Sexual & Reproductive Health Clinical Protocol

SEXUAL & REPRODUCTIVE HEALTH (SRH) PROGRAM SOUTHERN NEVADA COMMUNITY HEALTH CENTER



PURPOSE

The protocol document describes how to provide quality family planning services to men, women, and adolescents.

SCOPE

This protocol applies to all Southern Nevada Community Health Center (SNCHC) employees, i.e., associates and providers.

PROTOCOL

Medical Services are performed under the direction of a clinical services provider (CSP) with services offered within their scope of practice and allowable under state law, and with special training or experience in family planning. CSP's include physicians, physician assistants, nurse practitioners, certified nurse midwives and registered nurses with expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health and basic infertility care. (42 CFR § 59.5(b)(6) and 42 CFR § 59.2)

It is expected that all clinical employees will review this protocol on a regular basis and comply with the content and material herein.

It is the responsibility of the employee's manager or acting supervisor to ensure compliance with this protocol.

Managers or acting supervisors should consult with the Family Planning Medical Director when questions or issues regarding this protocol arise.

It is the responsibility of the Title X Program Director or her/his designee to review newly established guidelines, as needed, to ascertain that they are in conformity with this protocol, any related legal requirements, and to hear and to resolve all issues connected herewith.

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SECTION 1

Providing Quality Family Planning Services

A. INTRODUCTION

The Southern Nevada Community Health Center (SNCHC) Family Planning Title X Program Clinical Protocols were adopted from the document, Ohio Department of Health (ODH) Reproductive Health and Wellness Program (RHWP) Title X Clinical Services & Protocols 2021 and Providing Quality Family Planning Services (QFP) 2014, that provides recommendations developed collaboratively by Centers for Disease Control and Prevention (CDC) and the Office of Population Affairs (OPA) of the U.S. Department of Health and Human Services (HHS). The QFP document describes how to provide quality family planning services to men, women, and adolescents.

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

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

Quality Title X Family Planning includes these attributes: confidentiality, safety, effectiveness, client-centered, approach, timeliness, efficiency, accessibility, equity, and cost effectiveness.

QFP services include the following clinical elements:

- Contraceptive Services
- Pregnancy Testing and Counseling
- Achieving Desired Pregnancy (Fertility Awareness)
- Basic Infertility Service
- Preconception Health Services
- Sexually Transmitted Disease (STD)/Sexually Transmitted Infection (STI) Services

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

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

B. SERVICE PLANS AND PROTOCOLS

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

SNCHC offers a broad range of effective family planning methods (including contraceptive, natural family planning or other fertility awareness-based methods) and services (including infertility services, information about or referral for adoption, and services for adolescents) [§ 59.5]. Such projects are not required to provide every acceptable and effective FP method or service.

Clinical protocols must be written in accordance with the QFP document, SNCHC policies and procedures, Nevada state laws, and nationally recognized standards for medical care. Clinical protocols must be current and signed annually by the Title X Medical Director. The SNCHC Title X Clinical Services & Protocols must be available at each clinical site.

C. PROCEDURAL OUTLINE

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

- 1. Service delivery to all clients must include the following:
 - a. Assuring clients are treated courteously and with dignity and respect.
 - b. Professional recommendations for how to address the needs of diverse clients, such as lesbian, gay, bi-sexual, transgender, and queer questioning (LGBTQ) persons or persons with disabilities should be consulted and integrated into procedures, as appropriate. Providers should avoid making assumptions about a client's gender identity, sexual orientation, race, or ethnicity; all requests for services should be treated without regard to these characteristics. Similarly, services for adolescents should be provided in a "youth-friendly" manner.
 - c. Assurance of confidentiality and the provision of privacy.

- d. Opportunity to participate in planning their own medical treatment.
- e. Encouraging clients to voice any questions or concerns they may have.
- f. Materials and/or interpreter available for those with limited ability to read or understand English and for those who may be blind or hearing impaired.
- g. Explanation of all procedures, range of available services, agency fees and financial arrangements.
- 2. Individual client education must be offered.
- 3. Individual counseling. A client-centered, interactive process to assist the client in making an informed choice must be offered and/or provided prior to the client making an informed choice of family planning services.
- 4. Adolescent services must be offered and should be provided in a "youth-friendly" manner, making services accessible, equitable, comprehensive, and effective for youth. Counseling for minors must include the following:
 - a. Title X providers must offer confidential services to minors and must observe relevant state laws related to mandatory reporting of child abuse and neglect and human trafficking.
 - i. Minors must be informed that services are confidential, except in special cases (e.g., child abuse) where reporting is required.
 - ii. Concern with respect to confidentiality of information may not be used as a rationale for noncompliance with laws regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws.
 - iii. Maintain records to demonstrate compliance with each of the requirements, including records which:
 - a) Indicate the age of minor clients.
 - b) Indicate the age of the minor client's sexual partners if such age is an element of a state notification law under which a report is required.
 - b. Document each notification or report made pursuant to such Nevada notification laws.
 - c. Title X providers must encourage and promote communication between the minor and his or her parent(s) or guardian(s) about their decision to seek family planning services.
 - d. Title X providers must provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.
 - e. Adolescents seeking contraceptive services must be provided comprehensive information about how to prevent pregnancy, including sexual risk avoidance (abstinence) as an effective way to prevent pregnancy and STDs.
 - f. A preliminary screening will be conducted on any minor who presents with a STD,

pregnancy, or any suspicion of abuse, to rule out victimization of a minor. Screenings are permitted to diagnose, test for, and treat STDs.

- 5. Counseling for all clients must address the client's pregnancy intention or reproductive life plan.
- 6. The client's written general consent for services must be obtained prior to receiving any clinical services (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a) (2)).
 - a. The general consent for services must state that services are confidential and voluntary; provided without coercion to accept services or any method of family planning and provided without prerequisite to accept any other service.
 - b. The general consent for services must be language appropriate or obtained through an interpreter.
- 7. A medical history must be obtained that is appropriate to the type of service provided.
- 8. A physical examination, including necessary clinical procedures, must be provided, as indicated.
- 9. Laboratory testing must be provided, as indicated.
- 10. Medications and/or supplies must be provided, as indicated/requested.
 - a. Must provide written specific instructions on how to use medications, if dispensed.
 - b. Must include danger signs and when, where, and how to obtain emergency care return schedule and follow-up.
- 11. Follow-up and referral must be provided, as indicated.
 - a. Provision of referrals as needed.
 - b. Planned mechanism of client follow-up.
 - i. Suggested return visit date.
 - ii. Contact information for emergencies after hours.
 - iii. Discuss access to primary care services.
- 12. Emergency arrangements must be made available for after-hours and weekend care and should be posted, given to, and/or explained to clients.
- 13. Return visits should assess the on-going plan of care and family planning related services.

D. CLIENT ENCOUNTERS

- 1. The client's written general consent for services must be obtained prior to receiving any clinical services (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a) (2)).
- 2. Client encounters with women and men of reproductive age may require different services (i.e., contraceptive services, pregnancy testing and counseling, achieving pregnancy, STD services and related preventive health services). For all clients, the following questions must be asked and documented to help determine what family planning services are most appropriate for the visit:
 - a. What is the client's reason for the visit?

- b. Does the client have another source of primary health care?
- c. Does the client have a reproductive life plan or want a pregnancy in the next year?
 - i. Providers should assess the client's pregnancy intention or reproductive life planning by asking questions like.
 - a) "Would you like to become pregnant in the next year?"
 - b) "Have you thought about goals for having or not having children?"
 - c) "Do you plan to have children (or more children) in the future?"
 - d) "How long would you like to wait before you become pregnant?"
 - e) See One Key Question guidance at https://powertodecide.org/one-key-question.

OR

- f) CDC Guidance at: https://www.cdc.gov/preconception/overview.html.
- ii. Providers should encourage family involvement/partner participation in reproductive life planning and family planning decisions where possible and appropriate.

