CHC) is a category 2, a condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The risk for cardiovascular disease increases with age and might increase with CHC use. In the absence of other adverse clinical conditions, CHCs can be used until menopause. Combined oral contraception (COC) or vaginal ring may be continued to the early 50s unless contraindicated. Combined hormonal methods may be used for non-obese, nonsmoker clients without cardiovascular risk factors.

6. Seizure Disorders

    a. A majority of clients with seizure disorders will notice no change in the frequency or severity of seizure activity as a result of initiating oral contraceptives.

    b. Concurrent use of anti-seizure drugs that induce hepatic enzymes may reduce effective plasma steroid levels in combined hormonal contraceptive users. It is the responsibility of the provider to review a client's anti-seizure medication(s) for potential drug interaction with oral contraceptives.

    c. Use of backup barrier methods, and the benefits and risks of using combined hormonal contraceptives in clients with seizure disorders should be discussed with clients who use anti-seizure drugs but who need a high degree of protection. Clients who are on certain anti-seizure medications and choose to use combined hormonal contraceptives should be advised to use a backup method, such as condoms. Any breakthrough bleeding during this time may indicate a decrease in circulating levels of estrogen and progestin. Such a decrease could result in ovulation. Absence of breakthrough bleeding does not confirm adequate serum hormone levels.

    d. Continued use of a barrier method with combined hormonal contraceptives (dual method use) or switching to Depo Provera or an IUD may be advised.

7. Drug Interactions

    a. Anti-seizure medications: Concurrent use of anti-seizure drugs that induce hepatic enzymes may reduce effective plasma steroid levels in oral contraceptive users. These medications include phenytoin, carbamazepine, barbiturates, primidone, topiramate, and oxcarbazepine.

    b. Gabapentin (Neurontin®), vigabatrin, ethosuximide and lamotrigine (Lamictal®) have no effect on this enzyme system and do not interfere with contraceptive effectiveness. Valproate/ Valproic Acid (Depakote®) and felbamate (Felbatol®) do not increase breakdown of hormones and may even increase hormone levels. Pharmacokinetic studies show levels of lamotrigine decrease significantly during combined hormonal method use. This may result in an increase in seizure activity.

    c. Rifampin increases hepatic clearance of estrogen and progestin; it is recommended that clinicians not prescribe combined hormonal contraceptives for clients on this drug.

    d. Broad-spectrum antibiotics: Hormone levels in clients using combined hormonal methods are not lowered by the use of ampicillin, amoxicillin, clarithromycin, metronidazole, quinolones, doxycycline, tetracycline, or fluconazole. Virtually every COC user taking these antibiotics has hormone levels that remain well within the therapeutic range for contraceptive efficacy. As a result, back-up methods should not be necessary unless the client has problems taking the pills, e.g., if an underlying medical condition interferes with pill taking or absorption. (Contraceptive Technology, 21st Edition, pp. 271).

e. Combined hormonal methods can decrease clearance of benzodiazepines such as diazepam (Valium), nitrazepine, chlordiazepine, and alprazolam, which suggests the need for lower doses of these medications. Clearance of bronchodilators such as theophylline, aminophylline and caffeine as well as anti- inflammatory corticosteroids may also be reduced.

f. More rapid clearance of acetaminophen and aspirin is also reported.

g. The FDA has alerted providers that the use of St. John's Wort may decrease the therapeutic effect of combined hormonal methods.

h. Antiretroviral (ARV) drugs have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. Limited data suggest potential drug interactions between many ARV drugs (particularly some NNRTIs and ritonavir-boosted protease inhibitors) and hormonal contraceptives. These interactions may alter the safety and effectiveness of both the hormonal contraceptive and the ARV drug. Thus, if a woman on ARV treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms is recommended to both prevent HIV transmission and compensate for any possible reduction in the effectiveness of the hormonal contraceptive. When a combined oral contraceptive is chosen, a preparation containing a minimum of 30 ug ethinyl estradiol (EE) should be used.

i. Most studies suggest no association between use of hormonal contraception and progression of HIV, as measured by CD4+ count <200 cells/mm^3, initiation of antiviral therapy, or mortality.

(See Updated to CDC's US MEC; Revised Recommendations for the Use of Hormonal Contraception Among Clients at High Risk for HIV Infection or Infected with HIV MMWR/April 10, 2020/Vol.69/No.14 for more information)

C. Client Education/Informed Consent – must include:

1. Fact sheet on all contraceptive options available if they are a new client or are undecided as to what method they desire;
2. Fact sheet on the client's chosen method;
3. A copy of the FDA approved detailed client labeling pamphlet. The importance of reading the FDA pamphlet must be explained to the client;
4. Instructions on correct use of the method. See US SPR starting on page 22 and for COC instructions, see Contraceptive Technology, 21st Edition, pp. 263-315; for Contraceptive Patch and Vaginal Ring pp.227-261
5. Information about the effectiveness of their chosen method and that the effectiveness of combined hormonal contraception may be decreased by some medications (See Drug Interactions of this Section);
6. The importance of scheduled follow-up visits (See Follow Up of this Section);
7. Importance of informing other providers of their use of contraceptives;
8. Information regarding discontinuation of a method. If they do not wish to get pregnant, they should start using another method before the day they are due to start their next cycle;

Section 6: Tier 2 Method - Combined Hormonal Methods: Oral Contraceptives, Vaginal Ring, Hormonal Patch

9. Information regarding sexually transmitted infections (STIs), including counseling that combined hormonal contraceptives provide no protection. Use of either single-use internal or external condoms should be recommended for clients in need of protection from STIs.
10. Non contraceptive benefits of the method
11. Possible side effects and how to manage side effects
12. Warning signs and symptoms and to seek care immediately for rare but serious adverse events, such as heart attack, stroke, blood clot in extremity or lungs.

D. Medical Screening and Evaluation

1. History – (See Section 1- Health Care Services of the Clinical Manual)
2. Examination – (See Section 1 - Health Care Services of the Clinical Manual)
3. Laboratory – (See Section 1 - Health Care Services of the Clinical Manual)
4. Provision of hormonal contraceptives through Express Visit - (See Section 1. Health Care Services – of the Clinical Manual)

E. Provision of Combined Hormonal Contraceptive

Combined hormonal contraceptives can be initiated at any time if it is reasonably certain that the client is not pregnant. If the health care provider is uncertain whether the client is pregnant, the benefits of starting combined hormonal contraceptives likely exceed any risk. Starting combined hormonal contraceptives should be considered at any time with a follow up pregnancy test in 2-4 weeks.

1. A health-care provider can be reasonably certain that a client is not pregnant if they have no symptoms or signs of pregnancy and meets any one of the following criteria:
   a. is ≤7 days after the start of normal menses
   b. has not had sexual intercourse since the start of last normal menses
   c. has been correctly and consistently using a reliable method of contraception
   d. is ≤7 days after spontaneous or induced abortion
   e. is within 4 weeks postpartum
   f. is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum
2. A blood pressure must be documented for all clients starting a combined hormonal and then checked and documented periodically as long as the woman is using a combined method.
3. Provide or prescribe up to a 1-year supply of the contraceptive method, e.g. 13, 28-day pill packs. The more cycles provided, the higher the continuation rates.

Starting Combined Hormonal Contraceptives (US SPR)

CURRENT METHOD	START METHOD	BACK UP
No effective contraception in preceding cycle	Any time if provider is reasonably certain the woman is not pregnant.	If started with in first 5 days since menses started, no back up required. If > 5 days after menses started, use back up method for 7 days
Another hormonal method	Start immediately if it is reasonably certain woman is not pregnant.	If > 5 days since menstrual bleeding started back up method for 7 days is recommended
IUD	On the same day that the IUD is removed if no unprotected intercourse (used a barrier method) for 7 days before IUD removal Start hormonal method at least 7 days before the IUD is removed. *Consider need for ECPs at time of IUD removal	Back up method for 7 days No need for back up
After first or second trimester loss (up to 28 weeks gestation) or termination	Start immediately or up to 7 days after loss or termination	Back up method for 7 days unless method started at same time as termination
Postpartum Not breastfeeding	When medically eligible and reasonably certain the woman is not pregnant and at 21-42 days postpartum in clients who have no risk factors for VTE (Category 2); If greater than 42 days postpartum (Category 1) See Update US MEC: "Revised Recommendations for the Use of Contraceptive Methods During the Postpartum Period"	Back up method recommended for 7 days
Postpartum Breastfeeding	When medically eligible and reasonably certain the woman is not pregnant and at 30 – 42 days postpartum if no risk factors for VTE (Category 2); If greater than 42 days postpartum (Category 2)	Back up method recommended for 7 days

F. Guidelines for Combined Method Use

1. Oral contraceptives

   a. Missed or late Oral Contraceptive Pills: http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf

   b. Vomiting or diarrhea while using COCs: http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf

   c. Shortened hormone-free interval or Extended-cycle use: Consider offering clients the opportunity of fewer or no withdrawal bleeds during the year by skipping the placebo pills, particularly if they experience estrogen withdrawal symptoms such as headache when taking the placebo pills during the fourth week of the pill pack. The prescription needs to be written for 16-17 cycles/year, (or more if client plans to skip spacer pills all together). As an alternative to the more expensive products with dedicated packaging for extended use, select a monophasic pill for extended use or continuous cycling. Please refer to, Contraceptive Technology, 21st Revised Edition, pp. 268. Inform clients of the possibility of unscheduled bleeding with shortened hormone-free interval or extended-cycle use of combined hormonal contraceptives. This usually occurs during the first 3 to 6 months of use and is generally not harmful. If indicated, evaluate for incorrect use of method, interactions with other medications, infection, pregnancy, etc. (US SPR pp 28-29)

2. Ortho Evra

   a. Delayed application or detachment of patch: http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf

   b. Ortho Evra should be stored below 85 degrees F.

   c. May be applied to abdomen, buttock, upper outer arm or upper torso (excluding breast)

   d. Ortho Evra is applied weekly for 3 weeks on the same day of the week each week. There is a one-week patch free interval. This should never be more than seven consecutive days.

   e. It is preferable for the client to place a new patch on a fresh area of skin to avoid skin reactions

   f. Recommendations for continuous cycling of Ortho Evra vary.

3. Contraceptive Vaginal Rings

   a. NuvaRing®- weekly vaginal ring is the only one-month contraceptive vaginal ring available in the U.S.

      i. Delayed insertion or reinsertion with vaginal ring: http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf

      i. NuvaRing® must be stored in the refrigerator at 36-46 degrees F prior to dispensing. NuvaRing® may be stored by the client for up to 4 months at or below 77 degrees F (room temperature). The client label should have an expiration date that does not exceed 4 months from the date of dispensing or the product expiration date, whichever comes first.

      ii. The exact position of NuvaRing® in the vagina is not important for efficacy.

      iii. If the client feels discomfort, NuvaRing® is probably not inserted far enough in the vagina.

Section 6: Tier 2 Method - Combined Hormonal Methods: Oral Contraceptives, Vaginal Ring, Hormonal Patch

iv. NuvaRing® should be inserted and removed on the same day of each week (three weeks apart) and at about the same time

v. Dispose of the used ring in a waste receptacle.

vi. The menstrual period will usually begin two to three days after the ring is removed and may not have finished before the next ring is inserted. Clients may use vaginal yeast medication while NuvaRing® is in place.

vii. Extended Use or Continuous Cycling: Consider offering clients the opportunity of fewer withdrawal bleeds during the year by skipping the ring-free week, particularly if they experience estrogen withdrawal symptoms such as headache during the ring-free week. Each ring can be left in place for one calendar month, then removed and immediately replaced with a new ring on the first of each month. The prescription is still written for 12 or 13 rings/year. Inform clients of the possibility of unscheduled bleeding with extended or continuous use of combined hormonal contraceptives. This usually occurs during the first 3 to 6 months of use and is generally not harmful. If indicated, evaluate for incorrect use of method, interactions with other medications, infection, pregnancy, etc.

b. Annovera™

FDA approved combined hormonal contraceptive ring that can be used for an entire year. Prescribing information can be found here. Annovera™ is a segesterone acetate and ethinyl estradiol vaginal system.

G. Follow Up

1. Routine follow up is not recommended unless indicated. Provider recommendations for follow up visits are based on factors such as whether the woman has certain medical conditions or multiple medical conditions in need of monitoring.
2. Advise women to return to the clinic at any time to discuss side effects, problems or if they want to change methods.
3. At other routine visits, the client should be assessed for satisfaction with chosen method, changes in health status including medications that would affect the safe use of the method (e.g. category 3 and 4 conditions for the method), assess blood pressure, and consider assessing weight changes.
4. Monitor blood pressure as indicated or when the client returns for annual visit.

Section 7: Tier 2 Method - Progestin Only Pills (POP)

A. Method selection
A broad range of contraceptive methods must be available to the client either in the clinic or by referral.

Progestin only oral contraceptives are considered moderately effective. US MEC Categories of medical eligibility criteria for contraceptive use to use when assessing the safety of a contraceptive method for clients with specific medical conditions or characteristics.

The recommendations address medical eligibility criteria for the initiation and continued use of all methods evaluated. The issue of continuation criteria is clinically relevant whenever a woman develops the condition while they are using the method.

Category 1: A condition for which there is no restriction for the use of the contraceptive method.

Category 2: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The method generally can be used but follow up may be required.

Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. Use of the method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account, and careful follow up is required. The provision of a method to a woman with a condition classified as Category 3 requires careful clinical judgment and access to clinical services.

Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

B. Management of Clients with Special Considerations Requiring Further Evaluation
   1. Drug Interactions
      a. Anti-seizure medications: Concurrent use of anti-seizure drugs that induce hepatic enzymes may reduce effective plasma steroid levels in oral contraceptive users. These medications include phenytoin, carbamazepine, barbiturates, primidone, topiramate, and oxcarbazepine.
      b. Gabapentin (Neurontin®), vigabatrin, ethosuximide and lamotrigine (Lamictal®) have no effect on this enzyme system and do not interfere with contraceptive effectiveness. Valproate/ Valproic Acid (Depakote®) and felbamate (Felbatol®) do not increase breakdown of hormones and may even increase hormone levels. No drug interactions have been reported among epileptic clients taking lamotrigine and using POPs.
      c. Rifampin increases hepatic clearance of estrogen and progestin; it is recommended that clinicians not prescribe hormonal contraceptives for clients on this drug.
      d. Use of broad-spectrum antibiotics, antifungals, and antiparasitics with POPs is a Category 1.
      e. The FDA has alerted providers that the use of St. John's Wart may decrease the therapeutic effect of combined hormonal methods.
      f. Antiretroviral (ARV) drugs have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. Limited data suggest potential drug interactions between many ARV drugs (particularly some NNRTIs and ritonavir-boosted protease inhibitors) and hormonal contraceptives. These interactions may alter the safety and effectiveness of both the hormonal contraceptive and the ARV drug. Thus, if a woman on ARV treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms is recommended to both prevent HIV transmission and compensate for any possible reduction in the effectiveness of the hormonal contraceptive.
      g. Refer to Contraceptive Technology for use of progestin-only contraceptives for clients with medical conditions, pp 547.

C. Client Education/Informed Consent – must include:
   1. Fact sheet on all contraceptive options available if they are a new client or is undecided as to what method they wish to use;
   2. Fact sheet on the client's chosen method;

3. A copy of the FDA approved detailed client labeling pamphlet. The importance of reading the FDA pamphlet must be explained to the client;
4. Instructions on correct use of the method, see US SPR and for progestin only pill instructions, see Contraceptive Technology, 21st Edition, pp. 317-326;
5. Information about the effectiveness of the method and that the effectiveness of hormonal contraception may be decreased by some medications (See Drug Interactions of this Section);
6. The importance of scheduled follow-up visits (See Follow Up of this Section);
7. Importance of informing other providers of their use of oral contraceptives;
8. Information regarding discontinuation of the method. If they do not wish to get pregnant, they should start using another method before the day they are due to start their next cycle;
9. Information regarding sexually transmitted infections (STIs), including counseling that hormonal contraceptives provide no protection. Use of the single-use internal or external condoms should be recommended for clients in need of protection from STIs;
10. Non contraceptive benefits of the method;
11. Possible side effects and how to manage side effects;
12. Warning signs and symptoms and to seek care immediately for rare but serious adverse events, such as heart attack, stroke, blood clot in extremity or lungs.

D. Medical Screening and Evaluation
   1. History – (See Section 1 - Health Care Services of the Clinical Manual)
   2. Examination – (See Section 1 - Health Care Services of the Clinical Manual)
   3. Laboratory – (See Section 1 - Health Care Services of the Clinical Manual)
   4. Provision of hormonal contraceptives through Express Visit (See Section 1 - Health Care Services of the Clinical Manual)

E. Provision of POPs
   1. Follow US SPR recommendations for initiation of POPs
   2. POPs can be started at any time if it is reasonably certain that the woman is not pregnant. If the health care provider is uncertain whether the woman is pregnant, the benefits of starting hormonal contraceptives likely exceed any risk.
   3. Starting hormonal contraceptives should be considered at any time with a follow up pregnancy test in 2-4 weeks POPs may be started in lactating and non-lactating clients at any time postpartum. The U.S. Medical Eligibility Criteria for Contraceptive Use lists POPs as a Category 2 (the advantages of using the method generally outweigh the theoretical or proven risks) for breastfeeding clients less than one month postpartum. (Also see Contraceptive Technology, 21st Edition, Chapter 17: Postpartum Contraception after Pregnancy, pp. 511-541)
   4. A health-care provider can be reasonably certain that a woman is not pregnant if they have no symptoms or signs of pregnancy and meets any one of the following criteria:
      a. is ≤7 days after the start of normal menses
      b. has not had sexual intercourse since the start of last normal menses
      c. has been correctly and consistently using a reliable method of contraception
      d. is ≤7 days after spontaneous or induced abortion
      e. is within 4 weeks postpartum
      f. is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum
   5. A pregnancy that does occur in a woman taking mini-pills is more likely to be ectopic. Some sources postulate that 10% of pregnancies that occur to mini-pill users are ectopic (Contraceptive Technology, 21st Edition, p. 321).
   6. POPs inhibit ovulation in about half of cycles, though rates vary widely by individual. Serum levels peak at two hours after taking a POP and return to baseline at 24 hours. Taking POPs at the same time each day is important. It takes 48 hours to achieve the contraceptive effect on cervical mucus.
   7. A blood pressure must be documented for all clients starting a hormonal method and then checked and documented periodically as long as the woman is using the method.

8. Provide or prescribe up to a 1-year supply of the contraceptive method, e.g. 13, 28-day pill packs. The more cycles provide, the higher the continuation rates.
9. See US SPR for instructions on missed POPs and vomiting or severe diarrhea that occurs within 3 hours after taking a pill.

F. Follow Up

1. Routine follow up is not recommended unless indicated. Provider recommendations for follow up visits are based on factors such as whether the woman has certain medical conditions or multiple medica l conditions in need of monitoring.
2. Advise woman to return to the clinic at any time to discuss side effects, problems or if they want to change methods.
3. At other routine visits, the client should be assessed for method satisfaction, changes in health status including medications that would affect the safe use of the method (e.g. category 3 and 4 conditions for the method), assess blood pressure, and consider assessing weight changes.
4. Monitor blood pressure as indicated or when the client returns for annual visit.

A. Method selection

A broad range of contraceptive methods must be available to the client either in the clinic or by referral.

Barrier methods are not as effective in preventing pregnancy as hormonal methods and LARCs.

US MEC Categories of medical eligibility criteria for contraceptive use to use when assessing the safety of a contraceptive method for clients with specific medical conditions or characteristics.

The recommendations address medical eligibility criteria for the initiation and continued use of all methods evaluated. The issue of continuation criteria is clinically relevant whenever a woman develops the condition while they are using the method. For complete US MEC guidance: http://www.cdc.gov/mmwr/pdf/rr/rr5904.pdf. Barrier methods are not addressed in the US SPR.

Category 1: A condition for which there is no restriction for the use of the contraceptive method.

Category 2: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The method generally can be used but follow up may be required.

Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. Use of the method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account, and careful follow up is required. The provision of a method to a woman with a condition classified as Category 3 requires careful clinical judgment and access to clinical services.

Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

B. External Condom, otherwise known as Male Condom

1. Non-contraceptive benefits
    a. Dual protection against pregnancy and sexually transmitted infections, including HIV.
    b. Available without a prescription at low cost.
    c. Male participation in contraception.
    d. Prevention of premature ejaculation.
    e. Prevention of sperm allergy in clients.
2. Subjective data

    Cautions - External condoms do have disadvantages that may lead to inconsistent or lack of use. Encourage couples to try different brands and lubricants until they find one that is acceptable.

    a. Allergy to condom materials or additives (i.e. latex, spermicide, polyisoprene, nitrile, etc.).
    b. An inability, in some men, to maintain an erection if condom is used.
    c. Male partner(s) will not accept responsibility for birth control.

d. Natural material membrane condoms (i.e. lambskin) are contraindicated where there is a risk of infection since they allow passage of very small viruses such as the human immunodeficiency virus (HIV).

e. Condoms with spermicidal lubricant should not be used for anal intercourse, for multiple acts of vaginal intercourse each day (>2 times), or for those at high risk for HIV.

3. Assessment and plan – Client Education (See Contraceptive Technology 21st Edition, male condom pgs.431-445 for more information)
   a. Give client a condom fact sheet
   b. Counsel on the consistent and correct way to use condoms. Inconsistent or nonuse can lead to STI acquisition. Counsel on the importance of dual method use of condoms plus a hormonal contraceptive in order to prevent both pregnancy and STIs. Condoms may be combined with most Tier 1 and Tier 2 methods or other barrier methods to enhance efficacy or to provide other non-contraceptive benefits, such as STI protection.
   c. Inform client of effectiveness: pregnancy rate 18% with typical use and 2% with perfect use. (Contraceptive Technology 21st Edition pg. 876-879)
   d. Counsel regarding emergency contraception in the event of condom breakage.