FAMILY PLANNING AND RELATED PREVENTATIVE HEALTH SERVICES FOR WOMEN

		Family planning services (provide services in accordance with the appropriate clinical recommendation)							
	Screening components	Contraceptive services ¹	Pregnancy testing and counseling	Basic infertility services	Preconception health services	STD services ²	Related preventive health service		
History	Reproductive life plan	V	V	V	V	V			
	Medical history	V	V	V	V	V	V		
	Current pregnancy status	V			1				
	Sexual health assessment	∨		V	V	V			
	Intimate partner violence				V				
	Alcohol & other drug use			,	V				
	Tobacco use	V (combined bassaga(methods for clients ≥35 years)			~				
	Immunizations				V	(HPV & HBI)			
	Depression				V				
	Folic acid				V				
Physical examination	Height, weight & BMI	√ (hormonal methodsP		V	V				
	Blood pressure	√ (combined bassase methods)			V4				
	Clinical breast exam			V			V4		
	Pelvic exam	√ (initiating dappagg or IUU)	√ (if clinically unducated)	V					
	Signs of androgen excess			V					
	Thyroid exam			V					
Laboratory testing	Pregnancy test	/ (if clinically undicated)	V						
	Chlamydia	V:				√4			
	Gonorrh ea	√s				V4			
	Syphilis					V4			
	HIV/AIDS					V4			
	Hepatitis C					√4			
	Diabetes				√4				
	Cervical cytology			1			V4		
	Mammography			1			V4		

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

FAMILY PLANNING AND RELATED PREVENTATIVE HEALTH SERVICES FOR MEN

		Family planning services (provide services in accordance with the appropriate clinical recommendation)							
	Screening components	Contraceptive services ¹	Basic infertility services	Preconception health services ²	STD services ³	Related preventive health services			
History	Reproductive life plan	/	1	1	1				
	Medical history	1	✓	✓	1				
	Sexual health assessment	/	✓	1	/				
	Alcohol & other drug use			✓					
	Tobacco use			✓					
	Immunizations			✓	✓ (HPV & HBV) ⁴				
	Depression			✓					
Physical examination	Height, weight & BMI			1					
	Blood pressure			/ 4					
	Genital exam		✓ (if clinically indicated)	100	✓ (if clinically indicated)	√ 4			
Laboratory testing	Chlamydia				/ 4				
	Gonorrhea				/ *				
	Syphilis				V*				
	HIV/AIDS				V*				
	Hepatitis C				/ 1				
	Diabetes			14					

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

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

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

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

The services listed here represent a sub-set of recommended preconception health services for men that were recommended and for which there was a direct link to fertility or infant health outcomes (Source: Frey K, Navarro S, Kotelchuck M, Lu M. The clinical content of preconception care: preconception care for men. Am J Obstet Gynecol 2008;199 [6 Suppl 2]:5389-95).

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

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

Family Planning Services

A. CONTRACEPTIVE SERVICES

Written protocols and operating procedures must be current and in place for contraceptive services. FP clinical staff must offer at least one (1) family planning method to clients who wish to delay or prevent pregnancy. The delivery of preconception, STD, and related preventive health services must not be a barrier to a client's ability to receive services related to preventing or achieving pregnancy. Receiving services related to preventing or achieving pregnancy is the priority; if other FP services cannot be delivered at the initial visit, follow-up visits should be scheduled.

Contraceptive services must include:

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

Broad Range of Contraceptives

- 1. Broad Range Contraceptives includes:
 - a. Hormonal Contraceptives
 - i. At least one (1) delivery method of combined hormonal contraceptives should be available on site.
 - ii. At least one (1) delivery method of progestin-only contraceptives should be available on site.
 - b. Condoms
 - i. At least male condoms should be available on site.
 - c. At least one (1) type of long-acting reversible contraceptive (LARC) method should be provided, either on-site or by paid referral, and should be offered for same-day insertion.
 - d. At least one (1) type of FABM should be provided at each clinical site.
 - e. Education materials and information regarding all methods including, hormonal contraceptives, abstinence, fertility awareness-based methods, barrier methods, intrauterine devices, sterilization, and emergency contraception.
 - f. The health center formulary must indicate:
 - i. Methods maintained and available on site.

- ii. Methods available on site within two (2) weeks of client request.
- iii. Methods available by paid referral.
- iv. Methods available by unpaid referral (i.e., sterilization).
- g. The health centers should maintain a formal referral agreement for any required broad range method not provided on-site.
- h. A referral resource list should be provided for contraceptives not available in the clinic.
- i. Agencies are encouraged to review current practices, the needs and preferences of their client population and maintain the most frequently chosen methods where feasible.
- j. The health center provides emergency contraception and maintains supplies on site
- k. Prescriptions may be written for contraceptives on the clinic formulary, on the client's insurance plan formulary, on patient's request when appropriate.

 Accepting a prescription must not pose a barrier for the client.

2. Emergency Contraception

Emergency contraception has been found by the FDA to be safe and effective for use when initiated after unprotected intercourse. Emergency contraception education and referral are provided to all female clients. When providing emergency contraception, the following must occur:

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

3. Permanent Contraception (Sterilization)

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

The Clinic Visit

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

- 1. For a female client, the medical history must include:
 - a. Reproductive Life Plan
 - b. Menstrual History
 - c. Gynecologic History
 - d. Obstetrical/Reproductive History
 - e. Contraceptive Use
 - f. Allergies
 - g. Medications
 - h. Immunizations
 - i. Recent Intercourse
 - j. Infectious or Chronic Health Condition (present)
 - k. Tobacco, Alcohol, and Drug Use
 - 1. Other characteristics and exposures (e.g., age, postpartum, breastfeeding) that might affect the client's MEC for contraceptive methods.
 - m. Social History/Risk Behaviors
 - n. Sexual History and Risk Assessment
 - o. Mental Health
 - p. Intimate Partner Violence (IPV)
- 2. For a male client, the medical history must include:
 - a. Reproductive Life Plan (RLP) and Self-Identified Need for Contraception (SINC)
 - b. Use of Condoms
 - c. Allergies (i.e., condoms)
 - d. Medications
 - e. Immunizations
 - f. Recent Intercourse
 - g. Partner History (use of contraception, pregnancy, has children, had a miscarriage or termination)
 - h. Infectious or Chronic Health Condition (present)
 - i. Tobacco, Alcohol, and Drug Use
 - j. Contraceptive Experiences and Preferences
 - k. Sexual History and Risk Assessment

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

Physical and Laboratory Assessment

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

Client-Centered Counseling and Education

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

- 1. When educating clients about contraceptive methods they can use safely, clients must be taught the following:
 - a. Method Effectiveness
 - b. Correct and Consistent Use of the Method
 - c. Benefits and Risks
 - d. Potential Side Effects
 - e. Protection from STDs, including HIV
 - f. Starting the Method
 - g. Danger Signs

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

Contraceptive Counseling to Adolescent Clients

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

Information should clarify that:

- 1. It should not be assumed that adolescent clients seeking family planning services are sexually active. Avoiding sex (abstinence) is an effective way to prevent pregnancy and STDs and can be chosen as a method at any time in life.
- 2. If the adolescent indicates that she or he will be sexually active, provide information about contraception and help her or him choose a method that best meets her or his individual needs, including the use of condoms to reduce the risk of STDs/HIV. Long-acting reversible contraception (LARC) is a safe and effective option for many adolescents, including those who have not been pregnant or given birth.

- 3. Title X providers must offer confidential services to minors and must observe state mandatory reporting laws related to child abuse, neglect, and human trafficking.
 - a. Minors must be informed that services are confidential, except that in special cases (e.g., child abuse) reporting is required.
 - b. Concern with respect to confidentiality of information may not be used as a rationale for noncompliance with laws regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws.
 - c. Maintain records to demonstrate compliance with each of the requirements, including records which:
 - i. Indicate the age of minor clients.
 - ii. Indicate the age of the minor client's sexual partners if such age is an element of a state notification law under which a report is required.
 - iii. Document each notification or report made pursuant to such State notification laws.
- 4. Title X providers must encourage communication between the minor and his or her parent(s) or guardian(s) about sexual and reproductive health and his or her decision to seek services, except that documentation of such encouragement is not to be required if the Title X provider has documented in the medical record:
 - a. That it suspects the minor to be the victim of child abuse or incest.
 - b. That it has, consistent with, and if permitted or required by, applicable State or local law, reported the situation to the relevant authorities.
- 5. Title X providers must provide counseling to adolescents on how to resist attempts to coerce them into engaging in sexual activities.

Counseling Returning Clients

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

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

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

Preventive Health Promotion and Referral

- 1. Title X providers should refer pregnant, parenting, and postpartum adolescents to home visiting and other programs that have been demonstrated to provide needed support and reduce rates of repeat teen pregnancy.
- 2. Title X providers should provide referral resources for mental health, domestic or intimate partner violence, and behavioral health including ethyl alcohol (ETOH), tobacco, and substance use as indicated.
- 3. Title X providers should provide a referral resource for immunizations as indicated.

E. PRECONCEPTION HEALTH SERVICES

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

Medical history for females must include:

- 1. Reproductive Life Plan (RLP) and Self-Identified Need for Contraception (SINC)
- 2. Sexual Risk and Health Assessment
- 3. Reproductive History
- 4. Pregnancy History (gestational diabetes or hypertension (HTN), pre-eclampsia, eclampsia, pregnancy outcomes)
- 5. Chronic Disease Management
- 6. Environmental Exposures
- 7. Medications
- 8. Genetic Conditions
- 9. Family History
- 10. Intimate Partner Violence (IPV)
- 11. Social History/Risk Behaviors
- 12. Immunizations
- 13. Depression

Medical history of males must include:

- 1. Reproductive Life Plan (RLP) and Self-Identified Need for Contraception (SINC)
- 2. Sexual Risk and Health Assessment
- 3. Past Medical and Surgical History, which impairs reproductive health.
- 4. Genetic Conditions
- 5. History of Reproductive Failures, or conditions that can reduce sperm quality (obesity, diabetes, varicocele)
- 6. Social History/Risk Behaviors
- 7. Environmental Exposures
- 8. Immunization Status
- 9. Depression

Physical Examination for all clients:

- 1. Height, weight, body mass index (BMI) (screen for obesity)
- 2. BP screen for hypertension based on American Heart Association (AHA) recommendations.
 - a. All clients screen yearly.
 - b. If BP < 120/80 screen yearly, continue yearly.
 - c. If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit and if average BP > 140/90 recheck at next visit or in one (1) week and refer if sustained BP > 140/90.
- 3. Additional vital signs: temperature, heart rate, respiration, pain.