4. Side effects and complications
   a. Breakage.
   b. Allergy or skin irritations.

C. Single-Use Internal Condom (previously the Female Condom)

In September 2018, the FDA issued a final order to reclassify the female condom, a sexual health device that protects against STIs and HIV, renaming the device "single-use internal condom". The reclassification moves the device from a class III to a class II device. Along with the FDA name change for the device, its description now includes "OTC" and "prevents transmission of STIs including HIV".

1. Non-contraceptive benefits
   a. Available without a prescription (currently not covered by insurance in Colorado)
   b. Dual protection, against pregnancy and ST/HIV
   c. Non-hormonal
   d. Empowers receptive partners to take control of their sexual and reproductive health
   e. Can be used by couples who cannot use external condoms (i.e. penis size or erectile dysfunction)
   f. Can be used by same sex couples for prevention of STIs and HIV (vaginal or anal intercourse).
   g. Not dependent on a male partner to maintain erection to stay in place.

2. Subjective data
   a. Allergy to condom materials or additives (i.e. synthetic nitrile and silicone-based lubricant). Safe to use in clients with a latex allergy.
   b. Male partner will not accept responsibility for birth control

3. Assessment and plan – Client Education (See Contraceptive Technology 21st Edition, pgs. 373-379.

a. The internal condom is reimbursable in Colorado for plans that are ACA compliant (see). If a client has difficulty obtaining FC2 internal condom for $0 copay at a pharmacy, visit coverher.org

b. Review instructions for the use of the only single-use internal condom, FC2, available in the U.S. here: FC2 website.

c. Clients must be comfortable and able to place the single-use internal condom vaginally.

d. Counsel on the consistent and correct way to use the single-use internal condom. Inconsistent or nonuse can lead to STI acquisition. Counsel on the importance of the dual method use of condoms plus a hormonal contraceptive in order to prevent both pregnancy and STIs. Condoms may be combined with most Tier 1 and Tier 2 methods or other barrier methods to enhance efficacy or to provide other non- contraceptive benefits, such as STI protection.

e. Inform client of effectiveness: pregnancy rate 21% with typical use and 5% with perfect use (Contraceptive Technology 21st Edition pg. 876-879).

f. Rates of failure (i.e. breakage, slippage, invagination, and misdirection) were highest in the first five uses. Counsel client to not rely on the single-use internal condom for their first several uses of the method and recommend that users be prescribed emergency contraception in advance.

5. Side effects and complications

a. Breakage, slippage, invagination or misdirection common during initial use. Requires practice to properly place in the vaginal canal.

b. Potential discomfort during use and local skin irritation during and following use.

D. Diaphragm (See http://www.caya.us.com/ for information about the Caya® single size contoured diaphragm and for information about Milex diaphragms)

1. Non-contraceptive benefits

a. Protection from some sexually transmitted infections.

b. Lower risk of cervical dysplasia and cancer.

2. Subjective data – History (See Section 1 Health Care Services)

Cautions - The following conditions may preclude satisfactory use or make use of the diaphragm inadvisable:

a. History of Toxic Shock Syndrome.

b. Allergy to rubber, latex, polyurethane, or spermicide. Current diaphragm on the market from Cooper Surgical, Milex Arching and Omniflex is made from silicone and is latex free according to the Cooper Surgical website. Package insert and directions for use in English and Spanish are available for download.

Caya® diaphragm (latex free according to web site) http://www.caya.us.com/index.html.

c. Recurrent urinary tract infections.

d. Abnormalities in vaginal anatomy that interfere with satisfactory fit or stable placement.

e. Inability of client to correctly insert or remove.

f. Full-term delivery less than 6 weeks ago.

g. Need for HIV protection -There is a lack of protection against HIV and some STIs. Clients should also use a condom if at risk.

h. A high risk for HIV infection is a condition that represents an unacceptable health risk if the contraceptive method (diaphragm with spermicide) is used. Repeated and high dose use of the spermicide nonoxynol-9 has been associated with increased risk for genital lesions, which might increase the risk for HIV infection. Category 4.

i. In patients with HIV, use of spermicides and/or diaphragms (with spermicide) can disrupt the cervical mucus, which may increase viral shedding and HIV transmission to uninfected partners Category 3.

3. Objective data

   a. Physical examination as indicated (See – Health Care Services).

   b. Laboratory tests as indicated (Health Care Services).

4. Assessment and plan - Client education (See Contraceptive Technology 21st Edition (2011) pgs.391-415 for more information).

   a. Instructions in use of method, including insertion technique.

   b. Inform client of effectiveness: pregnancy rate 12% with typical use and 6% with perfect use. (Contraceptive Technology 21st Edition pg. 50).

   c. Use and care of the diaphragm.

   d. Document that the client demonstrates the ability to properly insert and remove the diaphragm.

   e. Document that literature and instructions were given.

   f. The client should be able to leave the diaphragm in place for a minimum of 6-8 hours without discomfort at least once before using it for contraception.

   g. The client should also leave the diaphragm in place for a minimum of 6-8 hours at least once before returning for a fit check.

   h. Counsel regarding emergency contraception in the event the diaphragm is not used, or becomes dislodged during use.

5. Side effects and complications

   a. Toxic Shock Syndrome- Sudden high fever, vomiting, diarrhea, dizziness, fainting, weakness, sore throat, aching muscles and joints, and rash (like a sunburn) occurring in association with use of diaphragm has been reported. Clients must seek emergency care for symptoms of toxic shock syndrome.

   b. Vaginal or urinary tract infections.

   c. Local irritation.

   d. Allergic reaction to rubber, latex, polyurethane, or spermicide and/or local skin irritation of client or partner.

   e. Pelvic discomfort, cramps, or pressure on the bladder or rectum due to improper fit.

   f. Foul odor or vaginal discharge if the diaphragm is left in the vagina for longer than recommended.

6. Follow up visits
    a. Offer revisit approximately one month after the initial fitting.
        1) During the first month of use, instruct the client to practice insertion and removal, and to determine the comfort of the diaphragm.
        2) The day of the appointment, the client wears the diaphragm to the clinic. The clinician should check the position and fit of the diaphragm.
    b. The client should return for annual visits and evaluation of the diaphragm fit.
    c. The diaphragm should be refit annually after a weight gain or loss of 10 pounds or more, after an abortion, or after a full-term pregnancy.
    d. The client should be encouraged to call the clinic if they experience any problems with the diaphragm.

E. Foams, Jellies, Creams, Suppositories, Vaginal Contraceptive Film
1. Non-contraceptive benefits
    a. Available without a
    prescription.
2. Subjective data

    Cautions - spermicides are not a reasonable choice in the following circumstances:
    a. Vaginal intercourse multiple times each day.
    b. A high risk for HIV infection is a condition that represents an unacceptable health risk if the contraceptive method (spermicide) is used. Repeated and high dose use of the spermicide nonoxynol-9 has been associated with increased risk for genital lesions, which might increase the risk for HIV infection. Category 4.
    c. In patients with HIV or AIDs, use of spermicides can disrupt the cervical mucus, which may increase viral shedding and HIV transmission to uninfected partners Category 3.
    d. Allergy or sensitivity to spermicide.
    e. Abnormalities in the vaginal anatomy preventing proper insertion or retention of spermicide.
    f. Inability to learn correct insertion technique.
3. Assessment and plan – Client Education (See Contraceptive Technology 21st Edition, 2011 pgs.391-408 for more information)
    a. Clients should be advised to incorporate the use of the condom to increase the effectiveness of spermicidal creams, jellies, foams, suppositories, and film.
    b. Inform client of spermicide effectiveness: pregnancy rate of 28% with typical use and 18% with perfect use (Contraceptive Technology 21st Edition pg. 50).
    c. Provide clients with appropriate fact sheets specific to their product of choice and should be instructed to follow the package insert for directions on use.
    d. Counsel regarding emergency contraception in the event the spermicide is not used according to directions.

4. Side effects and complications
    a. Temporary skin irritation or allergy (male or female).
    b. Unpleasant taste during oral-genital sex.
    c. Failure of suppositories to melt or foam in the vagina, which may decrease effectiveness.
5. In May 2020, a new prescription vaginal gel, Phexxi, became available. Phexxi works by reducing sperm vulnerability to acidic environments (the vagina is an acidic environment). Phexxi is not a spermicide, but prevents pregnancy by changing the pH in the vagina, making it harder for sperm mobility. It can be used similarly to nonoxynol-9 spermicides. Phexxi should not be used in conjunction with vaginal ring methods. Facts sheets for Phexxi can be found here and here.

F. FemCap® (the only cervical cap available in the U.S. and FDA-approved)

1. Non-contraceptive benefit

    Possible protection against sexually transmitted infections affecting the upper genital tract.

2. Subjective data - History

    Cautions - The following conditions may preclude satisfactory use or make use of FemCap® inadvisable:

    a. History of Toxic Shock Syndrome.
    b. CIN or cervical cancer.
    c. Allergy to spermicide, rubber, latex or polyurethane.
    d. Abnormalities in vaginal anatomy that interfere with a satisfactory fit or stable placement.
    e. Vaginal bleeding from any cause, including menstrual flow.
    f. Full-term delivery within the past 6 weeks or recent spontaneous or induced abortion.
    g. Inability of client to correctly insert or remove.
    h. Need for HIV protection.
    i. High risk for HIV – Repeated and high-dose use of the spermicide nonoxynol-9 has been associated with creased risk for genital lesions, which might increase the risk of HIV infection. Category 4.
    j. HIV infection - Use of spermicides can disrupt the cervical mucosa, which may increase viral shedding and HIV transmission to uninfected sex partners. Category 3.

3. Objective data
    a. Obstetric history determines prescription size. There are no precise measurements or custom fitting.
        1) 22mm = Never been pregnant
        2) 26mm = Has been pregnant but didn't deliver vaginally (C-section, miscarriage, abortion)
        3) 30mm = Vaginal delivery
    b. Physical examination as indicated (Section1 Health Care Services)
    c. Laboratory tests as indicated (Section 1 Health Care Services)
4. Assessment and plan – Client Education (See Contraceptive Technology 21st Edition , 2011 pgs. 391-408 for more information)
    a. Review the use and care of the FemCap®.

Section 8: Tier 3 Methods - Barrier Methods

c. Inform client of effectiveness: pregnancy rate of 9.5% for nulliparous client and 20.5% for parous clients (Contraceptive Technology 21st Edition pg. 397).

d. Document that instructions for FemCap® use were reviewed.

e. Document that the client demonstrates the ability to properly insert and remove the FemCap®.

f. Instruct the client to stop using the FemCap® and return to the clinic for evaluation if symptoms of vaginal or cervical irritation develop.

g. Clients who would be successful in using FemCap include those that are highly motivated and have a high level of body literacy, cannot tolerate hormonal methods, and have contraindications to LARC methods.

h. Advise the client of signs and symptoms of Toxic Shock Syndrome (TSS) and instructions given to seek emergency medical care if they occur.

i. Counsel regarding emergency contraception in the event the FemCap® becomes dislodged or is not used properly.

5. Side effects and complications

   a. Toxic Shock Syndrome - sudden high fever, vomiting, diarrhea, dizziness, fainting, weakness, sore throat, aching muscles, and joints and rash (like a sunburn) has occurred in association with use of the cervical cap. Client to seek immediate emergency care with Toxic Shock Syndrome symptoms.

   b. Allergic reaction to rubber, latex, polyurethane or spermicide, or local skin irritation to either client or partner.

   c. Rare cases of vaginal/cervical trauma, including abrasion or laceration.

   d. Foul odor or vaginal discharge if the FemCap® is left in the vagina longer than recommended (48 hours maximum).

6. Follow up visits

   a. The client should return for annual visits and recheck of the FemCap® fit.

   b. The client should return for an examination and to have the cervical cap fit checked six weeks after childbirth, miscarriage, abortion, or pelvic surgery, including LEEP or conization.

A. Definition

1. Fertility Awareness-Based Methods (FABM) may assist clients in understanding how to avoid or achieve pregnancy by providing education on how to predict the days they are most fertile and least fertile using different indicators of fertility. FABMs may also be used to detect a pregnancy, impaired fertility or need for medical attention (i.e. infection). According to the CDC, the failure rate of these methods is 24% within the first year of typical use. See Contraceptive Technology 21st Edition, pages 395-413 for more information.

B. Types of Fertility Awareness-Based Methods

a. Methods Based on Tracking Days of the Menstrual Cycle

i. Standard Days Method is based on predicting ovulation using the client's menstrual history following a standard rule to determine fertile days during a menstrual cycle. If the cycle is consistently between 26 and 32 days long, the Standard Days method considers days 8-19 to be the most fertile days. To prevent pregnancy, clients should avoid sex or use a barrier method during these days. Standard Day Method®. First year probabilities of pregnancy for typical use is 12% and for perfect use is 5%. CycleBeads® is one example of a Standard Days Method; it uses color-coded beads (CycleBeads®) to monitor the days of a client's menstrual cycle and is now available via a smartphone application.

ii. Calendar Rhythm Method has a first-year probability for typical use between 14% and 19%. Perfect use data is not available. **Calendar Rhythm Method is not a commonly used FABM anylonger.**

iii. FABM menstrual tracking methods are contraindicated in clients with irregular cycles, including postpartum until cycle regularity returns.

b. Methods Based on Cervical Mucous Observation

i. Cervical mucous method or Two Day Method® evaluates cervical mucus changes signifying ovulation. Just before ovulation, the amount of mucous made by the cervix noticeably increases, and the mucous becomes thin and slippery. Just after ovulation, the amount of mucous decreases and it becomes thicker and less noticeable. To prevent pregnancy, clients should avoid sex or use a barrier method from the time you first notice any cervical mucous. Unprotected intercourse would be limited to the infertile times following ovulation. To promote pregnancy, sex should occur every other day when the thin and slippery mucous is present.

ii. Billings Ovulation Method™ suggests that the first-year probability of pregnancy is about 3% among perfect users and up to 23% among all users. Assistance of a specially trained instructor is necessary for correct use of this method.

iii. Cervical mucous methods are contraindicated in clients unable to interpret fertility signs correctly, reluctant to observe secretions, and those that have a vaginal infection, intermenstrual bleeding indistinguishable from menses or that masks secretions, or female genital cutting.

c. Methods Based on Tracking Multiple Indicators of Fertility

i. Marquette Method measures hormonal changes during the cycle as well as changes in cervical secretions. First year probability for typical use is 11%.

ii. The Symptothermal or Combined Method: Combines BBT with the cervical mucous method a woman to be more accurate in predicting safe days than if they use any one method alone. Multiple symptothermal applications (i.e. Kindara, Sympto and Lady Cycle) are available. The first year

probability of pregnancy for typical use is 2% and .4% for perfect use in one large German study. However, multiple other studies estimate 33% for typical use.

iii. These methods are contraindicated in clients unable to interpret fertility signs correctly, reluctant to observe secretions, and those that have a vaginal infection, intermenstrual bleeding indistinguishable from menses or that masks secretions, or female genital cutting.

d. Application-Based Methods Using Algorithms

i. Natural Cycles is a FDA approved fertility awareness app for birth control. It involves the client taking a BBT and entering it into the application. Users may also enter menstruation and urinary hormonal data. The app then provides an assessment of their fertility. Studies of Natural Cycles report that the app is 93% effective (studies were done by the Natural Cycles company) in preventing pregnancy with typical use. The research has been criticized by being poorly conducted. The European Journal of Contraception & Reproductive Health Care reported that the 2016 Natural Cycles study calculated "perfect use" incorrectly and that the precision and accuracy of the algorithm the application uses to identify the day of ovulation (based on basal body temperature) has not been established. Contraceptive Technology (21st Edition, pg. 401) reports a 9.8% first year probability for typical use and 1% perfect use probability.

ii. Dynamic Optimal Timing (Dot) is based on statistical analysis of cycle length, timing of ovulation, and variable fecundability of the sperm and ovum to identify fertility status. Perfect and typical use has not yet been assessed. However, theoretical efficacy is estimated between 1% and 3%.

C. Patient education

1. Clients must be screened to determine likelihood of success for these methods. While all temporary methods require integration into the client's lifestyle and social and sexual practices, FABMs require additional attention. FABM education is time intensive and may involve multiple clinic visits during multiple menstrual cycles, especially for those that involve observing, recording, and interpreting fertile signs. This is particularly true for clients with partner(s) who have little or no education, understanding, or commitment to FABMs.
2. FABMs are unforgiving of incorrect or inconsistent use, making typical-use pregnancy rates much higher in most cases than hormonal methods and IUDs. It is critical that clients decide whether they are going to use abstinence or another contraceptive method during their fertile days in order to avoid pregnancy. If clients choose to use another method during their fertile days, this method must also be explained to the client (i.e. condoms).
3. FABMs do not have side effects
4. FABMs do not protect against STIs
5. Couples desiring to use the method out of religious conviction should be referred to local teachers able to provide the religious component. In no case should clinic staff attempt to provide religion-based education.
6. Clients interested in FABMs must take full responsibility for ensuring the sometimes lengthy periods of abstinence (sexual risk-avoidance) and must understand the need to control social situations (shift work, alcohol use, and attention to schedules and details) in the use of the Fertility Awareness-Based Methods. Poor sleep, stress and alcohol use can make FABMs less accurate.

7. Clients with irregular cycles may experience difficulty in using FABMs. Clients who have recently delivered, are currently breastfeeding, have anovulatory cycling (i.e. PCOS), have recently stopped a hormonal contraceptive method, or are approaching menopause may not be good candidates for a FABM.
8. ACOG issued a Fertility Awareness-Based Methods of Family Planning Patient FAQ in April 2015.
9. People with endometriosis should not use fertility awareness methods.
10. FABMs are not recommended for clients unable to abstain from intercourse or use other contraceptive methods during fertile days for personal, partner, or cultural reasons.

D. Referrals

1. Group or one-to-one instruction is strongly recommended to all clients interested in this method.
2. Each clinic should develop its own referrals for Fertility Awareness-Based Methods since this expertise varies from community to community.

E. Documentation

Couple or single partner use of a Fertility Awareness-Based Method should be documented in the client's chart together with the plan for use.

A. Emergency Contraception (EC)

1. May be provided to a woman with a history of unprotected intercourse within the past 120 hours to prevent unintended pregnancy but should be used as soon as possible after unprotected intercourse.
2. Levonorgestrel 1.5 mg. EC may be purchased over the counter without restrictions on age or gender of purchaser.
3. There are no medical contraindications to the use of combined or progestin only emergency contraceptive pills with the exception of pregnancy. If a woman is already pregnant, treatment is ineffective. (Contraceptive Technology 21st Edition, p. 347). Breastfeeding is a category 1 (A condition for which there is no restriction for the use of the contraceptive method) for levonorgestrel and combined oral contraceptive pills used as EC.
4. Ulipristal acetate (UPA) (ella®) is a progesterone agonist/antagonist. Ella® reduces the risk of pregnancy the entire course of 120 hours after unprotected intercourse. Ella® is the EC method of choice for clients with an elevated BMI that do not desire the copper IUD for EC. Ella® is not recommended for breastfeeding clients. Ella® is contraindicated for use in the case of known or suspected pregnancy. The risks to a fetus when ella® is administered to a pregnant woman are unknown. If this drug is inadvertently used during pregnancy, the woman should be apprised of the potential for hazard to the fetus, according to the ella® package insert.
5. A copper-releasing IUD may be used for emergency contraception within 5 days after the first act of unprotected intercourse. Clients should be counseled that the copper IUD is the most effective form of EC, followed by UPA, and then by levonorgestrel, and that these differences are greater with increasing time from unprotected intercourse and increasing weight.

B. Examination/Laboratory

Testing Urine pregnancy test,

if indicated.

If inserting IUD, bimanual exam, cervical inspection, STI screening (See IUD Protocol).

C. Assessment/Plan (See US SPR pgs. 34 -35)

Please also see Contraceptive Technology 21st Edition, pgs. 331-333 for a complete list of pills that may be used for emergency contraception.

D. Follow-Up

1. Initiation of on-going contraception
    a. A contraceptive method can be started immediately after the use of levonorgestrel or combined estrogen and progestin EC. The woman needs to abstain from sexual intercourse or use barrier contraception for 7 days.
    b. Contraception can be started immediately after UPA treatment. Due to UPA's high affinity for binding to progesterone receptors, ulipristal acetate may reduce the effectiveness of a woman's regular contraceptive method, and a rapid return of fertility is likely following treatment with UPA. Therefore, contraception should be continued or initiated as soon as possible. In addition, clients must abstain from sexual intercourse or use barrier contraception for 7 days. The risk that the contraceptive method might decrease the effectiveness of UPA must be weighed against the risk of not starting a regular hormonal contraceptive method. DMPA, implants, and IUDs may be started at the time of UPA. Consider having the client return in 2-3 weeks for a repeat pregnancy test.

a. ParaGard® IUD may be inserted as an alternative to EC pills. (See IUD Protocol).

2. If the patient has not had any bleeding within three weeks of taking emergency contraception or has reason to suspect they may be pregnant, have the client return to the clinic for a repeat pregnancy test.