Laboratory testing must be recommended based on risk assessment:

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

Client Plan/Education

- 1. Discuss relevant medications that are contraindicated in pregnancy, and review current medications taken during pregnancy.
- 2. Encourage to take a daily supplement containing 400-800 mcg of folic acid or a prenatal vitamin.
- 3. Avoid smoking, alcohol, and other drugs.
- 4. Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Swordfish, Tile fish).
- 5. Offer any needed STD screening (including HIV) and appropriate vaccinations, if indicated.
- 6. Discuss prior pregnancy history complications and refer if necessary.

Referral

If client desires, refer for further diagnosis and treatment.

1. Refer male and female clients for additional services if screening results indicate presence of health condition or as indicated (i.e., tobacco cessation, obesity, diabetes, depression, immunizations).

F. ACHIEVING PREGNANCY SERVICES

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

Achieving pregnancy services will be offered to clients who respond to the reproductive life plan

questions stating they desire to become pregnant. Achieving pregnancy services include identifying and assessing clients who desire pregnancy; providing counseling and education (including key messages on achieving pregnancy) and addressing misperceptions that many women, men, and adolescents have about fertility and infertility.

Clients who have been trying to achieve pregnancy for twelve (12) months or longer with regular unprotected intercourse should be offered basic infertility services.

Client Assessment

- 1. Client assessment includes:
 - a. Reproductive Life Plan (RLP). Asking the client about his/her pregnancy intention and supporting the client in the decision making.
 - b. Time frame for desired pregnancy.
 - i. If less than one (1) year, provide counseling on maximizing fertility success.
 - c. Length of time she or they have been trying to become pregnant.
 - d. History of pregnancies or infertility.
 - e. Partner involvement and support system issues.
 - i. Support system issues may include family and community support, LGBTQ considerations, single parent considerations, cultural/familial considerations, and awareness of other concerns or influences.
- 2. Medical history includes:
 - a. Immunizations
 - b. Medications
 - c. Infectious or Chronic Health Conditions (present)
 - d. Genetic Conditions
 - e. Environmental Exposures
 - f. Social History/Risk Behaviors
 - g. Sexual Health Assessment and Risk Assessment
 - h. Mental Health
 - i. Medical history for females must include:
 - i. Reproductive History
 - ii. Obstetrical/Gynecology History
 - iii. Family History
 - iv. Intimate Partner Violence (IPV)
- 3. Medical history for males must include:
 - a. Past medical or surgical history that might impair reproductive health.

- b. Medical conditions associated with reproductive failure could reduce sperm quality.
- 4. Assessing and updating the client's physical, sexual, and medical history may reveal additional issues in the person's health history that need to be addressed. The results can also help determine the need for additional information like fertility awareness or other health services such as: STD screening, preconception care, infertility services, and other preventative health services.

Client Education and Counseling

Important information to include.

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

Maximizing Fertility Awareness

Education to provide on maximizing fertility awareness and success:

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

2. Lifestyle influences

- a. Advise that vaginal intercourse every one to two (1-2) days beginning soon after the menstrual period ends can increase the likelihood of becoming pregnant (women with regular menstrual cycles).
- b. Information that fertility rates are lower among women who are very thin or obese, and those who consume high levels of caffeine (e.g., more than five (5) cups a day).
- c. Discourage smoking, alcohol, recreational drugs, and use of commercially

available vaginal lubricants that may reduce fertility.

- d. Encourage a daily supplement containing folic acid or prenatal vitamins.
- e. Encourage males to avoid hot tubs.

Referral

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

G. PREGNANCY DIAGNOSIS AND COUNSELING

SNCHC provides pregnancy testing and diagnosis to all clients in need of this service. Pregnancy testing is one of the most common reasons for a first visit to a family planning agency. It is therefore important to use this occasion as an entry point for providing education and counseling about family planning services. A written protocol and procedure must be current, available, and consistent with national standards of care. Title X projects must not provide abortion as a method of FP (42 CFR59.5)

Pregnancy diagnosis services include:

- 1. General Consent for Services
- 2. Reproductive Life Plan (RLP) Discussion
- 3. Medical History (including chronic medical illnesses, physical disability, psychiatric illness)
- 4. Pregnancy Testing (qualitative urine with high sensitivity)
- 5. Pregnancy Test Results must be given to the client.
- 6. Counseling and Referral resource list as appropriate
- 7. CT and GC testing must be offered to females < 25 years of age and to females ≥ 25 years with risk factors, including HIV and syphilis testing.

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

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

Nondirective Pregnancy Counseling and Referrals

- 1. Title X projects must offer pregnant clients the opportunity to be provided with information and counseling regarding each of the following options (42 CFR 59.5 (a) (5)(i))
 - a. Prenatal Care and Delivery

- b. Infant Care, Foster Care, or Adoption
- c. Pregnancy Termination
- d. If requested to provide such information and counseling, provide neutral, information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.
- 2. The list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) must be available to clients.
- 3. Providers also must assess the client's social support and refer her to appropriate counseling or other supportive services, as needed.
- 4. For clients who are considering or choosing to continue the pregnancy, a prenatal care referral must be provided, and initial prenatal counseling must be provided that includes:
 - a. Pregnant women with risk factors should be tested for STDs (including HIV) at the time of their positive pregnancy test if there will be delays in obtaining prenatal care (more than two (2) months).
 - b. Advise that some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (if current provider is unqualified).
 - c. Encourage to take a daily supplement containing 400-800mcg of folic acid or a prenatal vitamin.
 - d. Avoid smoking, alcohol, and other drugs.
 - e. Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Swordfish, Tile fish).
 - f. Refer for age-appropriate vaccinations if indicated.

Negative Test Visit

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

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

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

- 1. Services to help achieve pregnancy or basic infertility services.
- 2. Preconception Health Education
- 3. STD Services

4. RLP

Basic Infertility Service

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

The Clinic Visit

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

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

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

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

Basic Infertility Care for Women.

The infertility visit should focus on:

- 1. Understanding the client's reproductive life plan and difficulty in achieving pregnancy.
- 2. The medical history must include:
 - a. Past Surgeries
 - b. Previous Hospitalizations
 - c. Major Illnesses or Injuries
 - d. Medical conditions associated with reproductive failure (e.g., thyroid disorders, hirsutism, or other endocrine disorders).
 - e. Childhood Disorders
 - f. Cervical Cancer Screening results, and any follow-up treatment
 - g. Medication
 - h. Allergies
 - i. Social History/Risk Behaviors
 - j. Family history of reproductive failures
 - k. Reproductive History (i.e., time trying to achieve pregnancy, coital frequency, and timing)

- 1. Level of Fertility Awareness
- m. Previous evaluation and treatment results; gravidity, parity, pregnancy outcome(s), and associated complications; age at menarche, cycle length and characteristics, and onset/severity of dysmenorrhea.
- n. Sexual History (pelvic inflammatory disease, history of/exposure to STDs)
- o. Review of Systems (symptoms of thyroid disease, pelvic or abdominal pain, dyspareunia, galactorrhea, and hirsutism).
- 3. A physical examination must be offered if clinically indicated:
 - a. Height, weight, and BMI calculation
 - b. Thyroid Examination (i.e., enlargement, nodule, or tenderness)
 - c. Clinical Breast Examination (CBE)
 - d. Signs of Androgen Excess
 - e. A pelvic examination (i.e., pelvic, or abdominal tenderness, organ enlargement/mass; vaginal or cervical abnormality, secretions, discharge; uterine size, shape, position, and mobility; adnexal mass or tenderness; and culde-sac mass, tenderness, or nodularity).

Basic Infertility Care for Men

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

- 1. Client's RLP.
- 2. Medical history must include:
 - a. Reproductive History (methods of contraception, coital frequency, and timing; duration of infertility, prior fertility; sexual history; and gonadal toxin exposure, including heat).
 - b. Medical Illnesses (e.g., diabetes mellitus)
 - c. Prior Surgeries
 - d. Past Infections
 - e. Medications (prescription and nonprescription)
 - f. Allergies
 - g. Lifestyle Exposures
 - h. Sexual Health Assessment.
 - i. Female partners' history (pelvic inflammatory disease, STDs, and problems with sexual dysfunction)
- 3. A physical examination must be offered if clinically indicated:
 - a. Examination of the Penis (including the location of the urethral meatus)
 - b. Palpation of the Testes and Measurement of their Size

- c. Presence and Consistency of both the Vas Deferens and Epididymis
- d. Presence of a Varicocele
- e. Secondary Sex Characteristics
- f. Digital Rectal Exam

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

Infertility Counseling

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

Referral

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

H. SEXUALLY TRANSMITTED DISEASE SERVICES

Written protocols and operating procedures for sexually transmitted infections must be in place when STD/HIV services are provided. Screening and treatment must follow current CDC STD treatment and HIV testing guidelines.