E. Side Effects and Complications

1. See pages 16-19 for information on side effects and complications with use of the Paragard IUD.
2. No serious complications have been causally linked to emergency contraceptive pills. Short term side effects include: nausea, headache, irregular bleeding, breast tenderness, abdominal pain, dizziness, and fatigue (ACOG, Practice Bulletin, Number 152, September 2015, reaffirmed 2022)

F. Education

1. Emergency contraception information and the emergency contraception progress note form must be reviewed with the client. Consideration should be given to using the progress note as a means of documenting the client's need for emergency contraception. A record must be established for any client receiving a visit for emergency contraceptive services.
2. For some individuals, such as those facing reproductive coercion, repeated use of EC may be the best pregnancy prevention strategy they are aware of, or the one they feel best suits their needs. Consider screening these clients for contraceptive challenges, including coercion.
3. Counseling and documentation should be done regarding birth control methods.
4. There appears to be no harm for repeat use of levonorgestrel emergency contraception. Ulipristal emergency contraception is not recommended for repeated use in the same menstrual cycle.
5. The patient should be given a copy of the FDA package insert provided by the manufacturer of the pills.
6. There should be documentation of patient instructions to return for a follow up visit in three weeks if they do not have a menstrual period for a pregnancy test and/or family planning services.
7. The client must be given emergency contact information.
8. Provide information on emergency contraception regardless of the method the client is using. Consider including a package of emergency contraception to take home to interested clients for use when needed.
9. Please visit the 340B website for guidance on male clients accessing emergency contraception for their female partners. https://www.340bpvp.com/resource-center/faqs/patient-definition/

A. Guidelines

1. Clients applying for tubal ligations will be able to have the procedure done only through those agencies that have agreed to receive funding through a family planning contract and have agreed to handle all provider agreements and billing.
2. Project personnel must be informed that they may be subject to prosecution if they coerce or try to coerce any person to undergo a sterilization procedure.

B. Regulations and Consents

1. All sterilization requests must follow the guidelines of the Department of Health and Human Services.

   Sterilization of clients as part of the Title X Family Planning Program, must be consistent with 42 CFR part 50 subpart B, "Sterilization of Persons in Federally Assisted Family Planning Projects".

   The most recent edition of the guidelines is included in this section.

   Agency personnel must familiarize themselves with these requirements.
2. Physicians may request this information from the delegate agency.
3. Agencies must use the federal consent for sterilization. There are English and Spanish versions of the consent. All sections of the consent must be completed. In accordance with Converge, a consent form in Spanish must be used for those clients who are more familiar with that language.
4. The federal regulations state that the person must be 21 years of age at the time a sterilization consent is obtained and mentally competent. Consents may not be obtained while the person is in labor, under the influence of alcohol or other drugs, or having an abortion.
5. A 30-day waiting period between the time of consent and the time of the procedure is required with no more than 180 days passing between the date of informed consent and date of sterilization.

C. Postpartum Sterilization

1. Consent for sterilizations to be done during the immediate postpartum period (during hospitalization following delivery) must be signed 30 days before the expected date of delivery (EDD). Do not approve unless this 30-day period is met. In the case of a premature delivery, or emergency abdominal surgery, the 30-day consent may be waived if at least 72 hours have passed since the client signed the consent.

2. In order to approve a postpartum sterilization procedure for a pregnant client, the following conditions must exist:

    a. The client prior to pregnancy was a family planning client or is at the present time willing to fulfill all the requirements in order to be counted as a family planning client.

    b. The client signs the request for approval at least thirty days before their estimated due date (EDD).

D. Mental Competence

Clients who are known to be mentally incompetent, defined as individuals who have been found to be mentally incompetent by a federal, state, or local court of competent jurisdiction, shall not receive sterilization services. Clients who are believed to be in counseling or under the care of a psychiatrist, psychologist, or mental health counselor shall receive in-depth counseling prior to making a decision
regarding permanent sterilization.

E. Procedure

Personnel in all agencies must first determine if the client has private insurance, Medicaid, or Medicare. Converge Title X funding should only be used for those who have no other source of payment. For the purposes of this program, a large deductible may be considered enough of a barrier to services that the client is considered to have no coverage. This should be documented in the client's chart.

1. The agency shall negotiate MOUs (Memorandum of Understanding) with providers that allow payment to come from its (agency's) office and that explain the procedure for requesting reimbursement. Converge fiscal staff is available for consultation in arranging referral relationships and MOUs.

2. The agency will notify the client of instructions for setting up an appointment.

3. Agencies receiving sterilization funds will receive these funds through a separate contract. The agency does not submit any client specific information, procedure dates, or provider reimbursement information to the Converge Family Planning Program. Each agency will submit reimbursement requests a maximum of once per month.

4. Any agency providing or referring clients for tubal ligations or vasectomies must establish a follow-up protocol to determine if the client actually had the procedure done and the reason any procedures were not completed. Agencies must maintain a record of all clients sent for referral and document the follow-up to record whether or not the procedure was completed, including the HSG or sperm count, if indicated. Documentation that the provider was paid for the procedure and F/U testing is also needed. This information is necessary for any future audits that may take place. This follow-up information should also be documented in the client's file.

F. Laparoscopy Procedure (Tubal Ligation)

The laparoscopy procedure is the same method as described in the sterilization booklet. In most instances, however, two incisions are made, one at the umbilicus and the other midline approximately 2 inches above the pubic bone.

1. Medical guidelines require that the client must have had a physical exam within the past six months, and should bring the written results with them to the physician appointment. The following are guidelines for selecting appropriate clients:

    a. a.The client must consider body habitus.

b. The client's medical problems must be under current treatment and under control (includes hypertension and diabetes).

c. The client should be informed that the surgeon makes the final decision as to whether the tubal will be done after the initial medical evaluation.

G. Essure

1. Bayer has ceased U.S. sales of the sterilization device, Essure (effective December 2018).

2. Ongoing support services will remain available at Essure.com and EssureMD.com, as well as Bayer's customer call center, 1-888-84-BAYER. You can read more about the company's decision here and here.

H. Tubal Ligation or Vasectomy Procedure Complications

1. Complications arising from a sterilization procedure or an associated procedure (e.g., HSG) are not the financial responsibility of the delegate agency. The delegate agency shall provide clients with information on what is and is not paid for by the program or delegate agency prior to the client signing the consent.

2. Examples of such complications include but are not limited to the following:

a. Bleeding problems at incision sites or internally.

b. Infection on or near sutures or incision sites, or peritonitis (infection inside abdomen).

c. Problems relating to the use of anesthesia, e.g. allergic reactions to drugs; aspiration pneumonia, etc.

d. Perforation of the uterus or fallopian tube

I. Vasectomy

1. Some physicians send a tissue sample to a laboratory following a vasectomy. Consideration of the lab cost for this histology should be included in the negotiated charge from the provider.

2. Converge considers a pre-op exam and a post-procedure sperm count as part of the vasectomy procedure (package of services). Clients are not expected to pay an extra fee for these services.

3. A hospital fee will not be paid for a vasectomy procedure.

4. Complications arising from a sterilization procedure or an associated procedure are not the financial responsibility of the delegate agency. The delegate agency shall provide clients with information on what is and is not paid for by the program or delegate agency prior to the client signing the consent.

5. Examples of such complications include but are not limited to:

a. Bleeding problems at incision site or internally.

b. Infection on or near sutures or incision site.

c. Problems relating to the use of anesthesia, e.g. allergic reactions to drugs, etc.

J. Assistant Physician

An assistant physician fee is not reimbursable for any sterilization procedures.

K. Post Tubal Ligation and Vasectomy Follow-up Appointments

1. The delegate agency is encouraged to include a follow up appointment with the physician as part of the negotiated price in the MOU.
2. This follow up appointment shall be considered part of the package and shall not be billed as a separate visit.
3. The delegate agency may provide follow-up care if the client is not experiencing any complications.

L. Consent and Counseling

Each project should provide, either directly or by referral, voluntary female and male sterilization counseling and procedures for those clients requesting such, in accord with the following:

1. For female sterilization: ACOG's Sterilization of Women: Ethical Issues and Considerations Committee Opinion
2. All clients making inquiry about a sterilization procedure will be given initial counseling by a nurse, nurse practitioner, certified nurse midwife, physician assistant, physician, or allied medical personnel, and will be provided with printed and/or video educational material relevant to the procedure desired.
3. The decision for performing sterilization as a family planning procedure is a matter between a mentally competent individual of legal age and the physician, and must be the voluntary decision of the individual with no coercion. The client should participate in the decision as to the method of sterilization.
4. Each agency must ensure that the individual is given the necessary information to arrive at an informed decision. This must include but need not be limited to:
    a. Information concerning the permanence of the procedure.
    b. Review of available temporary contraceptive methods.
    c. Information concerning the surgical procedure and risks involved (complications and failures).
    d. Information and instructions concerning the need for follow-up, particularly for males.
    e. Information concerning relative merits of male vs. female sterilization in any specific situation (vasectomy as safer and easier procedure).
    f. Information that sterilization should not interfere with sexual function or pleasure.
    g. Information that sterilization will not necessarily resolve pre-existing psychological problems.
5. Consideration should be given to the following as indications for in-depth counseling prior to arriving at the decision to perform voluntary sterilization:
    a. The individual has physical, mental, or emotional conditions that they assume would be improved by sterilization.
    b. The individual is suffering from temporary economic difficulties, which may improve (if this is the basis of the request).
    c. The individual is making this decision during a time of crisis or extreme stress.
    d. The individual or couple is uncertain as to future reproductive goals.
    e. The individual counts on reversing the operation in the case of circumstances such as remarriage or death of children.

f. The individual is seeking sterilization because of pressure exerted by the sexual partner.

g. The individual is young and has never reproduced.

6. Contraindications to sterilization include:

a. Return of reproductive function may be desired.

b. The individual is not of legal age.

c. The individual is not mentally competent to give consent for sterilization.

d. Any evidence that the individual has been coerced.

e. The client has physical problems that place them at high risk for surgery (e.g., history of bleeding disorders or coagulopathies). The relative risk of sterilization as opposed to pregnancy should be evaluated.

f. The client is allergic to any anesthetics. (The physician should assess this relative risk.)

g. An examination of a male client reveals local scrotal pathology. (The physician should assess this relative risk.)

7. Projects receiving Federal funds to support sterilization must obtain the client's informed consent for "non- therapeutic sterilization" at least 30 days prior to the planned procedure. Informed consent shall comprise but not be limited to the following:

a. A fair explanation of the procedures to be followed.

b. A description of the attendant discomforts and risk.

c. A description of the benefits to be expected.

d. An explanation concerning appropriate alternative methods of family planning and the effect and impact of the proposed sterilization, including the fact that it must be considered to be an irreversible procedure.

e. An offer to answer any inquiries concerning the procedures.

f. An explanation that the individual is free to withhold or withdraw their consent to the procedure at any time prior to the sterilization without prejudicing their future care, and without loss of other project or program benefits to which the individual might otherwise be entitled.

g. An interpreter must be provided if the client does not understand the language used on the consent form or the language used by the person obtaining the consent.

h. Suitable arrangements must be made for effective communication for clients who are blind, deaf or otherwise handicapped.

i. The informed consent must be documented by a completed consent form (with all sections completed, including the provider performing the procedure signature). A copy of the completed consent should be included in the medical record. Pamphlets containing information that a client must have in order to give an informed consent have been published for the instruction of clients considering non-therapeutic sterilization. Videotapes on sterilization may be used as well.

j. If the physician performing the sterilization is not the person obtaining the individual's consent, there should be an oral explanation of the above points by such physician in order to be sure that the individual has been fully informed, understands the sterilization procedure, and has freely given consent.

8. Local laws should be followed concerning obtaining consent of the spouse. There is no Federal requirement for spousal consent.
9. "Non-therapeutic sterilization" means any procedure or operation, the purpose of which is to render an individual permanently incapable of reproducing and which is not either (1) a necessary part of the treatment of an existing illness or injury, or (2) medically indicated as an accompaniment of an operation on the female genito-urinary tract. For purposes of this paragraph, mental incapacity is not considered an illness or injury.
10. All males undergoing vasectomy should be given appropriate postoperative semen analysis until aspermia is documented. They and their partners should be provided with other contraceptive measures until their use is no longer necessary.
11. Questions counselors can use with clients considering sterilization:
    a. What are some of your reasons for considering sterilization?
    b. How do you think being sterile might affect your sexuality? Your self-image as a man/woman?
    c. How do you feel about children?
    d. How would you feel about being sterile if you (re)marry? How would you feel if something happened to your present children? If your economic situation were to change?
    e. How long have you been thinking about becoming sterilized?
    f. Have you been through any important life changes recently (such as divorce, abortion)?
    g. Does your partner (if there is one) know about and feel comfortable with your decision?
    h. Do you realize that this procedure is considered permanent and means that you will not be able to parent any additional biological children?

Pregnancy testing and nondirective pregnancy options counseling services are part of the core family planning services as outlined in Providing Quality Family Planning Services (QFP). Per Title X regulation, pregnancy testing must be available at each clinic site, and a prenatal care referral must be given to all clients with a positive pregnancy test result. Pregnancy testing and the test results must be provided to all clients requesting a pregnancy test. Visits for pregnancy testing should include discussion around the client's reproductive life plan.

A. Standard

1. All clients receiving a pregnancy test must be offered their test results, including limitations of the test itself.

B. Subjective Data

1. Clients complete "Request for Pregnancy Test" form or agency-specific form.
2. Data to be included in charting and referral:
    a. Menstrual History
        i. First day of last menstrual period
        ii. Was this a normal period, i.e., amount of flow, time of month?
        iii. If not, when was the last normal menstrual period?
        iv. Are periods usually regular? How often do periods come? How long do they last? Is the flow heavy, medium, scant?
        v. Has the client missed a period(s) before?
    b. Symptoms of Pregnancy Other Than Amenorrhea
        i. Early
            a) Breast tenderness
            b) Nausea or vomiting
            c) Urinary frequency
        ii. Late
            a) Enlargement of abdomen
            b) Fetal movement
    c. Obstetrical History
        i. Number of pregnancies (gravida)
        ii. Number of children (para)
        iii. Number of spontaneous abortions
        iv. Number of therapeutic abortions
        v. History ectopic pregnancies

d. Birth Control History

i. Is the client consistently using a method of birth control? If not, how long have they been having unprotected intercourse?

ii. If a client is presently using birth control, what method, and are they using it correctly?

iii. If a client had been using birth control in the past, what method, when, and why did they discontinue the method?

e. Sexual History

When was the last time that the client had intercourse?

f. Determine if this is a planned/wanted

pregnancy. How do they feel about being

pregnant?

C. Objective Data

1. Physical exam, as indicated

a. Clients with a positive pregnancy test should be counseled to have a physical exam performed as early as possible if not performed at the time of the pregnancy test.

2. Laboratory

a. Urine HCG

b. CT/GC testing

3. Assessment and Plan

a. Offer all clients the results of their tests, including accuracy and the chance for false negative or false-positive results.

D. Counseling Results

1. Positive test results

a. A prenatal care referral must be given to all clients with a positive pregnancy test regardless of the client's desire for the pregnancy (42 CFR 59.14)

b. Nondirective pregnancy options counseling and information may be offered to pregnant clients. Nondirective pregnancy counseling may include information on abortion, prenatal care, delivery, infant care, foster care, and adoption. Any trained and competent health care staff member may provide this counseling.

c. Nondirective pregnancy options counseling must not include referring clients for abortion services. This includes all written and verbal abortion referrals (42 CFR 59.14).

d. The USPSTF recommends that clinicians provide or refer pregnant and postpartum persons who are at increased risk of perinatal depression to counseling interventions (Grade B).

Help the client to explore alternatives and feelings as realistically as possible. Assist the client in understanding the impact of this life decision.

e. Evaluate the client's support systems. Which significant others in the client's life know about the pregnancy? How do they feel about the pregnancy and about the client's decision? Staff should realize that the kind of support that the client receives in decision-making is very important.

   i. Does the father of the child know? Is he involved in the decision-making? Does the client communicate well with the father of the child?

   ii. Do the parents know? Are they involved in the decision? Does the client communicate well with their parents?

f. Address the psychosocial implications of a positive test.

   i. Does the client have personal goals, i.e., education, career, and are these congruent with parenthood?

   ii. Does the client already have a child, or have they been involved in raising siblings, and can they utilize those experiences in decision-making?

   iii. Are they ready to be responsible for another person for at least eighteen years?

   iv. Is the client prepared for the change in lifestyle and identity?

   v. Are they ready for the financial responsibility?

   vi. Are they aware of the emotional responsibility of being a parent?

g. If the client has arrived at a decision you should ask, "Will you share with me how you made your decision?"

h. If the client is unable to decide, decision counseling should be initiated. The extent of the counseling is at the discretion of the provider and should be determined by the client's needs and the period available. Particular efforts should be made when counseling adolescents. Additional support may be available through a social worker or local mental health clinic.

2. Continuing the pregnancy

a. Provide information on the importance of early and continued prenatal care, basic guidelines regarding drugs, alcohol, smoking, and diet during pregnancy and referral to prenatal services.

b. Ensure that all clients understand the importance of prenatal care early in pregnancy and on a continuing basis, even if the client has not determined whether the pregnancy will be continued.

c. Emphasize the dangers to the fetus of smoking, alcohol and substance use.

d. Provide brochures regarding healthy behaviors during pregnancy and referrals to programs that help clients reduce or stop unhealthy behaviors.

e. Review danger signs and symptoms of pregnancy.

f. Counsel about the impact of diet on fetal development and appropriate nutrition information, particularly regarding folic acid supplementation.

g. Give information about Medicaid eligibility if applicable. The clients may also be referred to a Prenatal Plus or Nurse Home Visitor program if they meet eligibility criteria for either program.

Section 12: Pregnancy Testing and Nondirective Pregnancy Options Counseling

h. Agencies are encouraged to follow-up with clients to determine if they are receiving prenatal care.

i. Document counseling, required prenatal care referral and follow up attempts in the client's record.

j. Pregnant clients should be counseled prenatally about the effective option of immediate postpartum LARC. Systems should be in place to ensure that clients who desire LARC can receive it during a comprehensive postpartum visit if immediate postpartum placement is not provided.

3. Adoption

a. Staff responsible for nondirective pregnancy options counseling should be able to impart accurate information regarding adoption. This should include services offered by agencies, birth mother rights, a basic overview of the process, and appropriate referrals. It is important that staff doing nondirective pregnancy options counseling be well informed of current regulations.

b. Clients may be made aware of counseling, financial assistance, housing, and other services available through adoption agencies. In addition, the client may be given appropriate referrals to reputable agencies that can provide more extensive, non-coercive counseling. Each family planning agency should explore the adoption agencies in their community, determine services provided, qualifications of staff (adoption agency professionals' education and professional credentials), and assure coercion is not used.

c. A counselor can affect the decision made by a young person, particularly when they learn of an unintended pregnancy. Tone of voice, body language, and wording of various options can make a difference in the way a client looks at their choices. Staff providing nondirective pregnancy options counseling should have thoroughly explored their own views toward adoption. Exploring potential biases toward adoption can allow staff to put their own feelings aside when counseling.

d. Basic prenatal education, discussion of pregnancy danger signs and referrals for prenatal care, Medicaid and/or Prenatal Plus or Nurse Home Visitor program should always be offered as indicated (see previous section).

4. Pregnancy Termination (42 CFR 59.14)

a. Referral for abortion is prohibited under May 2019 Title X regulations, except for documented emergency care reasons. In cases where an abortion referral is made for emergency care reasons, a nurse practitioner, certified nurse midwife, physician assistant, or physician must make the referral.

i. Discuss pregnancy termination as a legal option for a client with a positive pregnancy test.

ii. Elicit how the client feels about pregnancy termination. Be sensitive to religious and cultural backgrounds. Assess for coercion. Assess whether the client has a support system of family and friends.

iii. Provide basic information about the procedure. As appropriate, explain, medical abortion, vacuum aspiration, and amnio abortion procedures, time limitations, and consent requirements. If additional medical information is requested beyond basic abortion information, a nurse practitioner, certified nurse midwife, physician assistant, or physician must be included in the discussion.

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iv. Inform minors that Mississippi requires parental notification or a judicial bypass prior to a minor obtaining an abortion.

v. Discuss methods of post-abortion birth control options. Clients should be counseled about the effective option of immediate post abortion LARC. Systems should be in place to ensure that clients who desire LARC can receive it during a follow-up visit.

1. Negative Test Results

b. Work with the client to determine other causes of delayed/missed menses including:

i. Pregnancy, but with hormone levels too low for a positive test and/or testing done too soon after the last act of unprotected intercourse.

ii. Not pregnant, with delay or absence of ovulation.

iii. Absence of menses due to medication, especially some hormonal contraceptives.

c. If the client is not using birth control and desires pregnancy, the following information should be given:

i. Information about optimizing chances of conception (i.e., timing and frequency of intercourse).

ii. The availability of infertility services, if the client has been unable to conceive for 1 year or more (six months if age $\geq$ 35).

iii. The impact of diet on fetal development, specifically, folic acid supplementation.

iv. Preconception counseling.

d. If the client is not using birth control and does not want to become pregnant, provide the following information and services:

i. Contraceptive services. Optimally, offer same day contraceptive services. If this is not possible, the client should be encouraged to return for a visit to obtain contraceptive services. Offer emergency contraception and information about emergency contraception.

ii. Reinforce the fact that client information is confidential, and that the family planning clinic is available as a resource for birth control information and pregnancy determination.

iii. If the client cannot "jump start" a hormonal method of birth control at the visit, an interim method of birth control should be made available (e.g., condoms).

iv. If the client desires to start a LARC method and the method cannot be provided on the day of visit, offer and provide a bridge method until the client can return for a LARC method.

e. If the client is using birth control, provide the following information:

i. Education, as appropriate, about the birth control method. Correct any misinformation leading to incorrect usage. If the client is not using a method correctly, consider providing emergency contraception as indicated.

ii. Reinforce the fact that the family planning clinic is available as a resource for emotional support, birth control information, and pregnancy determination, and that all information is confidential.

iii. If appropriate, have the client return to clinic in two weeks for a repeat pregnancy test if menses have not occurred or have them return 10-14 days after the last act of unprotected intercourse.

2. Document all test results, counseling and follow-up in the client's record.

Section 13: Achieving Pregnancy and Basic Infertility Services

Basic infertility services and counseling around achieving pregnancy are included as core family planning services in the Providing Quality Family Planning Services Recommendations (QFP). Pages 14-16.

Converge Family Planning Programs must provide basic infertility service including basic education and fertility assessment, as indicated. Basic services include history and physical exam, laboratory testing (i.e. hgb, CT/GC, etc.), counseling, and appropriate referral for those requiring further assessment.

A. Subjective

Comprehensive medical history, including:

1. Detailed reproductive history; sexual history including sexually transmitted infections and PID;
2. History for clients should include menstrual history; medical conditions associated with reproductive failure (e.g. thyroid disorders, hirsutism or other endocrine disorders) current medications (including prescription, non-prescription, and herbal) and allergies; prior surgeries; previous hospitalizations; serious illness or injuries; cervical cancer screening and any follow up treatment (QFP page 15);
3. History for male clients should include systemic medical illnesses such as diabetes mellitus, prior surgeries, medications and allergies, lifestyle exposures, gonadal toxin exposure including heat (QFP page 15);
4. Duration of infertility; previous tests and treatment; contraceptive history; coital frequency and timing;
5. Number of pregnancies, spontaneous abortions and current lactation status; if previous pregnancies were conceived with a different partner;
6. Length of time required to initiate each pregnancy;
7. Complications of any pregnancy.

B. Objective

1. Physical examination with special attention to body habitus, BMI, fat and hair distribution, acne, secondary sex characteristics, abnormalities of the thyroid gland, galactorrhea, and pelvic exam.
2. Male physical exam includes examination of the penis; including the location of the urethral meatus; palpation of the testes and measurement of their size; presence and consistency of both the vasa and epididymis; presence of a varicocele; secondary sex characteristics including body habitus, hair distribution and breast development; and digital rectal exam.
3. Appropriate laboratory testing, including a pregnancy test and STI screening. The QFP recommends a semen analysis for male clients and referral for further evaluation if the test is abnormal. Additional testing for women may include TSH and prolactin levels, FSH if menopause is suspected.

C. Plan

1. Client Education and Counseling
    a. Anatomy and physiology;
    b. Menstrual cycle and fertile periods;
    c. Timing of intercourse: Every 1-2 days beginning soon after the menstrual period ends. The cycle day of ovulation can be estimated by subtracting 14 from the number of days in a woman's usual menstrual cycle– e.g. day 14 in a 28-day cycle and day 16 in a 30-day cycle;
    d. Methods or devices designed to determine or predict ovulation, fertility awareness techniques, and optimizing timing of intercourse;
    e. Counsel regarding health issues that can reduce fertility: e.g. being overweight (or underweight in women), smoking, excessive alcohol consumption, recreational drugs, most vaginal lubricants;
    f. Validation of feelings/anxiety about fertility issues.
2. Referral
    a. Referral is indicated with report of regular, unprotected intercourse with the same partner for one year or more without conceiving.

Section 13: Achieving Pregnancy and Basic Infertility Services

b. Typically, the client and partner should try to conceive for 12 months before being referred, however; a referral should be expedited in the following circumstances:

- Woman is over the age of 35;
- History of irregular menstrual cycles;
- Man has history of bilateral cryptorchidism or other infertility risk factors or concerns;
- Known history of a disease or a condition in either partner which could cause fertility problems (i.e., previous pelvic surgery, PID, ectopic pregnancy or symptoms suggestive of endometriosis in the woman or mumps for the man);
- Neither partner has ever produced a pregnancy despite having unprotected intercourse.

D. Resources

1. The American Society for Reproductive Medicine provides resources for both clients and health professionals.
2. Resources are also available from the CDC Reproductive Health - Infertility
3. American Urological Association offers clinical guidelines and best practice statements.
4. CTCFP Basic Infertility Services in Family Planning Settings on demand webinar

Section 14: Preconception and Interconception Health Services

A. Preconception and Interconception Counseling

Emphasize the importance to family planning clients on establishing a reproductive life plan. Discuss a reproductive life plan with all clients receiving contraceptive, pregnancy testing, and counseling, and basic infertility, sexually transmitted infection and preconception health services. (QRP pg. 7).

Use the One Key Question®, "Would you like to become pregnant in the next year?" to make an initial assessment of a client's plans for pregnancy and contraceptive needs.

Further questioning may include asking if the client has children now, does the client want to have children (or more children) in the future, and how many children the client would like to have and when.

Provide preconception counseling as a part of family planning services, as appropriate. Couples or individuals planning a pregnancy, seeking infertility services, or at high risk for an unplanned pregnancy should be offered preconception counseling. Clients contemplating pregnancy within the next year should be given the opportunity for special counseling prior to discontinuing their method, with the objective of improving the outcome of a planned pregnancy. Before, Between & Beyond is a preconception resource and training resource for both male and female clients.

1. Female comprehensive health history and screening
    a. Medical history, including heart disease, hypertension, anemias or blood disorders, liver disease, diabetes, epilepsy, asthma, renal disease, SLE and Rheumatoid arthritis, thyroid disease.
    b. Reproductive and sexual health history including previous pregnancy problems, preterm delivery, stillbirth, recurrent pregnancy loss.
    c. STI history including genital herpes, HIV, Hepatitis B, chlamydia, gonorrhea, syphilis.
    d. Medication history.
    e. Occupational and environmental exposures history.
    f. Substance use disorder (SUD) screening. SAMHSA also provides resources for health care providers. Clinics should have SUD community referral resources available for clients in need of services. More information can be found on the Adolescent SBIRT website titled, Preparing the Workforce to Implement SBIRT through Training, Technical Assistance, and Evaluation.
    g. Social history including intimate partner violence (IPV). Clinicians should screen clients of childbearing age for intimate partner violence, such as domestic violence, and provide or refer clients who screen positive to intervention services. See Section 24 for more information on IPV screening.
    h. Nutritional history.
    i. Family history, including anemias or blood disorders, diabetes, genetic conditions or birth defects.
    j. Screen for immunization status including Rubella immune status and for age appropriate vaccinations such as influenza, Tdap, MMR, varicella, pneumococcal and meningococcal, Hepatitis B

k. USPSTF recommends screening for depression in the general adult population, including pregnant and postpartum clients. Screening should be implemented with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up (B recommendation) (USPSTF Screening for Depression Adults 2016). "Screening should be implemented with adequate systems in place. "Adequate systems in place" refers to having systems and clinical staff to ensure that patients are screened and, if they screen positive, are appropriately diagnosed and treated with evidence based care or referred to a setting that can provide the necessary care" (JAMA Volume 315, Number 4, January 26, 2016).

Consider using the Patient Health Questionnaire-2 (PHQ-2) as a first step to assess the need for more in-depth screening and referral for care.

In the last 2 weeks:

- Have you had little interest or pleasure in doing things?
- Have you felt down, depressed or hopeless?

A "yes" answer to either question is considered a positive screen. The Health Team Works web site provides more in-depth screening tools such as the Patient Health Questionnaire-9 (PHQ-9) or for women who are pregnant or have recently had a baby, the Edinburgh Postnatal Depression Scale.

Clinics must have mental health referral resources available for clients in need of services.

12. Male comprehensive health history and screening
    a. Past medical and surgical history that may impair reproductive health such as genetic conditions, history of reproductive failures, conditions that impair sperm quality such as obesity, diabetes mellitus, and varicocele.
    b. Environmental exposures, hazards and toxins.
    c. Tobacco, alcohol and drug use, including opioid misuse and abuse.
    d. Screen for immunization status and for age appropriate vaccinations such as influenza, Tdap, MMR, varicella, pneumococcal and meningococcal, Hepatitis B.
    e. STI history including genital herpes, HIV, Hepatitis B, chlamydia, gonorrhea, syphilis.
    f. Screen for depression when staff assisted depression care supports are in place to ensure accurate diagnosis, effective treatment, and follow up. (QRP pg. 17)

    A mental health resource for men: http://mantherapy.org/

13. Physical exam may include
    a. Height, weight, and body mass index
    b. Blood pressure
14. Lab tests as indicated

15. General education

    a. The need for early and continuing care during pregnancy, with the required referral to a prenatal care provider.

    b. The importance of good nutrition, including the addition of 400-800 µg of folic acid supplemented per day to decrease the risks of neural tube defects. The importance of being a healthy weight before and during pregnancy. January 2017, the USPSTF released a final summary for "Folic Acid for the Prevention of Neural Tube Defects: Preventive Medicine" and assigned the recommendation a Grade "A". This recommendation concludes that all clients who are planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg of folic acid.

    c. Warnings regarding the use of tobacco, alcohol, and drugs during the preconception period as well as during pregnancy.

    d. Counseling regarding HIV testing. The standard is for all pregnant clients to be tested, regardless of risk status (Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant women in Health Care Settings, MMWR September 22, 2006/55 (RR14); 1-17).

    e. The importance of being up to date on immunizations prior to pregnancy.

    f. The importance of spacing pregnancies.

    g. Explanation regarding referrals for care as indicated.

16. Recommendations for Stopping Birth Control Methods

    a. Oral contraceptive/contraceptive patch/contraceptive vaginal ring

        - There is no evidence to recommend that a period of time elapse between the cessation of hormonal contraceptive use and initiation of a planned pregnancy.
        - Clients may be advised to return for evaluation if menstrual periods do not resume six to eight weeks after cessation of these hormonal contraceptives.

    b. IUD

        No special recommendations

    c. Depo-Provera

        Since ovulation may take as long as 9-12 months to return, it is advisable to have the client plan to stop the injections up to a year before they wish to become pregnant, and to use another method of birth control until conception is desired.

    d. Contraceptive implant

        No special recommendations

Section 15: Sexually Transmitted Infections (STI) and HIV Screening Services

STI services, including HIV testing, are one of six core family planning services, which also include contraceptive services, pregnancy testing, nondirective pregnancy options counseling, achieving pregnancy, basic infertility services, and preconception health. (Providing Quality Family Planning Services Recommendations of the CDC and the US Office of Population Affairs (QFP) Pages 17-20). Providers should consult the Centers for Disease Control and Prevention (CDC) Sexually Transmitted Diseases Treatment Guidelines, CDC STD Guidelines 2015 (MMWR 2015; 64 (No. 3), the 2021 CDC STI Treatment Guidelines Update for GC, and the 2020 Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services Report (STD QCS). The CDC treatment app provides easy access to treatment guidelines.

Other resources:

- National Institutes of Health (NIH) HIV/AIDS Treatment, Prevention and R esearch
- CDC STD web site includes c lient handouts http://www.cdc.gov/std/
- UCSF Clinician Consultation Center

A. STI Prevention includes
   1. Risk reduction counseling.
   2. Pre-exposure vaccination: HPV, Hepatitis A and B.
   3. Barrier methods: single-use internal condoms or external condoms.
   4. Note: Spermicides containing N-9 may disrupt genital or rectal epithelium and have been associated with an increased risk of HIV infection. Condoms with N-9 are no more effective than condoms without N-9. Therefore, N-9 alone or in a condom should not be recommended for STI or HIV prevention. (2015 CDC STD Treatment Guidelines, pg. 5)
   5. Retest after STI treatment to check for re-infection (e.g. 3 months after treatment for chlamydia or gonorrhea).
   6. Abstinence (sexual risk-avoidance) and reduction of number of sex partners.

B. For each STI, the CDC Treatment Guidelines generally include the following information:
   1. Diagnostic considerations
   2. Treatment, recommended and alternative regimens
   3. Management of sex partners
   4. Follow up
   5. Special considerations such as pregnancy or HIV infection

Section 15: Sexually Transmitted Infections (STI) and HIV Screening Services

C. Please consult the CDC Treatment Guidelines directly regarding STI screening and treatment. The following is general information regarding providing STI services and topics specific to family planning.

1. History as indicated
    a. Signs and symptoms such as unusual discharge, presence of lesions, lower abdominal, scrotal or pelvic pain, fever/chills, dysuria, dyspareunia, spotting between periods or with intercourse and duration of symptoms
    b. Number of partners, any new partners in the last 60 days, partners are men, women or both
    c. Known recent exposure to STI
    d. Positive STI test in the past year
    e. Vaginal, oral, or anal intercourse
    f. LMP, any unprotected intercourse since LMP, contraceptive method using, pregnancy signs and symptoms
    g. Breastfeeding
    h. Medication allergies
2. Examination
    a. BP, heart rate and temperature, if indicated
    b. Throat exam if history includes oral intercourse
    c. Abdominal tenderness or masses
    d. Regional or generalized lymphadenopathy
    e. Visual inspection external genitalia for discharge or lesions
    f. Visual inspection vagina and cervix for discharge or lesions, cervical friability
    g. Uterus/ovaries or scrotal contents – palpation for uterine and adnexal tenderness, cervical motion tenderness
    h. Anal exam if history includes anal intercourse
3. Labs may include
    a. Chlamydia –gonorrhea Nucleic Acid Amplification Test (NAAT). Specimens of choice: urine for male clients, self-collected vaginal or urine for female clients..
    b. Provide CT/GC test annually for females 24 and younger, as well as any woman that is symptomatic (mucopurulent cervicitis and urethritis). Recommendation for clients with hysterectomy - urine specimen. Clients with a positive GC test result should be tested for HIV and syphilis. Best practices determined to increase CT/GC screening percentages in Family Planning clinics include:
        - Screening at all qualifying family planning visit types, which include annual visits, express visits, emergency contraception visits and pregnancy test visits
        - Change clinic flow for routine collection of specimens
        - Using opt-out language with clients
        - Provider EHR reminders to screen clients or use of a tracking system
        - There is an ongoing disproportionate burden of STIs among certain racial and ethnic groups, young people between 15-24 years old, and among women (who account for a disproportionate burden of severe STI outcomes and medical costs). The burden has worsened with the COVID pandemic. Offering telehealth, self-testing and self-collection, and mail order STI testing kits are strategies for increasing STI screening and access to testing and treatment.

c. Wet prep, if indicated

d. Pregnancy test, if indicated

e. Syphilis test, if indicated. The CDC currently recommends screening with a non-treponemal test (RPR or VDRL) and confirmation with a treponemal test (TPPA or FTA-ABS). Many laboratories are switching to screening tests based on detection of treponemal antibody: enzyme immunoassay (EIA) or chemiluminescent immunoassay (CIA). Check with your lab regarding the test used and interpretation. Syphilis screening guidelines for the adolescent client can be found here. Review this pamphlet if your clinic is considering adding rapid syphilis testing to your list of services.

f. HIV (go to H. for more information)

g. Hepatitis C

CDC Recommendations for the Identification of Chronic Hepatitis C Virus Infection among Persons Born During 1945–1965:

1) In addition to testing adults of all ages at risk for HCV infection, CDC recommends:
2) Adults born during 1945–1965 should receive one-time testing for HCV without prior ascertainment of HCV risk (Strong Recommendation, Moderate Quality of Evidence)
3) Testing should be initiated with anti-HCV. A reactive result should be followed by nucleic acid test (NAT) for HCV RNA.
4) All persons identified with HCV infection should receive a brief alcohol screening and intervention as clinically indicated, followed by referral to appropriate care and treatment services for HCV infection and related conditions.

4. Management of sex partners

a. All sex partners of clients who have a positive STI test should be evaluated and treated if their last sexual contact with the client was within 60 days before onset of symptoms or diagnosis of infection in the index client. If a client's last sexual intercourse was > 60 days before onset of symptoms or diagnosis, the client's last partner should be treated.

b. For clients with a lab confirmed positive CT or GC whose partner's treatment cannot be ensured or is unlikely, consideration should be given to the use of expedited partner therapy (EPT) (CDC STD Treatment Guidelines 2010, pg. 52)., except in cases of men who have sex with men (MSM). EPT is not routinely recommended for MSM clients due to the high risk of coexisting/undiagnosed infections (i.e. HIV and syphilis) among their partners, and limited data in the effectiveness of EPT in reducing persistent or recurrent CT among MSM. For additional information visit: https://www.cdc.gov/std/ept/gc-guidance.htm

5. Education

a. Provide the client information about the STI and the medication prescribed for treatment.

b. Inform the client of complications of untreated STIs, including PID, hospitalization, and infertility for women and epididymitis and prostatitis for men, increased risk of HIV transmission, disseminated GC, reactive arthritis.

c. Clients should be instructed to abstain from sexual intercourse until therapy is completed and they and their partners no longer have symptoms. If one-day treatments have been used, advise refraining from intercourse for 7 days following treatment. In cases where compliance is doubtful, recommend condom use and provide a supply of condoms.

6. Follow up

a. Clients with uncomplicated CT or GC who have been treated with any of the recommended regimens need not return for a test of cure. However, advise the client to be retested in 3 months after treatment. If the client does not seek retesting in 3 months, encourage retesting if the client presents to the clinic within the next year.

b. Clients who have symptoms that persist after treatment should be further evaluated.

c. Appropriate resuscitation equipment must be available in the clinic and clinic personnel must be up to date in its use if parenteral medications are used.

7. Reporting procedures

a. State law requires that positive STI tests be reported by the provider to the Mississippi Department of Health Registry. Clinic staff members are responsible for completing the state reporting form, including treatment information and faxing it to the STD Registry. See form for instructions.

b. Clinic sites using a lab other than the state lab must report both positive and negative CT and GC test results to the MSDH STI-HIV Section for prevalence monitoring.

D. CT/GC Screening: A Priority in Title X Family Planning Clinics

1. All female clients 24 years old and younger must have a screening CT/GC test annually. If the test is not done, there should be documentation as to the reason it was not done. Annual screening is to be on a sliding scale fee schedule. Clients who present for revisits should be tested as indicated. All screenings at revisits may be charged as non-required services. Clinics are advised to waive the fee if it is a barrier to testing.

2. On December 17, 2020, the CDC released updated treatment guidelines for uncomplicated GC infections in adults and adolescents. The updated recommendations for treatment of uncomplicated GC is to treat with one 500mg intramuscular (IM) injection of ceftriaxone. Treatment for coinfection with Chlamydia trachomatis (CT) with 100mg of oral doxycycline twice daily for 7 days should also be administered when CT infection has not been ruled out. Doxycycline 100mg PO twice daily x 7 days has been proposed as the preferred treatment of known CT infection (in absence of contraindications to doxycycline). At this time, Azithromycin 1gm PO remains an adequate treatment for CT. The MMWR containing the update to CDC's treatment guidelines for GC infection can be reviewed here. The 2021 release of the CDC's STI Treatment Guidelines can be found here: https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf

3. The CDC Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services, 2020

4. USPSTF added a wider variety of counseling options, including brief interventions lasting less than 30 minutes (i.e. SBIRT) to STI prevention recommendations in December 2019. The USPSTF continues to state there is not enough evidence to recommend for or against behavioral counseling for adolescents who aren't sexually active or for adults who aren't at increased risk. Grade: B Recommendation

E. Incorporation of ACOG's Primary and Preventive Care: Periodic Assessment Guidelines in to STI screening and treatment care

1. Converge Family Planning Program clinic providers have incorporated ACOG annual women's health care and well woman recommendations (http://www.acog.org/wellwoman) into practice. A pelvic examination (including visualization and inspection of external genitalia, vagina, and cervix, and bimanual exam) is not recommended for clients until age 21, unless indicated by medical history. Female clients also are seen in the clinic for express visits in which they are provided contraceptive counseling and a method of contraception without the provision of an exam. Asymptomatic male clients are also provided an opportunity for an express visit for contraceptive counseling and STI screening. Clients are asked to return to the clinic at a later date for a comprehensive history and an exam as indicated by the client's age or health history. Clinics have the capability of providing genital chlamydia and gonorrhea screening for asymptomatic clients without the necessity of performing an exam with the use of urine based or vaginal self-collected swabs for females and urine-based testing for men.
2. Providing chlamydia and gonorrhea screening to asymptomatic clients without requiring an exam helps reduce barriers to screening. Converge Family Planning clinic sites have adopted the practice of treating asymptomatic clients who have had screening chlamydia or gonorrhea testing without an exam and a positive test without performing an exam prior to treatment.
3. Clients who have received chlamydia and gonorrhea test screening without the performance of an exam and who have a positive chlamydia or gonorrhea test must be questioned regarding complaints or reports of STI symptoms and the possibility of pregnancy before treatment is provided. A physical exam should be provided to clients who report STI symptoms. An exam is particularly important to rule out complications of chlamydia and gonorrhea infections such as pelvic inflammatory disease (PID). Symptoms may include recent pelvic pain, pain with intercourse, or unusual discharge or bleeding.
4. Clients who have a positive chlamydia or gonorrhea tests, who received a screening chlamydia or gonorrhea test without an exam being performed and continue to be asymptomatic for STIs may be provided treatment without an exam being performed prior to treatment. Follow the RHNTC STI Testing and Treatment protocol.
5. Clients' partners should be treated as outlined in the STI Testing and Treatment protocol.
6. Clients should be counseled regarding STI prevention.
7. Clients should be counseled regarding the signs and symptoms of STIs and told to return to the clinic if any develop.
8. A repeat chlamydia or gonorrhea test should be offered 3 months after treatment to rule out re- infection.

F. Expedited Partner Therapy

1. The use of EPT in Mississippi is done with the approval of the State Board of Health.
2. Client selection: client has a lab confirmed positive CT and/or GC and partners of client. EPT is contraindicated for CT or GC infections in men who have sex with men (MSM).
3. Client should be counseled to encourage their partner to present to clinic or private provider for testing and

treatment; however, if partner(s) is not willing or able to be evaluated, then the client should be encouraged to use EPT. If the client selects EPT, then the client should be counseled to tell the partner(s) to read all the information in the partner pack before taking the medication

4. EPT is carried out with the use of "partner packs." A client may be offered up to 3 (three) partner packs. Partner packs contain the appropriate treatment drug for either chlamydia, gonorrhea, or both, information about the infection, and information about the medication(s) and how to take it.

5. Any medication dispensed as EPT must be properly labeled and logged out in the clinic's pharmacy log. If possible, collect the partner name, date of birth, and phone number. If unable to collect this partner information, use "Partner #1," "Partner #2," or "Partner #3" for the logbook and the label. Assign an Rx number as per usual, as well as provider name, lot #, expiration date, and instructions for use. Label is placed on the medication container.

6. Documentation in the client record must include whether EPT was offered, whether it was accepted, and how many and what type of EPT were given. If an agency chooses to use such a checklist then documentation in the client record should also indicate that this checklist was completed and signed.