The Clinic Visit

Initial steps of the clinic visit include:

- 1. Assess Client's RLP
- 2. Medical History:
 - a. Allergies
 - b. Medications
 - c. Medical Conditions
 - d. Sexual Health Assessment, based on gender identity, current anatomy and sexual behavior (partners, practices, protection, history of STDs, pregnancy prevention)
 - e. Immunizations: hepatitis B virus (HBV) and human papilloma virus (HPV).
- 3. Physical Exam as indicated (based on history or symptoms)
- 4. Laboratory testing including the following:
 - a. Chlamydia:
 - i. Testing must be offered annually for all females < 25 years. Sexually active women ≥ 25 years with risk factors (infected partner, partner with other concurrent partners, symptoms, history of STD or multiple partners

- in the last year) should be offered testing. Pregnant women should be screened for CT at the time of the pregnancy test if there might be a delay in obtaining prenatal care.
- ii. Clients who test positive for CT should be re-tested three (3) months following treatment for early detection of re-infection. Clients who are not present for three (3) months for re-test should be re-tested the next time they present for services in the twelve (12) months following treatment of the initial infection. Pregnant women should have a test-of-cure three to four (3-4) weeks following treatment.
- iii. CT screening for males can be considered at sites with high prevalence (adolescent clinics, correctional facilities, STD clinics) or males who have sex with males (MSM). Males with CT should be re-tested three (3) months following treatment.

iv. Follow Up:

a) Men and women who were tested for CT should be retested approximately three (3) months after treatment, regardless of whether they believe their sex partners were treated. If retesting at three (3) months is not possible, clinicians should retest whenever a patient seeks medical care, less than twelve (12) months after initial treatment.

v. Special Consideration:

a) Test of cure (i.e., repeat testing after completion of therapy) preferably by Nucleic Acid Amplification Tests (NAAT), at approximately four (4) weeks after therapy completion during pregnancy is recommended. In addition, all pregnant women who have a CT infection diagnosed should be retested three (3) months after treatment.

b. Gonorrhea

- i. Testing must be offered annually to sexually active women < 25 with high risks (previous GC, presence of other STDs, new or multiple sex partners, inconsistent condom use, commercial sex work, drug use) and those who reside in high prevalence areas. Other risk factors that place women at increased risk include infected partner, symptoms, history of STD or multiple partners in the past year. Pregnant women should be screened for CT at the time of the pregnancy test if there might be a delay in obtaining prenatal care.
- ii. All males with symptoms suggestive of GC (urethral discharge or dysuria or whose partner has GC) should be tested and empirically treated.
- iii. MSM should be tested at sites of exposure. Clients with GC infection should be re-tested for re-infection three (3) months after treatment. Clients who are not present for three (3) months for a re-test should be re-tested the next time they present for services in the twelve (12) months

following treatment of the initial infection.

iv. Follow Up:

a) Men and women who were tested for chlamydia should be retested approximately three (3) months after treatment, regardless of whether they believe their sex partners were treated. If retesting at three (3) months is not possible, clinicians should retest whenever a patient seeks medical care, less than twelve (12) months after initial treatment.

v. Special Consideration:

a) Test of cure (i.e., repeat testing after completion of therapy) preferably by NAAT, at approximately four (4) weeks after therapy completion during pregnancy is recommended. In addition, all pregnant women who have a CT infection diagnosed should be retested three (3) months after treatment.

c. Syphilis

- i. Testing should be offered to male and female clients at high risk, if they are sexually active and
 - a) MSM
 - b) Commercial Sex Workers
 - c) Persons Who Exchange Sex for Drugs
 - d) Those in Adult Correctional Facilities
 - e) Living in High Prevalence Areas
 - f) Pregnant Women
 - g) HIV Positive
 - h) Taking Pre-Exposure Prophylaxis (PrEP) for HIV Prevention
 - i) Have Partner(s) who have Tested Positive for Syphilis

d. HIV/AIDS

- i. Testing should be routinely recommended for all male and female clients thirteen to sixty-four (13-64) years of age.
- ii. Annual testing is recommended for high-risk individuals:
 - a) Injection Drug Users and Their Partners
 - b) Persons who Exchange Sex for Money or Drugs
 - c) Sex Partners of HIV Infected Persons
 - d) MSM or heterosexual persons who themselves or whose sex partner have had more than one (1) sex partner since their most recent HIV test.

iii. When the result is positive, the client will be referred immediately to SNCHC Ryan White (RW) for HIV linkage to care and when possible, a warm hand off.

e. Hepatitis C (HCV)

- i. According to the CDC, Hepatitis C (HCV) screening at least once in a lifetime for all adults aged ≥ 18 years, except in settings where the prevalence of HCV infection is < 0.1% and HCV screening for all pregnant women during each pregnancy, except in settings where the prevalence of HCV infection is < 0.1%.
- ii. The recommendation for HCV testing that remains unchanged is regardless of age or setting prevalence, all persons with risk factors should be tested for HCV, with periodic testing while risk factors persist.
- iii. Risk factors for HCV include people who currently or have ever used injection drugs; with HIV infection; with certain medical conditions, including those who ever received hemodialysis and those with persistently abnormal alanine transaminase (ALT) levels; who have received transfusions or organ transplants; health care, emergency medical, and public safety personnel who have been exposed to the blood of someone who has HCV; and children born to mothers who have HCV.
- iv. Any person who requests HCV testing should receive it, regardless of disclosure of risk, because many people might be reluctant to disclose stigmatizing risks. [Schillie, S., Wester, C., Osborne, M., Wesolowski, L., Ryerson, A.B. (2020). CDC Recommendations for Hepatitis C Screening Among Adults United States, 2020. MMWR Recomm Rep 2020;69(2). doi: http://dx.doi.org/10.15585/mmwr.rr6902a1]
 - a) If testing is positive, refer for additional care and management of HCV infection and related conditions. Assess alcohol use and refer for intervention if indicated.
 - b) With a grade B recommendation, the USPSTF recommends screening for HCV infection in all adults aged 18-79 years. [Chou, R., Dana, T., Fu, R. et al. (2020). Screening for Hepatitis C virus infection in adolescence and adults: Updated evidence report and systematic review for the US Preventative Services Task Force. JAMA, 323(10), 976-991. doi:10.1001/jama.2019.20788]
 - c) Clients with high-risk behaviors/conditions (e.g., past, or current injection of illegal drugs, HIV infected) should be recommended to have annual testing.

f. Hepatitis B (HBV)

- i. Screening is not recommended for the general population.
- ii. Testing should be recommended for high-risk populations (persons from high prevalence areas, HIV positive, intravenous (IV) drug users, MSM,

HBV household contacts).

Treatment

- 1. STD treatment should be provided on-site.
- 2. The current CDC STD treatment guidelines ensure all clients are treated in a timely manner and appropriate follow-up measures are provided.
- 3. Behavioral counseling for all sexually active adolescents and adults who are at an increased risk for STDs is recommended. [US Preventive Services Task Force. (2020). Behavioral counseling interventions to prevent sexually transmitted infections. JAMA, 324(7). doi:10.1001/jama.2020.13095]
 - a. Examples of behavioral interventions include individual or group counseling, media-based interventions, written materials, phone and text messages, websites, and videos.
- 4. PrEP for HIV prevention should be offered, as indicated.

Expedited Partner Therapy (EPT)

EPT should be offered as indicated for clients testing positive for chlamydia, gonorrhea, and trichomoniasis.

1. Under Nevada Administrative Code NAC 441A.200(2)(f), EPT is permissible in Nevada. These laws include the use of the most current CDC Sexually Transmitted Treatment Guidelines, which include the use of EPT for patients with chlamydia and gonorrhea. The State Board of Pharmacy has revised regulations under Nevada Revised Statutes (NRS 639.070 and 639.210) to allow for the use of Expedited Partner Therapy in treatment of these infections.

Counseling

- 1. Educate on risk reduction and available testing or referral for testing.
- 2. Encourage vaccination for HPV and HBV if indicated.
- 3. Encourage condom use to prevent STD/HIV infection.
- 4. Encourage clients with STDs to:
 - a. Notify their sex partners and urge them to seek medical evaluation and treatment.
 - b. Refrain from unprotected sexual intercourse during the period of STD treatment.
 - c. Return for re-testing in three (3) months if indicated.
- 5. Initiate Behavioral Counseling

Informational Materials: Health care professionals must provide patients participating in EPT with counseling and written materials to include:

- 1. A warning about administering EPT to pregnant partners.
- 2. Information about the antibiotic and dosage prescribed or provided.
- 3. Information about the treatment and prevention of STDs.