G. National HIV Recommendations

1. Title X program priorities include HIV prevention education, testing, and referral in accordance with Title X program requirements and nationally recognized standards. The incorporation of CDC's "Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in Health Care Settings" (CDC Revised Recommendations for HIV Testing), published in 2006, into family planning clinical services is a key issue for the federal Title X program. (Centers for Disease Control and Prevention. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings. MMWR 2006;55 (No. rr-14 [1-17]) See the following link for the full report: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm

2. The U.S. Department of Health and Human Services (HHS) has proposed the Ending the HIV Epidemic: A Plan for America initiative to end the HIV epidemic in the U.S. within 10 years. HHS also has a HIV National Strategic Plan for the United States: A Roadmap to End the HIV Epidemic (2021-2025).

3. The CDC released the Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention in 2020. The Compendium is organized into five chapters: Pre-Exposure Prophylaxis (PrEP), Structural Interventions, Linkage to, Retention to, and Re-engagement in HIV Care, Medication Adherence, and Risk Reduction.

4. The CDC Recommendations for HIV Testing include the following:

   a. Routine screening for HIV infection for all clients aged 13-64 years unless the prevalence of undiagnosed HIV infection is documented to be less than 0.1 %.

   b. In the absence of existing data for HIV prevalence, health care providers should initiate voluntary HIV screening until they establish that the diagnostic yield is less than 1 per 1,000 clients screened, at which point such screening is no longer warranted. Subsequently, health care providers should test clients who are at high risk for HIV at least annually.

   c. All pregnant clients in the US should be tested for HIV infection as early during pregnancy as possible (CDC Revised Recommendations for HIV Testing).

Section 15: Sexually Transmitted Infections (STI) and HIV Screening Services

5. The US Preventive Services Task Force (USPSTF) provides HIV screening recommendations, which also recommend expanded screening for HIV infection. The USPSTF recommends that:
    a. Clinicians screen for HIV infection in adolescents and adults ages 15-65 years. Younger adolescents and older adults who are at increased risk should also be screened (Grade: A).
    b. Clinicians screen all pregnant clients for HIV, including those who present in labor who are untested and whose HIV status is unknown (Grade: A)
    c. An approach to screening intervals, since there is not sufficient evidence to determine optimum testing intervals, is one-time screening of adolescents and adults to identify clients who are HIV positive, then provide repeat screening for clients at risk for HIV infection. Individuals at very high risk for HIV infection should be screened at least annually.
6. It is imperative that the clinic staff be educated about HIV/AIDS prior to instituting any counseling, education, or referral. This is to avoid any misinformation, as well as to ensure sensitivity and confidentiality.
    a. The Human Immunodeficiency Virus (HIV), the virus that causes Acquired Immune Deficiency Syndrome (AIDS), is transmitted by blood and body fluids.
    b. The HIV antibody test is a test for the presence of HIV antibody, not a test for AIDS.
    c. The body will produce HIV antibodies three weeks to six months after infection with HIV.
    d. Due to this time frame, it is important to consider the client's risk when interpreting HIV antibody test results.
    e. The type of exposure, the length of time since last exposure, and previous test history are all important factors.
    f. Return visits for HIV testing are recommended at 1 month and 3 months post exposure.
7. HIV infection leads to immune dysfunction and deficiency. In untreated individuals, the time between HIV infection and the development of AIDS varies from a few months to many years, with an estimated median time of approximately 11 years. (2015 CDC STD Treatment Guidelines)
8. Early diagnosis of HIV infection, prompt referral, and ensuring linkage to care and support services can help improve the health of the individual tested, and reduce the risk of HIV transmission to others.
9. The family planning and prenatal settings provide a climate conducive to HIV risk reduction counseling and HIV/AIDS prevention messages.

I. Recommendations for Testing

1. Each new family planning client must be offered HIV education, including information about pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for HIV prevention, and HIV testing information. Family planning clinic staff should provide community resources for the provision of PrEP and PEP for clients in need of these services.
2. All family planning clients should receive an educational handout on HIV and HIV testing.
    a. All family planning clients should be offered a one-time screening HIV test. Repeat screening should be based on client risk for HIV infection.
    b. The client may be tested at the family planning clinic site, or referral may be made to an HIV testing site or medical provider, with staff experienced in HIV testing.

3. Testing resources
    a. Mississippi's Public Health's website provides testing services and locations
    b. CDC National HIV and STD Testing Resources https://gettested.cdc.gov/
    c. http://www.cdc.gov/hiv/testing/laboratorytests.html. Many labs are moving to a 4th generation HIV test. Discuss the specifics of testing with the lab the clinic uses.
4. Point of Care (POC) testing using FDA-approved rapid HIV tests is recommended so that clients receive their test results on the day of their clinic visit.
5. The CDC HIV Testing Recommendations contain the following provisions:
    a. Voluntary HIV screening is recommended for clients in all health care settings after the client is notified that testing will be performed unless the client declines (opt-out screening).
    b. Oral or written information should include an explanation of HIV infection and the meaning of positive and negative results. The client should be offered an opportunity to ask questions and to decline testing.
    c. Persons at high risk for HIV infection should be screened for HIV at least annually.
    d. Repeat screening of persons not likely to be at high risk for HIV should be performed based on clinical judgment.
    e. Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass HIV testing.
    f. Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health care settings.
    g. Easily understood informational materials should be available in the clinic.
    h. If a client declines an HIV test, this decision should be documented in the medical record.
    i. HIV screening should be included in the routine panel of prenatal screening tests for all pregnant clients.
6. The USPSTF concurs with the CDC's recommendations that:
    a. HIV screening should be voluntary and done only with the client's knowledge and understanding;
    b. Clients should be informed orally or in writing that HIV testing will be performed unless the client declines;
    c. Clients should receive an explanation of HIV infection and the meaning of positive and negative results.
    d. The American College of Obstetrics and Gynecology, the American Academy of Pediatrics, and the CDC recommend the opt-out approach, meaning the client should be informed that an HIV test will be conducted as a routine part of prenatal care unless the client chooses to decline the test.
    e. If an individual is living with HIV and currently pregnant, refer for expert counseling and care. Inform clients of the benefits of antiretroviral therapy in pregnancy.
    f. The risk for perinatal HIV transmission can be reduced to <2% if antiretroviral regimens and obstetrical interventions (ex. elective Cesarean section and by avoiding breastfeeding. (See CDC Sexually Transmitted Diseases Treatment Guidelines, 2021)

7. The following procedure should be used with clients who are pregnant or considering pregnancy and are assessed to be at high risk for HIV infection:

    a. Encourage HIV counseling and testing prior to pregnancy or as soon as possible if already pregnant.

    b. If an individual is living with HIV and considering pregnancy, family planning providers must refer the client for expert counseling and care with a provider experienced in conception related services for individuals living with HIV (see linkage to care information below). Discuss delaying pregnancy until client receives expert counseling and information. Provide birth control information and contraceptives if the client wishes to start a contraceptive method.

    c. Resources for staff:
        - Prevention with Persons with HIV
        - https://www.cdc.gov/hiv/guidelines/persons.html
        - Prenatal and Perinatal HIV Virus Testing (ACOG, #752, September 2018)
        - Reproductive Options for HIV- Concordant and Serodiscordant Couples https://clinicalinfo.hiv.gov/en/guidelines/perinatal/reproductive-options-couples-when-one-or-both-partners-are-living-hiv Provide appropriate (internal or external) referral for further counseling and testing to at-riskclients or upon request.

J. Assessing Client Risk

1. The CDC recommendations indicate that prevention counseling should not be required as a part of HIV screening programs in health care settings. Prevention counseling, though, is strongly encouraged for persons at high risk for HIV in settings in which risk behaviors are assessed routinely, but should not be linked to HIV testing.

K. Education

Education of health care personnel regarding all facets of AIDS and HIV antibody testing, including the legal, ethical, and psychological ramifications is critical.

1. Client risk reduction behaviors include (CDC):

    a. Know your HIV status;

    b. Abstain from sexual activity or be in a long term mutually monogamous relationship with an uninfected partner;

    c. Limit the number of sex partners;

    d. Correct and consistent condom use;

    e. Get tested and treated for STIs and insist that your partners do, too;

    f. Male circumcision has also been shown to reduce the risk of HIV transmission from women to men;

    g. Don't use IV drugs. If you are using IV drugs don't share needles, syringes or other injection equipment;

    h. Obtain medical treatment immediately if you think you were exposed to HIV. Sometimes HIV medications can prevent infection if they are started quickly – within 72 hours of a possible exposure. This is called post exposure prophylaxis, or PEP. PEP is the use of antiretroviral drugs after a single high-risk event to stop HIV from making copies of itself and spreading through your body (CDC)

i. Pre-exposure prophylaxis, or PrEP, is a prevention option for people who are at high risk of getting HIV. It is meant to be used consistently, as a pill taken every day, and to be used with other prevention options such as condoms. The USPSTF recommends PrEP be offered to persons who are at high risk of HIV acquisition (Grade A). Mississippi resources include:

- CDC PrEP information
- MSDH PREP
- MS AIDS Education Training Center

2. Provide information about harm reduction programs in the community for individuals using IV drugs, such as needle exchange programs.
3. Documentation in the client's chart of the HIV/AIDS educational component will indicate that this protocol was used to inform the client about HIV screening and testing availability at the clinic or by referral.

L. Linkage to care for individuals who are HIV positive (Including case management and counseling)

1. Treatment as prevention - treating persons living with HV improves their health, reduces viral load in blood and genital fluids and reduces the risk of transmission to others.
2. Mississippi Metro Area
   a. HIV Resources Planning Council, http://www.msdh.state.ms.us/msdhsite/index.cfm/14,16445,150,684,html
   b. Mississippi Metro Area Counties, https://msdh.ms.gov/msdhsite/_static/14,13047,150.html
   c. Mississippi AIDS Foundation, https://locations.aidshealth.org/ms-jackson-hcc77
3. Mississippi Services for individuals living with HIV includes information about case management services, drug assistance, health insurance assistance, navigating care
4. Understanding test results counseling
5. Just Diagnosed: Next Steps After Testing Positive for HIV

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

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

A. National Breast Cancer Guidelines

1. American College of Obstetricians and Gynecology (ACOG) Breast Cancer Risk Assessment and Screening in Average-Risk Women (Number 179, Reaffirmed 2021)
2. American Cancer Society (ACS) Recommendations for the Early Detection of Breast Cancer & ACS recommendations for women at higher than average risk for breast cancer.
3. The USPSTF recommends (Grade B) that primary care clinicians assess those with a personal or family history of breast, ovarian, tubal, or peritoneal cancer or those who have an ancestry associated with breast cancer susceptibility 1 and 2 (BRCA1/2) gene mutations with an appropriate brief familial risk assessment tool. Clients with a positive result on the risk assessment tool should receive genetic counseling and, if indicated after counseling, genetic testing. The USPSTF recommends (Grade D) against routine risk assessment, genetic counseling, or genetic testing for those whose personal and family history or ancestry is not associated with BRCA 1/2 gene mutations (USPSTF, August 2019).
4. The 2021 National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for Breast Cancer Screening and Diagnosis Cancer (March 29, 2021). The NCCN mobile application for smartphones and tablets is available for download here: https://www.nccn.org/
5. Screening recommendations vary for clients considered to be at average or high risk for breast cancer. Breast cancer risk can be calculated using a screening tool such as the Breast Cancer Risk Assessment Tool from the National Cancer Institute and based on the Gail Model.

Please refer to Section 23 - Referral and Follow-Up of the Clinical Manual. Referrals for solitary breast masses are considered urgent, requiring follow-up within two weeks.

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

Clinics must stress the importance of and provide for cervical cancer screening as appropriate. Converge FPP does not specify which national guidelines FP agencies/clinics must follow, but allows individual agencies to choose the national cervical screening, management and treatment guidelines that best fit their provider and patient populations, and their communities.

American Society for Colposcopy and Cervical Pathology (ASCCP) Management Guidelines were published in April 2020. These new guidelines describe the recommended follow-up for all three screening strategies: primary human papillomavirus (HPV), co-testing with HPV and cytology, and cytology alone. Significant changes were made to these guidelines, previously published in 2012. The April 2020 guidelines rely on individualized assessment of risk for precancer (CIN3+), which takes into account past history, current results, and personal factors.

A. National Cervical Cancer Guidelines

1. A joint recommendation statement and final cervical cancer screening recommendations from USPSTF, ACS, ASCCP, and ASCP was released in 2018.
2. American Cancer Society (ACS) updated their Cervical Cancer Screening Guidelines in 2020.
3. The ASCCP's cervical cancer management guidelines are now risk-based and can be accessed here. The ASCCP mobile app has been updated to include the newest recommendations. Please reach out to the nurse consultant if you are in need of learning opportunities related to the new ASCCP cervical cancer management guidelines.

Converge FPP's preference is for FP clinics to utilize primary HPV or co-testing when possible, as national guidelines are moving away from cytology-only cervical cancer screening.

B. Patients Declining the Recommendation For Colposcopy Follow-Up

1. Document the client's declining follow up in the patient's chart.
2. When a patient declines colposcopy, cryotherapy or LEEP, the case should be reviewed by a consulting physician.

C. Management of Patients Reporting Previously Abnormal Cervical Cancer Screening Tests:

1. If a patient provides a verbal report of an abnormal cervical cancer screening test (or colposcopy, cryotherapy, conization, or laser ablation) within the last year, efforts should be made to obtain medical records. Do an initial exam or a delayed exam as appropriate.
2. If records cannot be obtained and the initial cervical cancer screening test is negative, patients should have a repeat cervical cancer screening test six to 12 months later.
3. If the initial cervical cancer screening test (through Family Planning clinic) is other than negative, the patient should be followed for the abnormality described, as outlined in the algorithms referenced in Section B. above.

D. Abnormal Pap Tests and Contraceptives

1. An abnormal Pap test does not constitute a contraindication to hormonal contraceptives or IUDs.
2. Cervical cancer (awaiting treatment) is a category 4 (IUD is contraindicated) for initiating an IUD and a category 2 for continuing an IUD.

Section 17: Cervical Cancer Screening and Follow Up

E. Management of Diethylstilbestrol (DES) - Exposed Women

1. Women who were born between 1940 and 1971 who were exposed to DES should be counseled about the potential risks, provided with DES information, and offered a baseline colposcopic evaluation, with iodine staining. It is not recommended to increase the screening interval beyond annual testing for women exposed in utero to DES.

    1. Physiological changes that occur include circular ridges in the wall of the vagina, cervical hood, and cervical cockscomb, adenosis, or persistence of immature glandular epithelium in the vaginal walls and/or endocervix.

2. Pap test sampling should include a vaginal 4-quadrant technique in addition to cervical sampling. Using the spatula, scrapings are taken from the upper to the lower third of the vagina. These samples should be submitted on two slides. One slide should have the endocervical/ectocervical sample, and the rest of the four quadrant samples should be placed on the second slide. If using liquid-based media, the four-quadrant vaginal specimen is put in one specimen container, and the endocervical/ectocervical sample in another specimen container. Label the slides or specimen containers appropriately, indicating cervical specimen and vaginal specimen. Send each specimen with a corresponding requisition noting a history of DES exposure. Examination of DES exposed women must include palpation of the vagina. Any unexplained vaginal or cervical mass or nodule detected on visual inspection or digital examination should be biopsied. Clear cell carcinoma of the cervix which occurs after DES exposure often originates along the anterior vaginal wall as opposed to vaginal cancer of older women which often occurs along the posterior wall. (Currently being updated 2022).

    1. A history of DES exposure or adenosis on a Pap test is not a contraindication to the use of hormonal contraceptives.

    2. See the following links for more information.
    http://www.cancer.gov/cancertopics/factsheet/Risk/DES
    http://www.cancer.org/Cancer/CancerCauses/OtherCarcinogens/MedicalTreatments/des-exposure

    3. Follow up

        1) DES-exposed daughters should have yearly gynecological exams with cervical and vaginal cytology, visualization and palpation of the vagina and cervix, and a bimanual exam.

        2) If the results of the exam, Pap tests, colposcopy, iodine staining, or biopsies are abnormal, the client should be referred to a provider experienced in evaluating DES exposed daughters

Section 18: Adolescent Services

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

A. Overview
   1. Adolescent clients (defined as <18 years of age) have specialized needs when they come to a family planning program for services. Many need skilled counseling and detailed information toavoid contraceptive failure. Comprehensive information should be provided regarding how to prevent pregnancy and STIs.
   2. While research shows most adolescent clients who come to a family planning program have been sexually active nine months to one year, some teenagers are seeking assistance in reaching a decision about sexual activity.
   3. Family planning programs should take steps to make their services youth friendly, which means they are: accessible, equitable, acceptable, appropriate, comprehensive, effective, and efficient for youth (Gavin, et al. QFP. MMWR 2014).
   4. Per May 2019 Title X regulations, "A preliminary screening of any teen who presents with an STI, pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor" should be completed (42 CFR 59.17).

B. Contraceptive Services
   1. Adolescents seeking contraceptive services must be informed about all methods of contraception, including abstinence (sexual risk-avoidance). Education should include an explanation that LARCs area safe and effective method for clients who have not been pregnant, including adolescents.
   2. Adolescents should be offered information about basic female and male reproductive anatomy and physiology.
   3. All counseling and education must be documented.

C. Confidentiality
   1. Confidentiality is critical for teens and can greatly influence their willingness to access and use services. Services provided to adolescents are confidential. Adolescents should be informed that contraceptive services are confidential and do not require parental consent. However, adolescents must be encouraged to discuss their needs and decisions with family.
   2. The family planning program recognizes the key role family members have to play in teenagers' lives and ideally as primary sex educators.
   3. Adolescents should understand that there are certain reportable situations (e.g. positive STI, child abuse, child molestation, sexual abuse, rape, or incest) that supersede confidentiality. Please refer to the Mandatory Reporting and Human Trafficking Section for more information regarding Mississippi mandatory reporting laws (42 CFR 59.17).
   2. Inform teens with private insurance that an explanation of benefits will be generated and sent to the policy holder if services are billed to private insurance. Minors, those under 18 years old, may opt out of using their private insurance if confidentiality is a concern and they can be charged on a sliding fee scale. Individuals 18 - 26 years old and covered under their parents' policy may contact their private insurance company and request that EOBs are only sent to the covered individual and not the policyholder.

5. Office of Population Affairs, Title X Policy Notice "Integrating with Primary Care Providers", release date November 22, 2016 clarifies how to preserve Title X client confidentiality when billing for services provided.
6. FPNTC Confidentiality Training Package can be accessed here: https://www.fpntc.org/training- packages/confidentiality

D. Encouraging Trusted Adult Participation

1. Trusted adult participation includes, but is not limited to, parental awareness of an adolescent's decision to seek family planning services, discussion of family Planning options, and encouragement of responsible sexual decision- making. By encouraging trusted adult participation into the family planning visit, the staff may help adolescents develop the interpersonal skills necessary to involve their families. Detailing how staff encourage engagement of a trusted adult in an adolescent's family planning care is a Title X requirement. Documentation that a trained staff member discussed, at a minimum, one specific action to encourage trusted adult participation is also required. If this counseling was not done, the reason must also be documented in the medical chart (42 CFR 59.5).
2. Sexual development is a normal part of the teen years. Parents have a strong impact on whether a teenager makes healthy decisions for themselves. Health care providers and educators should encourage and promote communication between an adolescent and their parent(s) or guardian(s) about sexual and reproductive health. Adolescents who talk with their parents about topics related to dating, health relationships, pregnancy prevention, and STI prevention are more likely to (CDC) Begin to have sex at a later age, use condoms or other birth control more often if they do have ex, have better communication with romantic partners, and have sex less often.
3. Motivating adolescents to involve family should include the following:
    a. A straightforward explanation of the confidentiality policy. This would include examples of what information would have to be shared, e.g., situations covered under the mandatory reporting laws, reporting of certain STIs, threats to the client's safety, etc.
    b. Stating it is the clinic policy to talk to all adolescents about trusted adult participation.
    c. Asking whether the adolescent has ever talked to their parent(s) about sex, birth control, or STIs.
    d. Being positive about the potential benefits of trusted adult participation while allaying any fears.
    e. Getting the adolescent to verbalize what the hardest part about talking to a parent or family member would be; what the worst part of the parent's or family member's response might be; what the best part of involving the parent or family member might be.

4. Counseling on Resisting and Avoiding Sexual Exploitation and/or Coercion (42 CFR 59.17)
    a. Sexual Exploitation is the act or acts committed through non-consensual abuse or exploitation of another person's sexuality for the purpose of sexual gratification, financial gain, personal benefit or advantage, or any other non-legitimate purpose. The knowledge that the use of children and youth for sexual acts is abuse and is inherently exploitative.

b. Sexual coercion is the act of persuading or coercing a person, including an adolescent, into engaging inan unwanted sexual activity through physical force, threat of physical force, or emotional manipulation. It differs from rape in that the coerced individual feels it is easier to consent to sexual activity than to decline, because of an imbalance in power. Coercive situations may not be obvious, even to the coerced individual.

c. Information about sexual coercion and counseling on how to resist coercion to engage in sexual activitymust be provided to all adolescent clients. It should be provided to any other client when there is suspicion of abuse or forced sexual activity. The imbalance of power can present itself through pressuring, intimidation, and threats; and it can be physical, emotional, psychological, or spiritual in nature. Education should include, but not be limited to:

a. an explanation of what coercion is

b. the right to refuse sex at any time without negative consequences

c. the right to set limits

d. an awareness of the different kinds of peer pressure that might lead to sexual coercion and how the influence of drugs and alcohol can affect behavior and decision-making ability

e. the importance of self-esteem and self-respect in avoiding coercive relationships

f. a list of any available community resources written information on the topic of sexual coercion that has been approved by your agency's I & E committee.

5. Documentation on Education/ Counseling

Education and counseling about trusted adult participation, sexual coercion, reproductive life planning (RLP) and/or pregnancy intention screening question(s) (i.e. One Key Question, PATH), and confidentiality must be documented in the client chart. Use of a check off box is acceptable. If the topic is listed as “Adolescent Counseling” or “Teen Counseling” then marking it off would mean that the information listed under both “B” through “E” above has been covered. If the topics are listed separately, as “trusted adult participation” and “sexual coercion” or “partner coercion,” then each topic would need to be marked, as indicated. Documentation of abstinence (sexual risk-avoidance) counseling is required. *How to counsel minors to resist sexual coercion is a required annual training for healthcare staff working with clients receiving FP services.*

6. Resources for Providers

- American Academy of Pediatricians (AAP) provides access to recommendations on how clinicians can assist and support in the delivery of sexual and reproductive health services to adolescents. YouTube videos on sexual health history, follow-up sexual health visit, gender identity, and LGBTQ+ Youth are also available here.
- FPNTC’s job aid “The Healthy Relationship Wheel” can assist in guiding conversation with adolescents about healthy relationships, including key characteristics of healthy relationships (respect, accountability, safety, honesty, support, cooperation, and trust).
- The CDC offers a Teen-Friendly Reproductive Health Visit Infographic with brief descriptions of the following: confidentiality, privacy, consent, cultural, linguistic appropriateness, comprehensive services, and parent/guardian involvement here.
- CDC’s Parent and Guardian Resources
- Cardea’s Promoting Adolescent Sexual and Reproductive Health
- American Sexual Health Association (ASHA) provides resources and information that is reliable, science-based, and stigma-fre

- National Coalition for Sexual Health's Essential Sexual Health Questions to Ask Adolescents pocket cards. This resource includes family participation and sexual coercion.
- FPNTC's video and training guide describes the requirement for encouraging family participation in the decision of minors to seek family planning services, as well as communication strategies and resources for working with parents/guardians and adolescents to encourage family participation.
- FPNTC's Encouraging Family Participation in Adolescent Decision Making Training Guide, Counseling Adolescents About Sexual Coercion and Abuse eLearning and Guarding Against Coercion While Ensuring Access: A Delicate Balance Publication
- Futures Without Violence offers providers questions to ask covering health vs. unhealthy relationships and taking control (http://ipvhealth.org/wp-content/uploads/2017/11/Repro-Card-English-Final-2016.pdf).
- Physicians for Reproductive Health's website provides evidence-based curriculum designed to train adolescent medicine healthcare providers https://prh.org/arshep-ppts/
- Guttmacher Institute, Adolescent Resources http://www.guttmacher.org/sections/adolescents.php
- Advocates for Youth, includes information and advice for parents http://www.advocatesforyouth.org/index.php
- http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Adolescent-Health-Care/The-Initial-Reproductive-Health-Visit (May 2014)

- Resources for Adolescents
  - StayTeen.org: http://stayteen.org/
  - Loveisrespect: http://www.loveisrespect.org/
  - Amaze.org from Advocates for Youth is a website that includes age-appropriate, short, animated videos on numerous adolescent topics, including consent, healthy relationships, askable adult, sexting, etc.
  - Futures Without Violence's "Hanging Out or Hooking Up?" is a tool for adolescents that covers resisting coercion and healthy relationships (http://ipvhealth.org/wp-content/uploads/2017/11/Repro-Card- English-Final-2016.pdf).
  - Please contact the FP nurse consultant for a comprehensive list of adolescent-friendly video resources.

The following recommendations and educational information are provided to assist with the care of menopausal clients transitioning from the need for contraceptive services. Services and supplies for menopausal clients are not required by Title X and do not have to be offered. The sliding fee scale does not have to be applied.

A. Definitions

1. Perimenopause - the interval of approximately 5-10 years that precedes and follows the last menses. It is characterized by fluctuating ovarian estrogen production secondary to decreased ovarian function. This transition may be relatively asymptomatic or can be associated with a wide variety of symptoms.
2. Menopause - the cessation of ovarian ovulatory function evidenced by the cessation of menses for a period of one year. Menopause may also be induced surgically (oophorectomy) or medically (chemotherapy or radiation treatment). The average age of menopause in the United States is 52. Smokers reach menopause 1.5 years earlier than non-smokers. Post-menopause is all the years beyond menopause.
3. Premature ovarian failure/insufficiency – transient or permanent loss of ovarian function prior to age 40 resulting in cessation of menses and associated signs and symptoms of menopause.

B. Perimenopausal Signs and Symptoms

The signs and symptoms associated with perimenopausal are primarily due to estrogen deficiency (and/or wide swings in estrogen levels) and can include:

- Hot flashes or flushes
- Insomnia / night sweats / poor quality sleep leading to fatigue
- Mood changes / anxiety / depression
- Memory impairment / difficulty concentrating
- Irregular menses / vaginal bleeding
- Vulvovaginal itching, pain, or dryness / vulvovaginal atrophy (usually a late sign)
- Urinary symptoms such as frequency, urgency, dysuria, frequent UTIs
- Dyspareunia / decreased libido
- Loss of bone density / osteoporosis

C. Assessment/Examination

1. Comprehensive health history and physical exam
2. Laboratory / Screening Tests
   a. Cervical cancer screening as indicated, according to ASCCP guidelines
   b. Fasting lipid screen (total cholesterol, HDL, LDL, triglycerides) per USPSTF guidelines

c. Pregnancy test, if indicated

d. Baseline mammogram or negative mammogram result is recommended prior to initiation of menopausal hormone therapy (MHT). MHT may be started and a mammogram ordered within 3 months.

e. Fecal occult blood testing annually or sigmoidoscopy every 5 years or colonoscopy every 10 years after age 45; younger if risk factors are present.

f. Fasting blood sugar (FBS) should be considered in all clients ≥ age 45. If normal, repeat every 3 years.

g. Bone mineral density (BMD) at age 65 or earlier if indicated by FRAX score assessment of risk factors.

3. Special circumstances lab testing:

a. Serum follicle stimulating hormone (FSH) –This test is only helpful when evaluating for premature ovarian failure/insufficiency (<40 years old). An elevated FSH implies that the ovary is unable to produce sufficient estradiol (secondary to depletion of ovarian follicles) to provide negative feedback to the anterior pituitary where FSH is released. This is an expensive test and only reflects the "snapshot in time" when the test is drawn. Symptom resolution following estrogen treatment is a reliable indicator for diagnosis of perimenopausal status. Treatment, if indicated, should be started without drawing an FSH, unless the client is <40 years old. If an FSH is drawn, it should be drawn on Day 3 of the menstrual cycle, if possible.

b. Endometrial biopsy or ultrasound assessment of the endometrial thickness as indicated for irregular bleeding.

D. Diagnosis

The diagnosis of menopause is usually made presumptively on the basis of amenorrhea (at least 12 months) and presence of menopausal symptoms in a woman at least 40 years of age. Perimenopause can be diagnosed with menopausal symptoms prior to complete cessation of menstrual periods and may also be an indication for treatment.

E. Treatment Alternatives

In July 2002, the Women's Health Initiative announced that it was ceasing the estrogen/progestin arm of the trial (women with an intact uterus) because researchers found that patients assigned to the treatment group demonstrated risks that outweigh benefits. While the estrogen and progestin therapy (EPT) users in the study did have a reduced risk of colorectal cancer and fractures (including hip fractures), they also experienced more strokes, heart attacks, blood clots, and an increased risk of invasive breast cancer. Subsequent analysis of the data revealed that the risk of coronary heart disease was primarily in women who began EPT after age 60. In this and other more recent studies, EPT or ET appeared to decrease cardiac risk in women who initiated the therapy before age 60. This may open up a safer therapeutic window for younger women, who are the most likely to require MHT to control menopausal symptoms.

The estrogen alone (ET) treatment arm was stopped in March 2004 because it also showed an increase in the rate of strokes and deep vein thrombosis/venous thromboembolism. However, there appeared to be no increased risk of coronary heart disease in this group. Like the EPT arm, the ET arm of the study demonstrated a reduction in osteoporosis and the risk of hip and other fractures. And in the final analysis, ET appeared to be associated with an actual decrease in breast cancer risk.

Section 19: Perimenopause

Treatment of moderate to severe vasomotor symptoms is the primary indication for MHT. The benefits outweigh the risks for most healthy, symptomatic women aged younger than 60 or within 10 years of the final menstrual period (NAMS 2014). The scale tilts even more toward benefits in women who have had a hysterectomy and require only ET. A woman's decision for therapy should be highly individualized based on their unique risk/benefit profile. The lowest dose necessary to relieve symptoms should be prescribed. ET/EPT is not recommended for long-term treatment to prevent cardiovascular or other chronic disease.

1. Menopausal Hormone Therapy (MHT)/Estrogen Therapy(ET)/Estrogen Progestin Therapy(EPT)
   a. Contraindications
      1) Known or suspected pregnancy
      2) Undiagnosed abnormal vaginal bleeding
      3) History of deep vein thrombosis or venous thromboembolism
      4) Known thrombophilic disorder
      5) History of stroke or ischemic heart disease
      6) Active liver disease, liver dysfunction
      7) History of or suspected breast or other estrogen-sensitive cancer
      8) Women with a history of malignant melanoma must have a consultation with an oncologist/dermatologist prior to receiving MHT

         Note: ET/EPT is not contraindicated in clients with hypertension, fibroids, diabetes, migraines, and/or varicosities.

   b. Side Effects
      1) Gastrointestinal – nausea/vomiting, bloating, abdominal cramping
      2) Breast tenderness/enlargement
      3) Vaginal bleeding/spotting
      4) Weight gain/changes, fluid retention
      5) Chloasma
      6) Headache
      7) Mood changes
      8) Gallstones, cholecystitis

   c. Benefits
      1) Relief of menopausal symptoms
      2) Protection against bone loss and osteoporosis
      3) May decrease risk of coronary heart disease if begun before age 60

   d. Risks
      1) Increased breast cancer risk in clients using combination MHT (EPT) continuously for more than3-5 years
      2) Increased coronary heart disease in women who begin EPT after age 60
      3) Increased risk of DVT/PE, primarily with oral therapy
      4) Increased stroke risk, may be higher with oral therapy

Section 19: Perimenopause

e. MHT Regimens

1) Continuous Combined Regimen (for clients with an intact uterus): Estrogen and progestin/progesterone daily.

a) Withdrawal bleeding and spotting may occur for the first 6-12 months. However, most women on continuous HRT experience amenorrhea within 6 months - 1 year.

b) Any woman with irregular uterine bleeding who has risk factors for hyperplasia (obese, diabetic, hypertensive, history of taking unopposed estrogen) or any woman with bleeding that persists for 6 months, should receive an ultrasound evaluation of endometrial thickness or an endometrial biopsy. If the endometrial stripe is greater than 4mm on ultrasound, an endometrial biopsy is indicated.

c) Based on the apparent negative effect of medroxyprogesterone acetate in the EPT arm of WHI, clinicians may wish to consider prescribing regimens formulated with other progestins such as norethindrone acetate, levonorgestrel, drospirenone, norgestimate, or progesterone itself.

d) Although off label for this use, the levonorgestrel containing intrauterine system is an excellent means of delivering progestin to the endometrium and protecting the patient from hyperplasia. Side effects of oral progestins are avoided with this treatment modality.

2) Cyclic Regimen (for clients with an intact uterus):

Daily estrogen plus progestin/progesterone for the first 14 days of every month.

a) Withdrawal bleeding can be expected during or after the completion of the progestin cycle, although some women experience very light or no bleeding.

b) Many clinicians start perimenopausal/newly menopausal women on a cyclic regimen, switching later to the continuous combined regimen.

3) Estrogen alone

a) Estradiol can also be prescribed in a systemic vaginal ring, creams, gels, or spray.

b) Post-hysterectomy, estrogen alone is taken every day. However, women with prior endometriosis and possible remaining endometriotic implants should consider adding progestin/progesterone.

c) With an *intact* uterus, estrogen alone requires yearly endometrial biopsy or ultrasound evaluation of endometrial thickness and is quite likely over time to lead to endometrial hyperplasia (which will necessitate higher-dose progestin therapy or even hysterectomy).

4) Other Regimens

a) Duavee®, a combination of 0.45 mg conjugated equine estrogens and the SERM bazedoxifene taken orally every day, is an innovative hormonal treatment for menopausal symptoms and prevention of osteoporosis. The SERM inhibits endometrial growth so that a progestin is not required for clients with a uterus. Contraindications are the same as those for EPT/ET.

b) Low-dose vaginal estrogen is preferred for women experiencing only urogenital symptoms:

(1) Estring® one ring every 90 days.

(2) Estradiol or Premarin® vaginal cream intravaginal 1/4 applicator full each day x 1-2 weeks then twice a week as indicated.

(3) Vagifem® vaginal tablets 1 tablet intravaginal each day X 2 weeks followed by

(4) maintenance of 1 tablet intravaginal twice a week.

(5) A progestin is not required with this therapy, but all bleeding that occurs while using it should be investigated with endometrial biopsy or ultrasound of the endometrial stripe.

c) Osphena® (ospemifene), a SERM given orally 60 mg/day, is a newer option for management of vulvovaginal symptoms that may be particularly useful for women who are uncomfortable with vaginal application. Contraindications are the same as those for estrogen therapy, andas with vaginal estrogen, any bleeding should be thoroughly investigated.

f. Follow Up

1) The first follow up visit should be scheduled in 3 months to assess symptom relief and evaluate side effects.

2) Continue annual well-woman checks.

2. Low dose oral contraceptives are effective in controlling perimenopausal symptoms and re-establishing cycle control in women with fluctuating levels of estrogen. They can be continued for this purpose up to age 52, but should be used only in non-obese nonsmokers without cardiovascular risk factors.

3. Non-hormonal Options

SSRIs, SSNRIs (such as venlafaxine), gabapentin, and clonidine have all been shown to be effective alternatives for reducing hot flashes. Use of these medications for vasomotor symptoms is off label, with the exception of Brisdelle® 7.5 mg. nightly at bedtime, a low-dose paroxetine that has been approved for this purpose. Most SSRIs, including Brisdelle®, should not be used in women taking tamoxifen, as they may compromise the efficacy of the tamoxifen.

4. Artificial lubrication and/or vaginal moisturizers (e.g. Replens®, Luvena®) can help alleviate vaginal symptoms and dyspareunia.

Clinical trials generally demonstrate benefits of complementary and alternative treatments for menopausal symptoms to be no better than placebo. In addition, herbs and botanicals are not regulated by the FDA, so safety is not assured and efficacy information is not available

5. Lifestyle recommendations for symptom relief include cooler environments, avoiding triggers (e.g. spicy foods, red wine), relaxation techniques such as meditation and yoga, aerobic exercise, weight loss, and discontinuing smoking.

Note: Recent data suggests that transdermal delivery of estrogen may be safer than oral therapy. Because it avoids first-pass through the liver effects on coagulation factors, transdermal delivery appears to be associated with less risk of DVT/PE, and possibly stroke and MI. It is also less likely to decrease libido. Transdermal delivery should be considered for all women, but may be preferred for those with cardiovascular risk factors.

F. Counseling and Education

1. Emphasize that menopause is a normal physiologic event and discuss normal changes in body systems and sexuality associated with aging.

2. Inquire about symptoms that may need to be addressed. Ask about sexual problems in particular, since the client may be uncomfortable bringing them up.

3. Stress that the menopausal transition is an important time for women to implement behavioral changes to ensure healthy aging.

4. Discuss the importance of good nutrition and adequate calcium intake (1200 mg each day if not on ET/EPT; 1000mg if on ET/EPT) and vitamin D at least 600 IU/day. Dietary calcium should be assessed, and supplements added if needed to reach the RDA.

5. Encourage regular exercise for heart health. Weight-bearing exercise also enhances bone density.

6. Promote a healthy lifestyle
    a. Maintain normal body weight.
    b. Stop smoking.
    c. Decrease alcohol consumption.
7. Counsel regarding the need for preventive health screenings such as cervical cancer screening according to ASCCP guidelines, breast self-awareness, annual clinical breast exam, mammography, bone mineral density, colon cancer screenings updated by the USPSTF, lipid and diabetes screens.
8. Discuss the importance of recommended immunizations, including a Tdap booster every 10 years, influenza immunization yearly, Zostavax® shingles vaccine at age 60, and pneumococcal vaccine at age 65.
9. Counsel regarding contraception if client has not experienced cessation of menses for 1 year. Serum levels achieved with EPT do not suppress ovulation and are NOT adequate for contraception. (Hormone levels are ~1/6 the levels of a pill containing 20 mcg of estrogen.)
    a. Combined oral contraception (COC) or vaginal ring may be continued to the early 50s unless contraindicated. As noted above, combined hormonal methods may be used for non-obese, nonsmoker clients without cardiovascular risk factors. Clients using COC or vaginal ring cyclically may experience hot flashes and difficulty sleeping at the end of the week of placebo pills because of lack of estrogen. They may choose to use the COC continuously, which will help control these symptoms, or they may transition to EPT if using a backup method of contraception. Intrauterine contraception, the subdermal implant, and depot medroxyprogesterone may be continued to the early 50s unless contraindicated.
    b. If a patient has a levonorgestrel-containing IUD or is using depot medroxyprogesterone acetate, they may initiate estrogen therapy with their method serving as the progestin.

G. Discuss issues pertinent to STI & HIV prevention as indicated.

H. Discuss treatment options for menopausal symptoms; refer to community and other supportive resources as needed.
    1. Assess client risk factors for osteoporosis, cardiovascular disease, breast cancer and other pertinent conditions.
    2. Discuss risks and benefits of MHT and alternative treatments.
    3. Assess client expectations/attitudes about menopause and symptom treatment.
    4. Menopause.org is an excellent resource maintained by the North American Menopause Society providing information for both patients and providers.

A. Standard

1. Informed consent must be obtained from each client prior to receiving any clinical service, including pregnancy test only visits, emergency contraception visits, express visits, STI visits which are expanded to qualify clients for family planning, etc.
2. If the consent is read or translated to the client, or interpretation services are utilized, there must be a signed statement by clinic staff that to the best of their knowledge, the client understood the content of the consent.

B. Consent for Service

1. At the time of admission to any clinical service, a signed informed consent must be obtained from the client for voluntary acceptance of services. All clients entered into AHLERS as family planning clients must have a signed family planning program consent in their medical record.
2. Program consent forms should state that receipt of family planning services is not a prerequisite to receipt of any other services offered.
3. This form should be completed before the client is provided any clinical services, which may or may not include an exam.
4. This consent must contain a statement about the client's potential financial liability for services not covered by the program. This could include, but would not be limited to, non-Title X services such as colposcopy, HIV testing, chlamydia screening for clients not at risk, as well as complications resulting from Title X-covered procedures, side effects from medications, etc.
5. The client should be given a copy of the consent and the original is kept in the chart.
6. This only needs to be obtained once, at the first visit.

C. Consent for Sterilization Procedure
(See Section 11: Sterilization - in the Clinical Manual)

D. Minors and Consent for Services

The following information is intended only for use as a reference. It is not legal advice. Consult your legal counsel for more information.

Minors may consent to Family Planning services, including contraceptive and STI services in Mississippi. A lower age limit is not noted in Mississippi statutes for these services.

Emancipated minors fifteen and older may consent for their own immunizations. Mississippi does not have an emancipation statute under which minors may petition a court for legal autonomy releasing them from the control and authority of their parents.

Title X projects may not require written consent of parents or guardians for the provision of services to minors. Nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services. All Title X providers must comply with State laws requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape or incest. (Office of Population Affairs clarification (OPA Program Policy Notice 2014-01) regarding confidential services to adolescents in the Program Requirements for Title X Family Planning Projects.

Defining the "line" between what services a teen versus the teen's parent may consent to when the teen has an adverse reaction may best be made on a case-by-case basis by the health care provider and with the agency's legal counsel, taking into consideration the confidentiality and privacy concerns of the teen.
Serious adverse reactions to contraceptives are not common. Reactions may vary from person to person and in severity. This may make developing a blanket policy regarding when to seek parental consent for care difficult.
For the above reasons, the Converge Family Planning Program cannot provide advice regarding when to seek parental consent for teens in need of care beyond family planning services and advise seeking legal counsel.

E. Resources
National Center for Youth Law, Adolescent Health Law Project, www.teenhealthlaw.org

Each agency must have internal written procedures for management of medical emergencies that occur in the clinic. Take into account the types of procedures done on site and the qualifications and training of the personnel in the agency. Clients must be informed about resources for after hour's emergencies and the process for accessing emergency care.

In cases in which emergency care is required following a positive pregnancy result, the Title X clinic must refer the client immediately to an appropriate provider of medical services needed to address the emergency (42 CFR 59.14).
Medical emergency procedure examples:

A. General Information

1. As a precaution, have a second staff member present when performing procedures that may result in client collapse, e.g., LARC insertion and removal.
2. Stop procedure.
3. Summon help by calling "HELP! STAT! ROOM!"
4. Stay with the client until help comes.
5. Call 911.
6. Monitor vital signs frequently.
7. Make sure the following have been assigned to staff:
    a. Record the client information, such as vital signs. This could be the same person who is doing the vital signs, or it could be a second person if staff is available.
    b. Communicate with the partner or family member who may have accompanied the client to the clinic.
    c. Guide the ambulance into the facility/the ambulance crew into the client's procedure room.
    d. Reschedule other clients, if needed.

B. Vaso-vagal reaction (faint)

1. Signs and Symptoms
    a. Pulse present SLOW (60 or less);
    b. Blood pressure hypotensive;
    c. Skin cool, clammy;
    d. Pallor around mouth;
    e. Client may be conscious or unconscious;
    f. Client may be nauseated or vomit.
2. Management
    a. Have client lie down;
    b. Turn client on their side, so that if they vomit, they will not aspirate vomitus;
    c. Snap ammonia capsule under client's nose for them to breathe;

d. Raise feet above chest level;

e. Cover client to conserve body warmth without overheating;

f. Watch for cardiopulmonary arrest;

g. Monitor blood pressure and pulse frequently;

h. If client recovers spontaneously within a few minutes, keep them resting quietly until stable and make sure they are completely OK before letting them go home with a friend

i. If the client does not recover within a few minutes, or if you are in any doubt about their recovery, call 911.