- 4. The requirement of abstinence until a period after treatment. No sex, no alcohol for seven (7) days. Condoms are encouraged all the time.
- 5. Notification of the importance of sex partners to receive testing for HIV and other STDs.
- 6. Notification of the risk to self, others, and the public health if the STD is not completely treated.
- 7. The responsibility of the sex partner to inform his/her sex partner(s) of the STD risk and importance of examination and treatment; and other information deemed necessary by the Southern Nevada Health District.

Referral

- 1. Clients with HCV and HIV infection should be linked to medical care and treatment.
- 2. Clients should be referred for needed immunizations.

Mandatory Reporting

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

I. GYNECOLOGIC SERVICES

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

J. RELATED PREVENTIVE HEALTH SERVICES

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

- 1. Clinics must offer and/or provide and stress the importance of the following to all clients:
 - a. Clinical Breast Exam (CBE)
 - i. According to the American Cancer Society (ACS), the CBE should be performed at least every three years for average-risk asymptomatic women beginning at age twenty-five (25) through age thirty-nine (39), and annually for women ≥ 40 years of age.
 - ii. According to American College of Obstetricians and Gynecologists (ACOG), the CBE should be performed annually for all women > 19.
 - iii. The USPSTF does not recommend CBE due to no evidence that benefits outweigh the harm.
 - b. Pap testing as indicated:
 - i. Age twenty-one to twenty-nine (21-29) years old, Papanicolaou test (PAP) every three (3) years.
 - ii. Age thirty to sixty-five (30-65) years old, PAP and HPV testing every five (5) years.

- iii. Abnormal results should be treated in accordance with professional standards of care (e.g., http://www.ascep.org/guidelines).
- c. The pelvic examination (including vulvar evaluation and bimanual exam) should be performed with routine PAP testing and should be provided if medically indicated.
- 2. Clinics must stress the importance of:
 - a. The USPSTF recommends biennial screening mammography for women aged fifty to seventy-four (50-74) years old.
 - b. Screening for women aged forty to forty-nine (40-49), should be based on patient preference, personal/family history, or other conditions that support screening.
 - c. The ACS recommends women between forty to fifty-five (40 to 54) should get mammogram every year. Women fifty-five (55) and older can switch to mammogram every other year, or they can choose to continue yearly mammograms. Women between forty and forty-four (40 and 44) have the option to start screening with a mammogram every year.
- 3. Clinics should conduct a genital examination for adolescent males and document:
 - a. Skin and Hair Distribution (observation)
 - b. Hydrocele, Varicocele, (observation and palpation)
 - c. Signs of STD (observation and/or palpation)

K. QUALITY MANAGEMENT

1. Referrals and Follow-up

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

Written protocols and operating procedures for referrals and follow-up must be in place for the following:

- Referrals that are made as result of abnormal physical exam or laboratory findings.
- Referrals for required services.
- Referrals for services are determined to be necessary but beyond the scope of family planning.
 - a. Referral procedures must be sensitive to clients' concerns about confidentiality and privacy.
 - b. Client consent for the release of information to providers must be obtained, except as may be necessary to provide care or as required by law.
 - c. Protocols and operating procedures for referrals and follow-up made because of abnormal physical examination or laboratory test findings within the scope of Title X that impact contraceptive management must include the following:
 - i. A system to document referrals and follow-up procedures must be in

place.

- ii. Follow-up procedures must include the following:
 - a) A method to identify clients needing follow-up.
 - b) A method to track follow-up results on necessary referrals (such as PAP and breast follow-up).
 - c) Documentation in the client record of contact and follow-up.
 - d) Documentation of reasons, actions, and follow-up where recommendations were not followed and/or protocols not acted upon.
- d. Referral procedures should include that the referral and need for follow-up be explained to the client including:
 - i. Reason and importance of the referral.
 - ii. Services to be received from the referral agency.
 - iii. Address of the referral provider/agency.
 - iv. Any instructions needed to follow through with the referral.
 - v. Patient is made aware referral specialist will follow up and assist patient to get the care needed. Bus passes are offered for patients with transportation barriers.
- e. For services determined to be necessary but which are beyond the scope of the project (such as thyroid abnormalities), clients must be referred to other providers for care. When a client is referred for non-family planning or emergency clinical care, agencies must:
 - i. Document that the client was advised of the referral and the importance of follow-up.
 - ii. Document that the client was advised of their responsibility to comply with the referral.
- f. SNCHC maintains a current referral list that includes health care providers, local health and human service departments, hospitals, voluntary agencies, and health service projects supported by other federal programs.
 - i. Referral lists must be current and updated annually.
 - ii. When possible, clients should be given a choice of providers.

Pharmaceuticals

SNCHC operates in accordance with federal and state laws relating to security and record keeping for drugs and devices. The inventory, supply, and provision of pharmaceuticals must be conducted in accordance with state pharmacy laws and professional practice regulations. Pharmacy is available at SNCHC to dispense medications the patient will take at home. Other medications and contraceptives are available at the clinical site to be administered directly to the patient.

It is essential that each facility maintain an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients. Projects should also ensure access to other drugs or devices that are necessary for the provision of other medical services included within the scope of the Title X project.

Clinical service providers write prescriptions for Title X clients who choose and can conveniently obtain their contraceptives and medications from a pharmacy. Prescriptions may be written for contraceptives/medications on the clinic formulary or on the client's insurance plan formulary.

A dispensing prescriber, except as authorized for EPT shall only dispense drugs to his/her clients with a valid prescriber-patient relationship.

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

- 1. Prescription of pharmaceuticals is done under the direction of a physician (who must have a drug control license for each location in which the storage and the dispensing of prescription drugs occur). The physician may dispense indirectly under his/her delegated authority to a registered nurse (RN) or certified mid-level clinician. Pre-labeled, pre-packaged oral contraceptives may be distributed if delegated by a dispensing prescriber.
 - a. All medications dispensed in Title X clinics must be pre-packaged.
 - b. Prescription medications dispensed (including samples) must be labeled and labels must contain the following information:
 - i. Name and address of location from which the prescription drug is dispensed.
 - ii. Name of the client unless prescription is authorized for EPT.
 - iii. Date the prescription drug is dispensed.
 - iv. Name, strength, and quantity of drug dispensed.
 - v. Directions for use, including frequency of use.
 - vi. Prescriber's name (medical director/prescribing practitioner).
 - vii. Expiration date of prescription drug.
 - viii. Record number of client.
 - c. All clients must receive verbal and written instructions for each drug. Medication education sheets should be kept current, annually reviewed and revised as needed. The nature of drug education should be documented in medical records.
 - d. There must be documentation that in-service training pertaining to the nature and safety aspects of pharmaceuticals is provided at least every two (2) years to staff involved in the provision of medications to clients.
- 2. The inventory, supply and provision of pharmaceuticals may be delegated to appropriately qualified health professionals.
 - a. FP health professionals delegated to deliver prescriptions drugs must be trained in all aspects of pharmaceutical and supply distribution.

- b. Delegate agencies must have proper segregation between requisition, procuring, receiving and payment functions for pharmaceuticals and supplies.
- c. Delegated agencies must have an inventory system to control purchase, use, and reordering of pharmaceuticals and supplies.
- d. Delegate agencies must have adequate controls over access to medications and supplies including:
 - i. Contraceptive and therapeutic pharmaceuticals must be kept in a secure place, either under direct observation or locked.
 - ii. Access to pharmaceuticals must be limited to health care professionals responsible for distributing these items.
 - iii. Safeguards must be in place to ensure that supplies purchased through the 340B program are provided only to clients of the SNCHC FP program.
- e. A system must be in place to monitor the expiration date on drugs and ensure disposal of all expired drugs.
- f. A system for silent notification in case of drug recall must be in place.
- g. Inventory levels should not exceed a six (6) month supply.
- 3. A current formulary, listing all drugs available for Title X clients, must be maintained, and reviewed at least annually. Formularies should be retained for three (3) years.
- 4. An adequate supply and variety of drugs and devices must be available to meet their client's contraceptive needs.
 - a. Purchase and use of generic drugs based on therapeutic equivalence as published by the FDA or in the Formularies of Therapeutic Equivalence accepted by the State Board of Pharmacy is acceptable.
 - b. Sub-recipient agencies may elect to identify certain supplies on the formulary, such as more expensive or infrequently used methods, which will be ordered upon client request and be available within two (2) weeks of the request.
- 5. At a minimum, each site that provides medical services must have the following:
 - a. Emergency drugs and supplies for treatment of Vaso-vagal reaction.
 - b. Emergency drugs and supplies for treatment of anaphylactic shock.
- 6. Prescriptive Methods for Transfer Clients
 - a. An informed (general) consent form must be obtained, and a client history must be completed/reviewed. A BP must be taken if the client desires to continue a combined hormonal contraceptive. The provider will review the transfer records and decide if the current prescription can be continued. The provider must document the prescription in the client's record.