3. Resource- Usefulness of physical maneuvers for prevention of vasovagal syncope

C. Shock/Hemorrhage

1. Signs and Symptoms

a. Pulse present, FAST, may be thready;

b. Blood pressure – hypotensive;

c. Skin cool, clammy;

d. Pallor around mouth or cyanosis;

e. Client may be conscious or unconscious.

2. Management

a. Cover client to conserve body warmth without overheating;

b. Assess for bleeding; if present, employ control measures;

c. Raise feet above chest level;

d. Call emergency ambulance;

e. Observe client closely for cardiopulmonary arrest;

f. Monitor vital signs frequently.

D. Cardiopulmonary arrest

a. It is each clinic's responsibility to ensure that staff are currently trained in basic life support

b. Call 911

E. Seizure

1. Signs and Symptoms:

a. Client unconscious;

b. Client is often incontinent of urine or feces;

c. Rhythmic movements of limb(s), jaw, and/or eyeballs may be present;

d. Pulse is generally above 60.

Section 21: Medical Emergencies

2. Management

   a. Be sure client does not hurt themselves by falling off table or against objects;

   b. Seizures generally run their own course; wait it out;

   c. Following seizure, the client may remain unconscious, be confused, or appear partially paralyzed. Keep the client lying down. Call 911 if indicated.

   d. Monitor vital signs.

      NOTE: Seizure-like activity may accompany cardiopulmonary arrest, shock, or vaso-vagal reaction. Check for these conditions.

F. Anaphylaxis

1. Signs and Symptoms

   a. Agitated, flushed;

   b. Rapid pulse;

   c. Difficulty breathing;

   d. May have itching, tingling sensations, coughing and sneezing, throbbing in ears.

   e. Hypotension

2. Management

   a. Have someone call for an ambulance immediately. Clients should be in a recumbent position with the lower extremities elevated to ensure the airway is clear (no foreign body, neck extended). Assess level of consciousness.

   b. Follow your agency internal anaphylaxis protocol.

   c. Consider supplemental oxygen

   d. Consider IV fluids

Section 22: Pharmaceuticals

A. Overview

1. Each agency registered with the Mississippi State Board of Pharmacy must have its own "Other Outlet License" at each clinic location unless otherwise negotiated with the Converge Family Planning Program.

3. pharmacy protocol must be utilized. The protocol must be reviewed and signed annually by a Registered Pharmacist.

4. Services provided, including pharmacy services, operate within written clinical protocols that are in accordance with nationally recognized standards of care.

5. Advanced practice nurses with prescriptive authority must follow the Board of Nursing Rules and Regulations regarding Prescriptive Authority. The following link lists requirements for an APN with prescriptive authority to procure pharmaceuticals. You must ensure that your agency complies with these and any other Pharmacy, Medical and Nursing Board requirements if pharmaceuticals are ordered and procured under an APN or physician license.
https://www.colora do.gov/pacific/ dora/Pharmacy_Prescri ptive_Authority#APRN

6. Registered nurses (RNs) give medications per chart order or physician authorized and signed standing orders.

7. RNs and advanced practice nurses without prescriptive authority work under a medical plan such as protocols or standing orders authorized and signed by a physician and practice under the responsible direction and supervision of the physician when administering or dispensing medications.

B. Drug Stocks

1. Ordering (All delegate agencies are eligible to purchase drugs at the 340B Public Health Service (PHS) pricing):

   a. A written order signed by the Program Coordinator is necessary when ordering prescription items. Prescription items may be ordered through:

      1) Arrangements with pharmaceutical supply companies or distributors.

2. Wholesale distributors participating in the 340B Prime Vendor Program https://www.340bpvp.com/controller.html Labeling, Storing, Repackaging of Pharmaceuticals - Follow Mississippi Pharmacy rules and regulations regarding labeling, storage and repackaging of pharmaceuticals.

C. Consultant Pharmacist

Each program will have a consultant pharmacist with the following responsibilities:

1. To serve as a consultant for any pharmaceutical related issue.
2. To review pharmacy protocols and sign annually along with the program coordinator.
3. To make on-site inspections quarterly to ascertain compliance with protocols and the Pharmacy Practice Act.

4. To make follow-up visits in the event of non-compliance until compliance is assured.

D. Formulary

1. Agencies should provide and stock a broad range of acceptable and effective family planning methods, including IUDs, implant, DMPA, at least three varieties of OCs (e.g. monophasic, multiphasic and ultra-low dose, a progestin only OC, extended cycle pill), vaginal ring and/or hormonal patch, fertility awareness based method counseling, and barrier methods such as condoms and diaphragms.
2. Each agency should keep a list, on-site, of prescription medications maintained at the site.
3. Agencies no longer need to notify the Pharmacy Board of any drugs added to the formulary.
4. Prescriptions for contraceptives may be written if 3rd party insurers decline to reimburse the agency for contraceptives dispensed from the clinic.

DI. 340 Discount Drug Program

a. Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign an agreement with the Secretary of Health and Human Services. This agreement limits the price manufacturers may charge certain covered entities for covered outpatient drugs. The resulting program is called the 340B Program. The program is administered by the Office of Pharmacy Affairs (OPA), a part of the federal Health Resources and Services Administration (HRSA) Department of Health and Human Services. Only nonprofit health care organizations that have certain federal designations or receive funding from specific federal programs are eligible organizations (covered entities) that can register, be enrolled and purchase discounted drugs through the 340B Program. Upon registration on the OPA database as a participant in the 340B Program, entities agree to abide by specific 340B program statutory requirements, prohibitions and policies. Questions about the 340B Discount Drug Program should be directed to the available resources below.

b. The 340B Prime Vendor Program (PVP) is managed by Apexus through a contract awarded by Health Resources and Services Administration (HRSA), the federal government branch responsible for administering the 340B Drug Pricing Program. The Apexus 340B PVP is a free service for 340B eligible entities. The Apexus 340B PVP negotiates sub-ceiling 340B pricing on branded and generic pharmaceuticals among other services. Apexus publishes a quarterly 340B and sub-340B pricing drug list for Title X agencies.

c. Apexus 340B PVP Resources:

- Apexus Call Center
- Phone: 1-888-340-2787
- E-mail: ApexusAnswers@apexus.com or ApexusAnswers@340bpvp.com
- Live chat www.340bpvp.com
- Frequently Asked Questions

- Apexus 340B Prime Vendor Program Patient Definition
- 340B Tools on the Apexus Website
- Comprehensive 340B Policy and Procedure Manual (by entity type) (PDF)
- 340B University™ and 340B OnDemand

d. HRSA 340B Resources:

- HRSA Program Integrity website
- HRSA Annual Recertification website
- 340B Peer-to-Peer Webinars
- HRSA Office of Pharmacy Affairs "The Importance of Establishing and Following 340B Program Policies and Procedures", released February 2016

di. Enrollment and Recertification in the Apexus 340B Prime Vendor Program (PVP) is completed through the
Annual Recertification website (listed in the resources above). Please review the registration windows noted on the website. Complete the online Apexus PVP registration (https://www.340bpvp.com/register/secure-website-access/).

dii. If an agency requests reimbursement from Medicaid for 340B discount purchased pharmaceuticals, the agency assures against duplicate discounts and rebates. The agency assures that Medicaid is billed appropriately.

diii. The agency assures that drugs purchased under 340B are not provided to anyone other than patients or clients of the agency, and maintains a medical record for clients receiving 340B purchased pharmaceuticals.

Section 23: Referral and Follow Up

A. Referral Services

1. Referral services must include either onsite options or "a robust referral linkage with primary health providers who are in close proximity" to the Title X site. Agencies should provide coordination with other providers of healthcare services, local health and welfare departments, social services, hospitals, voluntary agencies, and health services supported by other federal programs.
2. A written list of resource and referral services should be maintained and updated annually. Agencies noted as resource and referral sites must be made aware that they are included on the resource and referral list. A statewide resource and referral list is noted at the end of this section.
3. Providers of family planning services must be trained and equipped to offer family planning and family planning related preventive health services, with referral for specialist care, as needed. "Other preventive health services" should be available either on-site or by referral. Examples of "other preventive health services" are lipid disorders, skin cancer, colorectal cancer, or osteoporosis. These services are not addressed in the QFP. (QFP pg. 5).

B. In-Patient Services

1. The program must maintain a liaison with hospital backup facilities.
2. Either directly or by referral, the program must maintain a referral mechanism for hospitalization of clients with complications arising from contraceptive methods.

C. General Referral Policy

1. Every client has the right to elect or refuse treatment.
2. If during the examination, conditions are found which indicate that further treatment is necessary, the condition should be fully explained to the client.
3. required in cases of medical necessity. When possible give up to three referral options.

D. Services for Special Populations

1. Physically/Developmentally disabled:
    a. Services provided by the agency must be in compliance with ADA regulations.
    b. It is up to the staff to develop sensitivity to the needs of this population.

E. General Follow-up Policy

1. The program has a responsibility to follow-up in any situation that may be, or is known to be, life- or health- threatening.
2. Follow-up measures are directed towards informing the client about their health risks and providing the client with appropriate referral sources for treatment/resolution.
3. Provide a written referral to the client. This information should include recommendations of the clinic.
4. Informing a client they are at risk:
    a. When information or results are received indicating a client is at risk and the client is not in the clinic. All attempts to contact a client should be made with regard for the confidentiality of the client and included in the chart.
    b. Referrals for conditions which are not urgent or life-threatening require written documentation in the chart noting that the client is aware of the need for follow-up, i.e., the return receipt of a certified letter or note in the client's handwriting.

Section 23: Referral and Follow Up

c. Urgent or potentially life-threatening conditions require on-going attempts to ensure follow-up.

F. Referral

1. Internal - The client may be asked to return to the family planning clinic at a later date for further evaluation or follow-up. Documentation should be made in the chart, including the time frame for and purpose of this return visit.

2. External - If the client is referred to an outside agency or health care provider, the client should be given a referral form that identifies the reason for the referral. Clients should give consent for transfer of medical records as indicated.

3. Agencies must have in place a mechanism for tracking all internal and external referrals from initial date/reason to completion of follow-up. Time frames for referral follow-up are dependent upon the urgency of the client's problem.

G. Financial Responsibility for Referrals

1. Referrals for required Family Planning services through an outside contractor, such as IUD or implant insertions, must be provided on the sliding fee scale developed by the agency and reviewed annually by the Family Planning Program at Converge. An MOU with the referral agency is required in these cases (42 CFR 59.5(a)(13)(ii)).

2. Referrals for non-required services (including but not limited to such services as colposcopy, HIV testing, hypertension evaluation) or for complications resulting from procedures or medications provided by the program are the financial responsibility of the client. The agency is not expected to assume part or all of this financial liability. It is recommended that the agency help the client identify available resources.

EXAMPLES OF TIME FRAMES FOR REFERRAL AND FOLLOW UP POLICIES

Emergency – follow up in 12-48 hours or sooner (i.e. possible ectopic, severe PID, complicated GC/CT, malignant hypertension, severe UTI or pyelonephritis)

Urgent – follow up within 2-4 weeks or sooner (i.e. initial episode of herpes, solitary breast nodule (following determination of risk factors), hypertension, positive GC/CT or other STI)

Essential – follow up in 1-2 months or sooner (hematocrit about 55% on repeat or anemia after trying increased iron, hypertension, abnormal pap, enlarged thyroid, solitary breast nodule with low risk determination)

Discretionary – referrals made at the request of the client, follow up at the next clinic visit. Further follow up may not be necessary, but should be based on professional judgment.

J. Statewide Resource and Referral List

The following are statewide resources and referral sites. Many of the links will take you to referrals and resources that are found by entering your location. The list is not all-inclusive. Please also continue to use your established local resources and referral sites. Many of the web sites have either a Spanish language option or translation into multiple languages.

*The views and opinions expressed within these referral and resource sites are those of the authors and do not necessarily reflect the official policy, position or opinions of Converge.

3. Planned Parenthood Hattiesburg, MS
   - List of all Planned Parenthood Health Centers in Mississippi. Select city for phone number or book online option https://www.plannedparenthood.org/health-center?location=Mississippi&service=&channel=any&age=
4. Primary Care
   - Find a Community Health Center including Federally Qualified Health Centers, School Based Clinics https://chcams.org/
5. Medicaid: https://www.magnoliahealthplan.com/ and https://medicaid.ms.gov/
6. Adoption
   - Mississippi Families for Kids https://mffk.org/
   - Adoption Options http://www.adoption-options.com/
7. Prenatal Care
   - Certified Nurse Midwives https://msfriendsofmidwives.org/directory.html
   - Community Health Centers https://chcams.org/
   - Center for Mississippi Health Policy https://mshealthpolicy.com/comprehensive-maternal-health-coverage-2/
   - UMMC Physician Search. Find a physician by location and specialty https://www.umc.edu/doctorsearch/
8. Human Trafficking
   - MSDH Human Trafficking Resources https://msdh.ms.gov/msdhsite/_static/44,0,388,747.html
   - Mississippi Bureau of Investigation Human Trafficking Special Unit (https://www.dps.ms.gov/humantrafficking/)
9. STI/HIV testing and referral
   - The Mississippi STD/HIV Resource Registry https://msdh.ms.gov/msdhsite/_static/14,0,150,570.html
   - Mississippi Department of Health - Services for people with HIV https://msdh.ms.gov/msdhsite/_static/14,13047,150.html
   - Mississippi Public Health – list of STI/HIV testing sites https://msdh.ms.gov/msdhsite/_static/14,0,150,786.html
10. PrEP/PEP
    - Mississippi Department of Public Health - Services for people at risk for HIV. PrEP provider map and listing https://msdh.ms.gov/msdhsite/_static/14,0,150,790.html
    - Please Prep Me https://www.pleaseprepme.org/mississippi
11. Behavioral/Mental Health/ Substance abuse disorders (drug and alcohol treatment providers)
    - Mississippi Behaviorial Health Services – https://msbehavioralhealth.org/
    - Mississippi Department of Mental Health – Find Behavioral Health Help https://www.ms.gov/Agencies/department-mental-health

13. Infertility
    - Planned Parenthood Mississippi Health Centers https://www.plannedparenthood.org/health-center/mississippi/hattiesburg/39401/hattiesburg-center-4078-90330
    - Mississippi Reproductive Medicine https://reproductivemedms.com/
14. Women, Infants and Children Program (WIC)
    - WIC – Mississippi Department of Public Health https://msdh.ms.gov/msdhsite/_static/41,0,128.html

15. Abnormal breast screening (diagnostics such as mammogram, ultrasound & biopsy)
    - Mississippi Breast and Cervical Cancer Program https://msdh.ms.gov/msdhsite/_static/41,0,103.html
    - Family Health Line 1-800-688-7777 or 303-692-2229
    - American Cancer Society Cancer Helpline 800-227-2345
16. Abnormal cervical screening (Colposcopy and LEEP)
    - Planned Parenthood Mississippi Health Centers https://www.plannedparenthood.org/health-center/mississippi/hattiesburg/39401/hattiesburg-center-4078-90330
    - Mississippi Breast and Cervical Cancer Program https://msdh.ms.gov/msdhsite/_static/41,0,103.html
    - Family Health Line 1-800-688-7777 or 303-692-2229
    - American Cancer Society Cancer Helpline 800-227-2345
17. Sexual dysfunction/human sexuality
    - Planned Parenthood Mississippi Health Centers https://www.plannedparenthood.org/health-center/mississippi/hattiesburg/39401/hattiesburg-center-4078-90330

A. Mandatory Reporting

Agencies must be compliant with all applicable state laws regarding the mandatory reporting of child abuse, child molestation, sexual abuse, rape, incest, or domestic violence. Agencies must have written procedures in place demonstrating compliance and must show that this training is completed on an annual basis for all family planning employees. Mandatory Child Abuse Reporting Policy.

Family Planning Coordinators must assure that all staff members are trained and familiar with Mississippi law regarding mandatory reporting / human trafficking (summarized below) on an annual basis for all family planning employees. *This is a required annual training*.

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

References are made to various Mississippi statutes in the information below. Statutes are noted for use as reference. This is not legal advice, consult legal counsel for legal advice. Staff should consult the Colorado Revised Statutes for the most current and complete wording of the child abuse and neglect reporting laws.

Mandatory Reporting Statues chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.msbar.org/media/4125/mandatory-reporting-statutes.pdf

1. Who are mandatory reporters?

   Mississippi law specifies the persons or professions that are required to report child abuse or neglect. Mississippi mandatory reporters are listed in Mississippi Revised Statute. (Miss. Code Ann. §§ 43-21-105, 43-21-353, 43-21-355). Failure of a mandatory reporter to report suspected child abuse or neglect or to knowingly make a false report is a class 3 misdemeanor and punishable under Mississippi law.

2. How is a report made?

   Reporting procedures are detailed in Miss. Code Ann. §§ 43-21-105, 43-21-353, 43-21-355.

   A report is made immediately to the county child protective service, local law enforcement agency, or through the child abuse reporting hotline followed by a written report prepared by the mandatory reporter.

   Child protective services (CPS) personnel are required to assess reports of child abuse and/or neglect. CPS works with community professionals, who are mandated reporters, to prevent, identify, and respond to child abuse and/or neglect.

3. To whom should a mandatory report be made?

   Generally, intrafamilial abuse (includes abuse that occurs within a family context by a child's parent, stepparent, guardian, legal custodian, relative, spousal equivalent or any other person who resides in the child's home) is reported to the child protective services in the county where the victim lives. Third party abuse (includes abuse by any person who is not a parent, stepparent, guardian, legal custodian, spousal equivalent) is reported to law enforcement where the crime occurred. Local child protective services can provide guidance regarding to whom a report should be made.

4. Are there concerns about violating HIPAA privacy regulations when reporting child abuse or neglect?HIPAA regulations permit covered entities to disclose certain types of personal health information, without an individual's authorization or giving an individual the opportunity to object or agree to the disclosure, if the law requires the disclosure. Reporting suspected child abuse or neglect by designated mandatory reporters is required by Mississippi law and thus permitted by HIPAA regulations. The report of suspected child abuse or neglect must be made to the government authorities authorized by Mississippi law to receive reports, child protection services or law enforcement agencies. (4Miss. Code Ann. §§ 43-21-105, 43-21-353, 43-21-355)
5. What information should be included in a mandatory report?

   Reports of known or suspected child abuse or neglect, when possible, should include the following information

   a. The child's name, age, address, gender and race,
   b. The name and address of the person(s) responsible for the suspected abuse and/or neglect,
   c. The nature and extent of the child's injuries, including any evidence of previous cases of known or suspected abuse or neglect of the child or the child's siblings,
   d. The family composition,
   e. The source of the report and the name, address, and occupation of the person making the report.
   f. Any action taken by the reporting source.

   Please note that CRS 25-1-122 (4) (d) (concerning epidemic and communicable diseases, morbidity and mortality, cancer in connection with the statewide cancer registry, environmental and chronic diseases, sexually transmitted infections, tuberculosis, and rabies and mammal bites) limits the information an officer or employee of the state department of public health and environment may provide when making a report.- (1) (d) (concerning HIV infection) limits the information an officer or employee of the county, district, or municipal public health agency or state department of public health and environment may provide when making a report.
6. Assistance for mandatory reporters:

   Staff should follow the reporting policies established by their local agency. A suspicion of abuse or neglect is adequate for reporting to child protective services. Staff should not attempt to further investigate or probe suspected child abuse or neglect. Staff making a report may find speaking with a fellow staff member or supervisor helpful but the mandatory reporter is ultimately responsible for complying with reporting laws. If staff are unsure about whether a report should be made, they should contact their local child protective services for guidance.
7. What happens when a report is made?

   When a report of suspected child abuse and/or neglect is made, child protective services collects relevant information from the reporting party and screens the call to determine if a report will be accepted for assessment. Child protective services will prioritize accepted reports and assign them for assessment or for referral to other agencies, community services or another jurisdiction.

   After a report is made, the county is required to notify the person who made the report within 30 days regarding whether or not the referral was assigned for assessment. A call may also be made to the county to follow-up to see if the report was assigned. If the referral was assigned, the person making the report may be contacted for additional information.

8. Mandatory reporting laws also apply for minor victims of human trafficking. Child abuse or neglect includes unlawful sexual behavior as defined in Miss. Code Ann. §§ 43-21-105, 43-21-353, 43-21-355(9) and includes sexual assault, trafficking in children, sexual exploitation of children, procurement of a child, procurement of a child for sexual exploitation, and inducement of child prostitution.)

    a. Resources

        a. HHS Family Violence Prevention & Services Program http://www.acf.hhs.gov/programs/fysb/programs/family-violence-prevention-services
        b. CDC's violence prevention technical packages: https://www.cdc.gov/violenceprevention/pub/technical-packages.html

FPP clarification: Mississippi State laws do not require providers to document patient partner ages, unless it is part of other information that the person making the report believes may be helpful in furthering the purposes of the mandatory report. Therefore, documenting the age of a minor's sexual partner is not required.

B. Intimate Partner Violence (IPV)

1. Definition and Overview of IPV

IPV is physical violence, sexual violence, stalking, or psychological aggression by a current or former intimate partner. IPV, also referred to as domestic violence, is widespread, affecting one in four women and one in seven men. IPV disproportionately affects pregnant women, adolescents, racial/ethnic minorities, the LGBTQ+ community, people with disabilities, people living with HIV/AIDS, and individuals with substance use disorders. Evidence suggests that screening for IPV in primary care settings and educating all patients about IPV, improve physical and mental health, and improve safety. Clients who talk to their providers about their experience of abuse are four times more likely to be connected with a safety planning resource or plan for safety, and are more likely to use an IPV intervention (The HRSA Strategy to Address Intimate Partner Violence, 2017-2020). In October 2018, USPSTF released a final recommendation on screening for IPV in women of reproductive age, giving it a Grade B. USPSTF recommends that healthcare providers screen for IPV in women of reproductive age and provide or refer women who screen positive to ongoing support services.