Medical Emergencies

Emergency situations involving clients and/or staff may occur at any time; therefore, all agencies

must have written plans and protocols/operating procedures for the management of on-site medical and non-medical emergencies.

- 1. At a minimum, written protocols must address:
 - a. Vaso-vagal reactions/Syncope (fainting)
 - b. Anaphylaxis
 - c. Cardiac arrest
 - d. Shock
 - e. Hemorrhage
 - f. Respiratory Difficulties
- Protocols must also be in place for emergencies requiring emergency medical services (EMS) transport, after-hours management of contraceptive emergencies and clinical emergencies.
- 3. All staff must be trained in emergency procedures and must be familiar with the plans. Licensed medical staff providing direct patient care services must be trained in cardio-pulmonary resuscitation (CPR) and hold current certification.
- 4. There must be a procedure in place for maintenance of emergency resuscitative drugs, supplies, and equipment.

Medical Records

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

2. Record Contents

The client's medical record must contain sufficient information to identify the client, indicate where and how the client can be contacted, justify the clinical diagnosis, and warrant the treatment and end results. Records must include the following:

- a. Personal data:
 - i. Name
 - ii. Address, Phone Number(s), and How to Contact
 - iii. Age
 - iv. Sex
 - v. Marital Status
 - vi. Income Assessment
 - vii. Unique Client Number
 - viii. Race and Ethnicity
 - ix. Medical History
 - x. Allergies Recorded in a prominent, consistent location.
- b. Physical Exam
- c. Documentation of clinical findings, diagnostic/therapeutic orders.
 - i. Laboratory test results and follow-up done for abnormal results.
 - ii. Treatments and special instructions.
 - iii. Documentation of continuing care, referral, and follow-up.
 - iv. Documentation of scheduled revisits.
- d. Contraceptive Method at Entry.
- e. Contraceptive Method at Exit.
- f. Informed Consents
- g. Documentation of all counseling, education, and social services given.
- h. Documentation of deferrals, reason for deferral, and refusal of services.
- i. Date and signature of clinician or health professional for each entry, including documentation of telephone encounters of a clinical nature.
 - i. Signature includes the name and title of the provider.
 - ii. A signature log if full name and title are not used in medical record.
- j. A confidentiality assurance statement in the client's record.
- k. A list of identified problems should be maintained to facilitate continuing management and follow-up.
- 3. Confidentiality and Release of Records

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

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

Quality Improvement (QI)

SNCHC FP program has a system in place that provides for the ongoing evaluation.

- 1. SNCHC FP program conducts QI based on identified measures, encounter level data driven from FPAR 2.0 results, participation in collaboratives such as RHNTC, NVPCA and other partner community organizations, staff feedback and SNCHC initiatives.
- 2. The quality improvement system must include the following elements:
 - a. A tracking system that identifies clients in need of follow-up and/or continuing care must be in place. (Referrals and Follow-up)
 - b. A system to ensure that professional licenses and CPR certifications are current must be in place. (Personnel & Emergencies)
 - c. <u>Medical Audits</u> to determine conformity with agency protocols, current standards, and acceptable medical practices must be conducted quarterly by the medical director.
 - i. A minimum of two to three (2-3) charts per clinician must be reviewed by the medical director biannually.
 - d. <u>Chart Audits/ Record Monitoring</u> to determine completeness and accuracy of the medical record must be conducted quarterly by quality assurance committee or identified personnel.
 - i. Chart audits must represent a minimum of three percent (3%) of the agency's quarterly caseload, or a minimum of ten (10) charts, whichever is more, randomly selected and reviewed by staff.
 - ii. All clinical sites should be represented in the sampling.
 - iii. Topic audits are strongly suggested.

- e. Clinical protocols and procedures must be reviewed and signed annually by the medical director.
- f. Infection control policies and procedures reflecting current CDC recommendations and Occupational Safety and Health Administration (OSHA) regulations must be in place.
- g. Laboratory audits to ensure quality and Clinical Laboratory Improvement Amendments (CLIA) compliance must be in place.
- h. Equipment maintenance and calibration must be documented.
 - i. A process to implement corrective actions when deficiencies are noted must be in place.
- 3. A QI Workgroup should be in place. This workgroup should meet quarterly, or as deemed necessary by the Project Director, to discuss quality assurance issues and to make recommendations for corrective action when deficiencies have been noted.
 - a. If a formal QI Workgroup is in place, minutes should be kept of all meetings.
 - b. The function of the QI Workgroup may be assumed by an in-house nursing or medical advisory committee with ongoing documentation of quality improvement activities.

References

Centers for Disease Control and Prevention (CDC). (2016). Providing quality family planning services: Recommendations of the CDC and the U.S. Office of Population Affairs, 2015. MMWR, 65(9). https://www.cdc.gov/mmwr/volumes/65/wr/mm6509a3.htm

SECTION 2

SNCHC and National Title X Training Programs

A. STAFF TRAININGS

SNCHC FP program staff are provided with training opportunities to promote and improve the delivery of family planning services. These trainings are provided utilizing different resources such as The Reproductive Health National Training Center (rhntc.org), The National Clinical Training Center for FP (https://ctcsrh.org/), CDC, Essential Health Access, etc., face-to-face workshops, webinar offerings, and collaboratives. Continuing education and contact hours are available whenever possible.

The national family planning program was authorized in 1970 as Title X of the Public Health Service Act (P.L.910572). The nationally funded Title X program is administered by the Office of Family Planning in the Office of Population Affairs (OPA) within the Department of Health and Human Services (HHS). Information about the Reproductive Health and Wellness is available on the OPA Website at: http://www.hhs.gov/opa/title-x-family-planning/. The Reproductive Health and Wellness is administered through ten Public Health Service Regional Offices throughout the United States. Nevada is part of Region IX and SNCHC obtains program consultation and direction from the Office of Population Affairs (OPA) and Title X project officer. SNCHC works with RHNTC liaison for technical assistance.

The Title X program, under Section 1003, provides training grants for personnel working in family planning services projects, with the purpose of promoting and improving the delivery of family planning services.

The Reproductive Health National Training Center (RHNTC) provides resources, materials, and educational opportunities to ensure Title X and Teen Pregnancy Prevention grantees have the knowledge, skills, and attitudes necessary to deliver high -quality services and programs.

Clinical Training Center for Sexual and Reproductive Health (CEC – SRH) provides clinical training for nurse practitioners, certified nurse midwives, physicians, and physician assistants.

For more information about these centers see: http://www.hhs.gov/opa/title-x-family-planning/training/national-training-centers/.

To access upcoming National Training Center (NTC) training events or archived online programs and resources visit: https://rhntc.org/.

Updates issued to date: https://www.cdc.gov/mmwr/volumes/65/wr/mm6509a3.htm.

THE SNCHC Family Planning Program

Overview

The SNCHC FP program is a group of diverse individuals committed to improving access to family planning services for the people of Nevada. Having the skills and resources to plan the timing and size of families improves birth outcomes, protects the health of parents, and reduces the likelihood of that family living in poverty. Towards that end, our Federally Qualified Health Center (FQHC), individuals representing the state government, local health departments, hospitals, adolescent health centers, advocacy agencies, social workers, and community members have joined together to enhance access to family planning services.

SECTION 3

Clinical Protocol Review by Clinicians

The SNCHC Sexual and Reproductive Health Program clinical protocols provide a consistent approach to the provision of quality family planning services. A clinical protocol is a written plan of clinical management for an identified health condition. It is used to guide the clinician in the provision of health care to a client in an ambulatory health care setting.

Clinical protocols incorporate standards of health care and reflect compliance with appropriate laws and regulations. Clinicians include nurse practitioners, certified nurse midwives, physician's assistants, and physicians.

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

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

Medical Director:	Date:
Physician:	Date:
Nurse Practitioner:	Date:
Nurse Practitioner:	Date:
Nurse Practitioner:	Date:
Physician's Assistant:	Date:

SECTION 4

General

What are clinical lab services?

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

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

There are four (4) types of CLIA certifications for laboratories which include:

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

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

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

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

Protocol

All SNCHC FP clinical staff performing any laboratory test will be provided with an orientation when hired, as well as ongoing competency assessment on laboratory policies, and procedures at least annually, and additional training when laboratory tests are added or changed.

Certification:

- A CLIA certificate is required to operate a clinical laboratory.
 - Applications and renewals are submitted to Nevada State Health Division Bureau of Health Care Quality and Compliance CLIA laboratory Program.
 - The fee is determined by the Centers for Medicare and Medicaid Services (CMS) according to the complexity level of testing.
 - The CLIA certificate will be displayed in a prominent place in view of the public. SNCHC will display the lab certificate in each clinic locations lab area.

CLIA Laboratories: Waived

- Are subjected to inspections only:
 - o If a complaint is made.