2. Screening Tools for IPV and Resources

In 2019, Title X regulations were updated to include screening clients for IPV and sexual violence victimization using a validated screening tool (i.e. HITS, STAT, WAST-SF, PVS, AAS, etc.). The CDPHE FFP recommends the following resources to ensure appropriate screening:

- HIV, Intimate Partner Violence (IPV), and Women: An Emerging Policy Landscape (Kaiser Family Foundation, December 2019)
- Futures Without Violence website and resources
- IPVHealth.org and the IPV Health CUES: an Evidence-Based Intervention for addressing domestic violence in health settings
- IPVhealthpartners.org and the Prevent, Assess, and Respond: A Domestic Violence Toolkit for Health Centers & Domestic Violence Programs
- CDC Preventing Intimate Partner Violence Across the Lifespan: A Technical Package of Programs, Policies, and Practices

- National Domestic Violence Hotline http://www.thehotline.org
- Mississippi Coalition Against Domestic Violence https://mcadv.org/
- Mississippi Coalition Against Sexual Assault http://www.mscasa.org/
- The Office of Women's Health HRSA Strategy Address IPV Toolkit

C. Human Trafficking

1. Definitions and Overview
   a. Labor trafficking is defined as the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery.
   b. Human trafficking for sexual servitude of an adult or minor in Colorado is a felony offense and is defined as a person who knowingly sells, recruits, harbors, transports, transfers, isolates, entices, provides, receives, or obtains by any means another person for the purpose of coercing the person to engage in commercial sexual activity commits human for sexual servitude. If the victim is under 18 years of age, the offense is known as human trafficking of a minor for sexual servitude.
   c. Family Planning Coordinators must assure that all staff members are familiar with Federal and Misssissippi human trafficking law. Family Planning agencies must develop written internal procedures for staff on how to address human trafficking incidents. It is expected that the Family Planning Coordinator will solicit input from various agencies and entities before writing a procedure regarding support and resources for victims of human trafficking. The RHNTC eLearning course, Identifying and Responding to Human Trafficking in Title X Settings, is a helpful resources for staff training and in developing policies and procedures.

2. Screening Tools for Trafficking
   a. Adult Human Trafficking Screening Tool and Guide, National Human Trafficking Training and Technical Assistance Center (NHTTAC), January 2018.

3. Mississippi Statutes and Federal anti-trafficking laws include, but are not limited to:

   a. Mississippi Statues also contain criminal statutes related to human trafficking. Please consult the Mississippi Revised Statutes for the most current language. MS Code § 97-3-54.1 (2016)

   b. Federal anti-trafficking laws include Victims of Trafficking and Violence Protection Act of 2000 and Trafficking Victims Protection Reauthorization Acts of 2003, 2005, 2008, and 2013.

4. Trafficking Resources

   a. Mississippi Resources:

      - MSDH Human Trafficking Resources https://msdh.ms.gov/msdhsite/_static/44,0,388,747.htmlo
      - Mississippi Bureau of Investigation Human Trafficking Special Unit (https://www.dps.ms.gov/humantrafficking/)

b. National Resources:

- National Human Trafficking Resource Center - http://www.polarisproject.org/ what-we-do/national-human-trafficking-hotline/the- nhtrc/overview 24-hour hotline 1-888-373-7888

(BeFree)

The National Human Trafficking Resource Center (NHTRC) is a national, toll-free hotline available to answer calls and texts from anywhere in the country, 24 hours a day, 7 days a week, every day of the year. The NHTRC is operated by Polaris, a non-profit, non-governmental organization working exclusively on the issue of human trafficking. NHTRC is not a government entity, law enforcement or an immigration authority

Section 24: Mandatory Reporting, IPV & Trafficking

- Polaris Project http://www.polarisproject.org/

  The Polaris Project provides human trafficking victim assessment tools for health care providers entitled "Identifying Victims of Human Trafficking – What to Look for During a Medical Exam/Consultation" and "Medical Assessment Tool" at http://www.traffickingresourcecenter.org/audience/service-providers

  The Polaris Project also provides a range of social services to survivors of human trafficking including emergency services, comprehensive case management, group therapy, transitional housing, and victim outreach. Email: info@polarisproject.org Telephone: (202) 745-1001

- US Department of Health and Human Services, Office of Refugee Resettlement http://www.acf.hhs.gov/programs/orr/programs/anti-trafficking

  The Anti-Trafficking in Persons Program (ATIP) identifies and serves victims of human trafficking, assisting foreign trafficking victims in the United States to become eligible refugees. The program also raises awareness of human trafficking through the HHS Rescue & Restore Victims of Human Trafficking campaign. Email: Trafficking@acf.hhs.gov

- Administration for Children and Familes (ACF) and Family and Youth Services Bureau (FYSB) resources include a fact sheet, issue brief, and a webinar training

D. Sexting

a. Prior to the enactment of this law, prosecutors' only option for charging teen sexual behavior (even among consenting friends) was felony exploitation of a child. HB17-1302 went into effect January 1, 2018 and uses a tiered approach that separates abusive forms of sexting (such as malicious distribution) from consensual electronic exchange of explicit images.
b. Visit safe2tell.org/sexting for more information on sexting laws and reporting in Mississippi. They also have a Sexting Fact Sheet available for review.

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

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

A. Custody of Records

1. The agency is the legal custodian of client records. It is responsible for the provision of a safe place for storage of client records to prevent disclosure to unauthorized persons.
2. Client records should be kept in locked files when not in use and must not be left where individuals other than authorized persons have access to them. EMRs must be password protected and should have an automatic time out when not in use. Users should lock the EMR when not in use to ensure against unauthorized access. Also, consider that portable laptops should not be left in a room with a client. An additional layer of security can be provided with the use of biometrics.

B. Confidentiality and HIPAA

1. Agencies must be compliant with HIPAA regulations. HIPAA covered entities are expected to have adequate administrative, technical and physical safeguards in place to protect personal health information under its control.
2. A summary of the HIPAA privacy rule
3. A summary of the HIPAA security rule
4. In January 2013, HHS announced a final rule that implements a number of provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act to strengthen the privacy and security protections for health information established under HIPAA.
5. Clients must be informed of agency privacy practices and a signed acknowledgment of receipt of the notice must be part of the medical record. Model notices of privacy practices that reflect 2013 regulatory changes are available at http://www.hhs.gov/ocr/privacy/hipaa/modelnotices.html

C. Other Considerations in Maintaining Confidentiality

1. All staff must be oriented to the importance of safeguarding the confidential nature of PHI.

2. Privacy and confidentiality in gathering client information by interview or any other means is essential.
3. Office and clinic facilities should be such that client information is not inadvertently revealed to persons in the waiting room or any place else.
4. Use discretion in engaging a client in discussion in his home or on the street while neighbors, relatives, or other persons are present.
5. Electronic email exchanges with clients should be encrypted.

F. Documentation

1. Each entry must be signed by the person providing the information or service. If the full name of the signer is not used in the medical record, a signature sheet with full name, title, and signature of each individual making entries in the chart must be maintained.
   For the purpose of quality assurance, a physician should also co-sign a percentage (10% is recommended) of the entries of an appropriately trained person for whom the physician is responsible (examples - an RN providing services under physician signed standing orders or APRN without prescriptive authority).
2. It is also recommended that the agency have an internal policy in place regarding the percentage of charts that are to be cosigned by the physician.
   See the Mississippi Medical Board Rules and Regulations for Licensure of and Practice by Physician Assistants (Rule 1.7) for instruction regarding review and signature of a Physician Assistant's (PA) charts by the PA's supervisory Physician.
3. All laboratory, X-ray, and referral follow-up reports should be reviewed, initialed, and dated by; (1) the provider (preferable); or (2) the clinic nurse/coordinator before filing in the chart. The provider(s) must be notified as soon as possible of any abnormal lab results for appropriate treatment, referral, or follow- up. This information must be documented in the medical record.
4. Document in the medical record when information is presented to the client either by means of translationor reading the information aloud to the client. Drug and food allergies alerts should be prominently noted in the medical record to inform the provider.

G. Accessibility of medical records

1. The records must be systematically organized to facilitate retrieval and compiling of information.
2. Funding agencies, such as the U.S. Department of Health and Human Services, have the right to review charts of those individuals whose care is supported by their funds.
3. The original medical record is the property of the clinic. However, the client or their attorney, upon presentation of appropriate documentation, is entitled to copies of the record.

H. Retention of records

1. Each agency should have an established written policy regarding the length of time for retention of records and the method of disposing of client records. This is usually done by obtaining a ruling from the agency or county attorney
2. It is recommended that all client records be retained for a minimum of 7 years plus current year after discharge; or, in the case of a minor, 7 years after their 18th birthday.

Section 25: Medical Records/Personal Health Information/Confidentiality

I. Destruction of records

1. When materials no longer need to be retained, in order to ensure the confidentiality of records, they should be destroyed. Agencies that use EMRs should establish a business plan that addresses how and when records will be deleted or moved to a secure network drive.

II. Content of client record

1. The medical record must contain sufficient information to identify the client, justify the diagnosis or clinical impression, and warrant the treatment and end results.
2. The record should contain the following:
    a. Personal Data
        1) Client identification.
        2) Name, address, and telephone number.
        3) Name of someone who may be contacted to reach a client.
        4) Name, address, telephone number, and relationship to the client of a person who may be contacted in the event of a medical emergency. For the client under 18, the parent or guardian should be listed.
        5) Dates of visits.
        6) Identification of other sources of medical care.
    b. Clinical data
        1) Medical history, which must be updated at least annually or more often as indicated.
        2) Documentation of physical examination.
        3) Documentation of laboratory tests ordered, results, and follow-up.
    c. Diagnostic and therapeutic orders, observations, clinical findings, and action taken
        1) Indication of treatments and/or medications given, observations, and action taken.
        2) Progress notes.
        3) Special instructions.
        4) Follow-up contact when applicable.
        5) Any telephone calls to or from a client regarding medical problems.
        6) Referral forms.
        7) Follow-up of referrals.

III. Record audit

a. Internal record audits should be performed at least monthly, to determine completeness of records, e.g., blanks filled in, releases and consent signed appropriately, physician and staff signatures, etc.

b. A full Clinical Chart Audit under the direction of Converge will be performed every Fifth year.

A. Overview

1. Risk management is the system used to minimize the probability of events that have adverse effects and cause loss of human or financial resources.
2. It involves the prevention of circumstances that will lead to a loss of resources.
3. Errors are reduced through a comprehensive quality assurance plan that includes activities at both the state and local level.
4. Note that the Title X Federal Review Tool is incorporated by reference in the clinical manual, including implementation strategies that document compliance with Title X requirements.

B. Activities

1. At the State level, quality assurance activities include the following:
   a. Office of Population Affairs (OPA) Title X program reviews
   b. State of Mississippi audits
   c. Periodic clinical chart audits and clinical and administrative site visits
   d. Orientation to the department, division, and program
   e. Annual work plans and objectives
   f. Performance evaluations of state staff that can include input from delegate staff
   g. Services provided according to national evidenced based recommendations and guidelines
   h. Continuing education and training records
   i. Review of site visit reports, plans for correction
   j. Medical Policy Advisory Committee (MedPac) meetings
   k. Evaluation and audits of the family planning data system
   l. Quality improvement activities
   m. Progress reports on grant objectives
   n. Insurance requirements and policies
   o. Emergency plans
   p. Consultation with the Medical Director
2. At the local level, quality assurance activities include the following:
   a. Clinical chart audits
   b. Clinical, administrative and fiscal site visits
   c. Data audits

d. Independent financial audits

e. Client satisfaction surveys

f. Job descriptions

g. Performance evaluations

h. Documentation of staff orientation to the agency and program (an orientation plan to Title X Family Planning can be done here: https://www.fpntc.org/resources/title-x-orientation-program-requirements- title-x-funded-family-planning-projects)

i. Continuing education and training records, including training on the QFP (e.g. training available from the Title X National Training Centers: https://www.fpntc.org/).

j. Services provided based on national evidenced based recommendations and guidelines

k. Quality improvement activities

l. Documentation of staff training and proficiency testing related to the performance of CLIA waived laboratory procedures and provider performed microscopy. All CLIA waived tests must be performed following the instructions in the most current manufacturers' product insert, without modification.

m. Documentation of the running of controls for CLIA waived tests according to the manufacturers' recommendations/package insert (generally with each new lot number or shipment of a CLIA waived test).

n. Documentation of instrument maintenance as directed by the manufacturer (examples: devices used for CLIA waived tests, autoclave to include ensuring effective sterilization such as spore testing, microscope, refrigerator including temperature log).

o. Clinic resources:

MMWR Good Laboratory Practice for Waived Testing Sites

Ready? Set? Test! Booklet

p. Documentation of an infection control policy and measures (cleaning of exam rooms, instruments, lab, autoclave, and devices) and blood borne pathogens/Occupational Safety and Health Administration (OSHA) staff training and proficiency.

Clinic Resources:

Center for Disease Control and Prevention (CDC) Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.

CDC Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care May 2011

Occupational Safety and Health Administration (OSHA) Blood Borne Pathogens and Needlestick Prevention

q. Management of BBP Exposure

1) Agencies must have written BPP policies and procedures for staff that clearly outline the steps the agency and worker need to perform if a worker has a possible BBP exposure.

2) Workers performing exposure prone procedures should discuss antiretroviral prophylaxis with their care provider in advance and decide if antiretroviral prophylaxis would be desired in the event of a possible exposure.

3) HIV and Hepatitis B post-exposure prophylaxis (PEP) and expert consultation in the management of health-care personnel who have occupational exposure to blood and other body fluids that might contain HIV/Hepatitis B should be provided within 2 hours of the exposure.

4) An incident report should be completed each time a worker has a potential exposure and full documentation of the event and the follow-up should be included.

5) See the following links for more information:

UCSF Clinician Consultation Center
http://www.nccc.ucsf.edu/

Information on HIV/AIDS treatment, prevention and research
http://aidsinfo.nih.gov/guidelines

HIV pre and post exposure prophylaxis
http://www.cdc.gov/hiv/prevention/research/index.html

Post exposure prophylaxis resources
https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/

r. Documentation of pharmacy protocols and procedures.

s. Peer review

t. Bill of Rights for clients

u. Advisory council meetings and minutes

v. Progress reports on grant objectives

w. Insurance policies and requirements

x. Emergency plans and incident reports

y. Consultation with the Medical Director

C. Clinical Chart Audit

1. A clinical chart audit is required every three years.

2. This requirement is met by programs submitting charts to the family planning program to be audited by a contract provider. Delegates scoring below 90% on any criteria in the clinical chart audit are asked to provide a plan for correction.

3. AHLERS reports are provided annually. Converge IT staff pull specific demographic and clinical data from AHLERS to evaluate and compare clinic sites.

D. Clinical Site Visit

1. A clinical site visit document checklist will be sent to the Family Planning Coordinator at least 6 weeks before the visit to assist the Coordinator in collecting the documents and information that will be reviewed during the site visit.
2. The Nurse Consultant arranges a date with the agency's Family Planning Coordinator approximately 45 - 60 days in advance for the site visit. It is important to schedule the site visit on a clinic day. Copies of a confirmation letter should go to the coordinator's supervisor.
3. At the beginning of the site visit, an entrance interview is held with the appropriate local agency staff to discuss the process involved and the day's agenda. Agency staff should have all of the materials requested for review available at this time.
4. The consultant will spend part of the day with the Family Planning Coordinator to review the site visit tool, and materials requested. Whenever possible, the consultant should confirm compliance by observation vs. report.
5. The consultant will spend part of the day 'shadowing' several clients through the clinic, from check in to check out and all stops in-between. The purpose of this activity is to observe the flow of the clinic and the content of the visits.
6. The consultant will review approximately 10 charts of clients who have had a recent annual visit and 5 pregnancy test charts.
7. An exit interview is held with all appropriate agency staff, including, whenever possible, the supervisor of the Family Planning Coordinator. Discussion should include the preliminary results of the evaluation and possible recommendations. Strengths are emphasized before deficiencies.
8. A final report is completed and emailed to the delegate agency within four weeks of the visit. Copies should be circulated among State program staff, and sent to the local coordinator's supervisor. Compliance issues should be clearly outlined in the report. Delegate agencies are given six weeks to submit a written compliance plan to the Converge Family Planning Program, with full compliance achieved within three months of the report. It is the consultant's responsibility to assure that a compliance plan has been received by the due date and that the agency has addressed all compliance issues in a satisfactory fashion.
9. The purpose of the site visit is to determine whether delegate agencies are managed effectively and comply with Title X, federal, and state requirements. The Nurse Consultant conducts a clinical site visit every third year, alternating with administrative site visits and clinical chart audits.

Guidance and Resources for Clinical Laboratory Improvement Amendments (CLIA) Waived Testing, Provider Performed Microscopy, and General Laboratory Practices: https://wwwn.cdc.gov/clia/

A. Introduction

1. Clinic sites that perform CLIA waived tests are required to have a CLIA Certificate of Waiver. Anyone can serve as the lab director, but it should be someone who is knowledgeable of the testing performed and willing to provide oversight of the lab. MMWR Good Practices for Waived Testing Sites: https://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf
2. If clinical healthcare providers (advanced practice nurses, including certified nurse midwives, physician assistants, physicians) use a microscope to perform certain tests, such as wet preps, then a Certificate of Provider Performed Microscopy (PPM) is required. This Certificate also allows CLIA waived tests to be performed. Because PPM procedures are of moderate complexity, the clinic lab must have a written quality assessment (QA) plan.
3. Also provided and linked are CLIA regulations regarding PPM and Guidelines for Certificate of Provider- Performed Microscopy Procedures, a summary of CLIA PPM regulations.
4. The Converge Clinical Manual Sections Risk Management/Quality Assurance and Referral and Follow Up sections also address lab practices. Please see these sections for more information.
5. Please ensure that your clinic lab complies with CLIA regulations and regularly review and update your CLIA waived and provider performed microscopy (PPM) laboratory manuals.

B. Laboratory quality assurance activities must include the following:

1. Documentation of staff training and proficiency testing related to the performance of CLIA waived laboratory procedures and provider performed microscopy.
2. All CLIA waived tests must be performed following the instructions in the most current manufacturers' product insert, without modification. The most current manufacturers' product insert must be available in the lab to staff members performing CLIA waived tests.
3. Documentation of the running of controls for CLIA waived tests according to the manufacturers' recommendations (generally with each new lot number or shipment of a CLIA waived test).
4. Documentation of instrument maintenance as directed by the manufacturer of the test or device (examples: devices used for CLIA waived tests, microscope, refrigerator including temperature log).
5. Provider performed microscopy proficiency testing or comparison testing must be performed and documented twice annually.
6. Proficiency testing should have a grading system that includes what a passing score is and what corrective action is taken if a staff member does not pass, described in the clinic lab policies and procedures.
7. The clinic may do proficiency testing in house using client samples for double reads or by using photographs of potential elements in a wet prep in quiz form. Clinics may sign up for proficiency testing through an approved proficiency test provider (this is not required though) and receive a score for testing unknown samples. See list below for contact information for proficiency test services.
8. Clinics must have a lab procedure and protocol manual available for review during clinical site visits.

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C. Proficiency testing services and laboratory quality assurance programs:
The American Proficiency Institute (API) 800-333-0958 https://www.api-pt.com/Default.aspx
American Association of Bioanalysts (AAB) PTS Proficiency Testing Service 800-234-5315 http://www.aab-pts.org/
American College of Physicians (ACP) Medical Laboratory Evaluation 800-338-2746 option 5 http://www.acponline.org/running_practice/mle/enroll.htm
Collage of American Pathologists (CAP) 800-323-4040
http://www.cap.org/web/home/la b?_adf.ctrl-state=45x25auek_4&_afrLoop=186789525778790
AAFP Proficiency Testing Program 800-274-7911
http://www.aafp.org/practice-management/labs/about.html?cmpid=_van_183
See a more complete list provided by Colorado CLIA Certificate

D. Wet Prep training:
Denver Prevention Training Center
https://www.denverptc.org/

E. Resources:
Regulations and guidance regarding Clinical Laboratory Improvement Amendments (CLIA) http://www.cms.gov/Regulations-and-Guida nce/Legislation/CLIA/index.html
Ready Set Test Booklet from the CDC - great resource for performing CLIA waived tests in the clinic.

Available at the following CDC web site
http://wwwn.cdc.gov/CLIA/Resources/WaivedTests/default.aspx

F. General Laboratory Operations
1. All clinic sites must provide onsite pregnancy testing.
2. Agencies may make a business decision regarding the choice of outside lab the agency will use.

Section 27: Laboratory

3. Clinic sites provide the following tests when required by the specific contraceptive method (FDA or prescribing recommendations) or according to screening recommendations in the QFP.
    a. Chlamydia and gonorrhea
    b. Diabetes
    c. Syphilis
    d. HIV
    e. Hepatitis B
    f. Cervical cancer screening
4. All clinic sites must have a tracking system for test specimens results sent to outside laboratories that includes test date and date test results are received back in the clinic or EMR.
5. All specimens must be properly labeled and lab requisitions must be correctly completed. Include private insurance or Medicaid information on requisitions so outside lab can bill the 3rd party payer directly.
6. Incoming test results must be signed off by clinic staff. Abnormal test results must be reviewed and signed by the provider with a plan for follow up documented in the medical record.
7. All clinic sites must have a tracking system for abnormal lab results in need of follow up or continuing care.
8. Clients are notified of abnormal test results and the notification procedure maintains client confidentiality.
9. All positive STI and HIV tests must be reported to the MSHD STI Registry.

End of Manual. This version is dated April 2022