- o To validate that:
 - Only waived categorized tests are performed under a waived lab certificate.
 OR
 - If there is a risk of harm to the client due to inaccurate testing.
- Waived laboratories may perform only those tests categorized as waived.
- Written Orders:
 - o Waived tests may be performed at the written request of a:
 - Medical Doctor (MD)
 - Doctor of Osteopathy (DO)
 - Naturopathic Doctor
 - Physician Assistant (PA)
 - Certified Nurse Practitioner (NP)
 - Written protocols, policies, and procedures cover the use of standing orders when specific guidance is provided.
- Waived tests may be performed by any individual following appropriate training and documentation.
- PPMP testing may be performed only by a:
 - Medical Doctor (MD)
 - Doctor of Osteopathy (DO)
 - Physician Assistant (PA)
 - Certified Nurse Practitioner (NP)
- Written procedures will be developed and maintained for all tests performed in the waived and PPMP laboratory and will be approved by the laboratory director and/or health officer.
- A PPMP laboratory must have a lab director who is legally liable and responsible for all aspects of testing and must be a:
 - Physician (MD or DO), licensed to practice in Nevada by the Board of Medical Examiners.
 - Nurse Practitioner (NP) or nurse midwife licensed and certified by the Nevada Board of Nursing.
 - o Physician Assistant (PA) licensed by Nevada Board of Medical Examiners.
- SNCHC will maintain:
 - Complete records on each test kit/device per manufacturer's recommendations, for three (3) years, including:
 - Quality Control

- Calibration
- Instrument Maintenance
- Records on all testing personnel indicating laboratory training and competency assessment.
- o Meet department standards for safety, disposal of hazardous and infectious waste.
- o Refer specimens only to laboratories operating in compliance with CLIA.
 - To determine if a referred lab is CLIA compliant staff may access information at https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/laboratory-registry.
 - Staff may call the laboratory directly to ask about their CLIA status.
 - Laboratory staff will re-evaluate the CLIA status when the referred lab's certificate expiration date is due.
- SNCHC laboratory will not revise results or information directly related to interpretation of results provided by the testing laboratory.
- Inform Laboratory Compliance Section of changes in laboratory name, owner, director, or address within thirty (30) days after a change occurs.

Procedure

Test Preparation:

- Tests will be performed in an area with adequate space while maintaining client privacy.
- Testing and storage must meet specific environmental requirements according to the manufacturer's instructions.
- Clinical equipment will be maintained, and calibration checks performed as directed in manufacturer's instructions. Points to consider:
 - o Clean work area before and after testing.
 - o Perform testing in well-lit area.
 - Check and record temperatures of the testing and reagent storage areas.
 - O Check and record expiration dates of reagents/kits, discard when expired.
 - o Do not mix reagents.
 - o Inspect reagents for damage, discoloration, or contamination and discard if found.
 - o Prepare reagents according to the manufacturer's instructions.
 - o Allow time for refrigerated reagents/samples to come to room temperature.
- External quality control (QC) per manufacturer's instructions.
 - Will be performed at a minimum:
 - With each new shipment of kits/reagents.
 - With a change in number.

- By each new testing staff before conducting testing.
- New user.
- Any unacceptable temperature storage failure.
- Results will be recorded on the lab's results log; and records kept for three (3) years.

Performing Tests:

- SNCHC clinical staff will:
 - o Confirm test order.
 - o Confirm client's identification.
 - o Confirm client is aware of what test(s) is/are being done.
 - o Confirm client has followed pretest instructions, if indicated.
 - Wear appropriate personal protective equipment.
 - Use the proper specimen collection device.
 - o Follow the testing steps in the exact order per manufacturer's instructions.
 - Use a timer to follow the required timing interval.
 - o Interpret test results according to the manufacturer's instructions.
 - o In-house test results will be given to the client at the time of testing.
 - o If test results are invalid, compromised, or disagree with client's clinical information, the test will be repeated.
 - o Record test results in client's chart and on the lab's results log.
- Any test not performed in this laboratory will be referred to a licensed reference laboratory.
 - o Specimens sent out will be documented on a specimen tracking log.
 - o The original report form from the reference laboratory will be filed in the client's chart.
 - Abnormal cervical cytology results will be entered into a client management tracking system. (See Section 7: Management of Abnormal Cervical Cytology Policies and Procedures)

Critical Values:

- SNCHC will:
 - Establish critical values which require immediate treatment or evaluation from an ordering provider.
 - O Define which tests have critical values.
 - o Ensure staff are aware of the critical values.
 - o Provide staff directions on how to alert the provider in a timely manner.

o Document when and to whom the critical values are reported.

Notification of Lab Test Result(s): See FQHC

- All clients will be notified of test results.
- Clients with special requests will be notified per client preference.
- Client's document mother's maiden name/password on registration form, staff documents in eCW. When patient request confidential services, staff documents in global alerts "FP client requesting confidential services.
- Client will have the option to access patient portal for lab results or may opt to be notified of normal test results by mail.
- Client with abnormal lab test results will be contacted by:
 - o Phone:

If unsuccessful after a minimum of three (3) attempts, or telephone number is disconnected or no other emergency contact number documented in eCW, a clinical staff member will mail a regular or certified letter (depending on result type) in eCW addressed to the patient. Patients requesting confidential services may opt to receive notification using the portal or personal email to contact the clinic.

- The client notification process will be documented in the client's chart.
- The contact Protocol for STD and PAP will be followed by clinical staff.

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American Academy of Family Physicians. (2025). Clinical laboratory improvement amendments (CLIA). https://www.aafp.org/family-physician/practice-and-career/managing-your-practice/clia.html

Centers for Disease Control and Prevention. (2024). Clinical laboratory improvement amendments (CLIA). https://www.cdc.gov/clia/php/about/index.html

Government Publishing Office. (2025). Electronic code of federal regulations. http://www.ecfr.gov/cgi-bin/text-

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Centers for Medicare & Medicaid Services. (2024). Clinical laboratory improvement amendments (CLIA). http://www.cms.gov/Regulations-and-duidance/Legislation/CLIA/index.html

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

Centers for Medicare & Medicaid Services. (2012). What do I need to do to assess personnel competency? http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA CompBrochure 508.pdf

Resources

CLIA application for certification: https://www.cms.gov/medicare/cms-forms/cms-

forms/downloads/cms116.pdf

Center for Disease Control and Prevention. 2024. Ready? Set? Test! Patient Testing is Important booklet: https://www.cdc.gov/lab-quality/docs/waived-tests/readysettest 2024 final.pdf

Tests granted waived status under CLIA: https://www.cdc.gov/clia/docs/tests-granted-waived-status-under-clia.pdf

Centers for Medicare & Medicaid Services – list of PPMP (Provider Performed Microscopy Procedures): http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ppmplist.pdf

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

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

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

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

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

Protocol

SNCHC clinical staff will be trained in the operation of the autoclave and follow the manufacturer's recommendations for proper maintenance to ensure not only their safety, but also to ensure that equipment is correctly sterilized.

Procedure

Safety Practices of the Autoclave:

- Follow manufacturer's instructions for loading, operating, maintaining, cleaning, and performing quality assurance checks.
- Before using the autoclave, check inside the autoclave for any items left by the previous user that could pose a hazard.
- Clean the drain strainer before loading the autoclave.
- Load the autoclave properly as per the manufacturer's instructions (do not overload).
- Make sure the door of the autoclave is fully closed and latched when in use.

- Make sure the correct cycle for the material is selected.
- When the cycle is complete, open the door slowly. Keep your head, face, and hands away from the opening.
- <u>Do not</u> autoclave items containing corrosives, solvents or volatiles, or radioactive materials.

Prepare and Package Items Needing Sterilization:

- Thoroughly clean instruments first by rinsing with water.
 - Use of personal protective equipment (PPE) shall be worn for handling and cleaning contaminated instruments.
- Pre-clean with appropriate cleaning product.
 - o If detergent based, ensure that it is mixed to the correct in-use dilution.
 - Avoid prolonged soaking; soak for allotted time recommended by the cleaning agent's manufacturer.

• Clean

- Completely submerge items during the cleaning process to minimize aerosolizing of microorganisms and assist in cleaning.
- o Remove gross soil using tools such as brushes and cloths.
- Inspect brushes and other cleaning equipment for damage after each use, and discard if necessary.
- o Clean, disinfect, dry, and store tools used to assist in cleaning after each use, or else discard.

Rinse

Rinse all equipment thoroughly with water after cleaning to remove residues which may react with the disinfectant/sterilant.

Dry

- o Follow the manufacturer's instructions for drying of the device.
- o Instruments may be air-dried or dried by hand with a clean, lint-free towel.
- o Dry stainless-steel instruments immediately after rinsing to prevent spotting.

Post Cleaning

- Visually inspect instruments to ensure cleanliness and integrity of the device.
- o Repeat cleaning on any item that is not clean.
- o Follow the manufacturer's guidelines for lubrication.
- o Those instruments requiring lubrication shall be lubricated prior to sterilization.
- Package in autoclave wrap or pouches.
 - o Use of heat-sensitive tape on the autoclave wrap provides monitoring which

- indicates the load has undergone an effective steam sterilization process and indicates the proper temperature has been reached.
- o If the heat-sensitive tape does not turn brown (indicating the load did not undergo proper sterilization process) the load must be reprocessed.
- Autoclave pouches have a color sensor strip on the outside of the pouch which also must turn brown to indicate the package was effectively sterilized.
- Write the date, batch number that day, employee initials, and label contents on the wrap or pouches to be sterilized.

• Loading the Autoclave

- o Do not mix unwrapped and wrapped items or sterilized and non-sterilized items.
- Do not overload.
- o Close and latch the door firmly.

• Operating the Autoclave

- o Follow individual autoclave manufacturer's operating instructions.
- Press the ON/Standby button.
- Refer to Standard Cycle Parameters to select the proper sterilization program time and temperature.
- Select and press the appropriate sterilization program button.
- o Press the START button.
- o If the autoclave is not working properly discontinue using immediately.
 - Post sign alerting others not to use the autoclave.
 - Contact the service company responsible for maintenance of the autoclave.
- Address any error messages; make corrections and reprocess the instruments.

• Unloading the Autoclave

- Allow the load to cool down to room temperature.
- Examine the load items for:
 - Any signs of compromised packaging integrity.
 - Change to brown color of the heat-sensitive tape or pouch color strip.

Recordkeeping

- o Entries must be placed on the log form each time the autoclave is used.
- o Entries should include the operator's name, date, and time.
- o Log forms should be kept by the autoclave for easy access.
- o Log maintenance and repairs into log forms.

Monitoring

- o Monitoring of the autoclave should be performed routinely using.
- Mechanical indicators.
- Assessment of cycle time and temperature after each load.
 - Chemical indicators
- Affixed to the outside of each pack; changes color when sterilization parameters are present for each package.
- o Biological indicators (e.g., spore-strip biological indicators).
 - Sterilizer should be monitored at least weekly.
 - Perform monthly spore testing.

• Contingency Plans

- o If autoclave does not operate as expected, do not attempt to fix the problem.
 - Record the problem on the log form.
 - Notify the clinical site practice manager to report the problem.
- o Burn emergency.
 - If you are burned, seek medical treatment as soon as possible.
 - Burns to the face, third degree burns, or burns over large area should be treated as emergencies.
 - Minor burns should be treated using first aid procedures.
 - Regardless of the degree of severity, report the burn to the clinical site practice manager as an occupational injury.

Maintenance

- Preventative and Scheduled
 - Follow the manufacturer's recommendations for routine maintenance and cleaning.
 - Daily:
 - Clean the door gasket with a soft cloth.
 - Weekly:
 - Clean the tray holder and trays with a cleaning agent and water and a soft sponge.
 - Clean and descale the chamber and reservoir with a descaling agent.
 - Clean the outer parts of the autoclave with a soft cloth.

Training

• All users must become familiar with the manufacturer's operation manual prior to the use of the autoclave.

- All users must be trained before operating an autoclave.
- All training should be documented, and records should be maintained in the lab with other safety training records.

References

Center for Disease Control and Prevention. (2024). Guidelines for disinfection and sterilization in healthcare facilities. https://www.cdc.gov/infection-control/media/pdfs/guideline-disinfection-h.pdf

Arizona State University. (n.d.). Standard operating procedure for autoclave operation. http://www.asu.edu/ehs/documents/autoclave-sop.pdf

BC Ministry of Health. (2013). Best practices for cleaning, disinfection, and sterilization of medical equipment/devices in all health care settings. https://www.publichealthontario.ca/media/documents/B/2013/bp-cleaning-disinfection-sterilization-hcs.pdf

What is cleaning and disinfection for healthcare settings?

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

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

Protocol

All SNCHC staff will follow the standard precautions for disinfection and sterilization of patient care areas and common use areas.

Procedure

Those surfaces in proximity to the patient and those that are touched frequently in the exam room will be cleaned between each patient and disinfected daily. These include surfaces such as:

- Exam Tables
- Counter Tops
- Mayo Stand
- Chairs and stools
- Door handles
- Tabletops

Select Environmental Protection Agency (EPA) registered disinfectants or detergents/disinfectants with label claims for use in healthcare.

Follow the manufacturer's recommendations for use of cleaners and EPA registered disinfectants (this includes):

- Amount
- Dilution
- Contact Time
- Safe use
- Disposal

Use appropriate PPE, as indicated. Change the paper covering the exam table between patient use.

Place any used linens (e.g., exam gowns, sheets) in a designated container located in each exam room after each patient uses it.

Clean personal and diagnostic equipment regularly; disinfect if equipment becomes contaminated with blood or body fluids.

Proper Hand Hygiene:

- Use of alcohol-based hand rub with emollients is the preferred method.
- Use soap and water when hands are visibly soiled or in contact with suspected infectious material.
- Decontaminate hands with alcohol-based hand rub before and after each patient encounter.
- Decontaminate hands with alcohol-based hand rub after contact with body fluids or excretions, mucous membranes, and nonintact skin if hands not visibly soiled.
- Decontaminate hands with alcohol-based hand rub after removing gloves.
- Wash hands with soap and water before eating and after using the restroom.

Clean floors in exam rooms, lab, and bathrooms daily.

Promptly clean and decontaminate spills of blood and other potentially infectious materials.

If reusable cleaning cloths or mops are used, they should be decontaminated regularly to prevent surface contamination.

Cleaning Common Areas:

- Floors in common areas shall be cleaned daily.
- Common area surfaces (e.g., counters, doorknobs, telephones) will be disinfected daily or more frequently, using an EPA registered disinfectant.

Training

- Job or task-specific infection prevention education and training will be provided to all healthcare providers.
- Training will focus on both healthcare staff safety and patient safety.
- Training on bloodborne pathogens will be provided upon orientation and repeated at least

annually for all staff whose assigned tasks may lead to occupational exposure.

- Competencies will be documented upon orientation to clinic, should be repeated annually, and any time policies or procedures are updated or revised.
- Assessments of current infection prevention measures and updates as needed will be performed annually.

References

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

Center for Disease Control and Prevention. (2016). Guide to infection prevention for outpatient settings: Minimum expectations for safe care. https://www.cdc.gov/infection-control/media/pdfs/Outpatient-Guide-508.pdf.

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

What is a reproductive life plan?

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

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

Subjective Data

History must include:

• All clients of reproductive age must be assessed at least annually as to their reproductive plans.

Clinical Pathway of family planning services for men and women of reproductive age (See Figure 2)

Client encounters with women and men of reproductive age may require different service needs (i.e., contraceptive services, pregnancy testing and counseling, achieving pregnancy, STD services and related preventive health services). The following questions will determine what family planning services are most appropriate for a given visit and must be asked and documented:

• What is the client's reason for the visit?

- Does the client have another source of primary health care?
- What is the client's reproductive life plan?

Reproductive Life Plan

Providers should assess the client's reproductive life plan by asking the client questions such as:

- Do you have any children?
- Do you want to have (more) children?
- How many (more) children would you like to have and when?
 OR
- Would you or your partner like to become pregnant in the next twelve (12) months?
 AND
- Do you want to prevent a pregnancy now?

Plan (See Figure 2)

- If the client does not want a child currently and is sexually active, then offer contraceptive services.
- If the client desires pregnancy testing, then provide pregnancy testing and counseling services.
- If the client wants to have a child within the next twelve (12) months, then provide achieving pregnancy services.
- If the client wants to have a child and is having trouble conceiving, then provide basic infertility services.
- If the female client of reproductive potential is not pregnant but at risk of becoming pregnant, or the male client is at risk for impregnating his female partner, then provide preconception health services.
- If the client is at risk for STD exposure, provide STD services.

Patient Education/Counseling

- Nearly half of pregnancies are unintended.
- Risks associated with unintended pregnancies:
 - Late Entry to Prenatal Care
 - Maternal Depression
 - o Increased Rates of Abortion
 - o Exposure to Potentially Harmful Substances during Pregnancy
 - o Poor Pre-pregnancy Disease Control
 - Reduced School Completion and Lower Income Attainment (for an unmarried woman)

- Preconception, contraception, STD prevention counseling etc.
- Importance of planning and goal setting.
- Importance of birth spacing. Women with interpregnancy intervals of less than eighteen (18) months are more likely to have premature infants and low birthweight babies.
- Reproductive life plans are fluid and are never right or wrong.
- If the client does not have a plan to prevent pregnancy, the client has a plan to get pregnant.
- Benefits of a reproductive life plan:
 - o Choose contraceptive methods that best fit the plan.
 - o Decrease risks for unintended and short interval pregnancies.
 - o Increase the likelihood of achieving life goals (e.g., graduating school or college, obtaining a certain job).

Consultation/Referral

• Based upon client's need.

Self-Identified Need for Contraception (SINC) is a single question reproductive health needs screening tool, using service needs approach. Providers/Clinical staff will ask the question at least once per calendar year.

Purpose: The purpose of SINC is not to get more people to use birth control. Rather, the purpose is to find out if a person wants contraception during their visit to be able to meet their needs. This question assesses whether patients' needs related to contraception are being met.

At SNCHC, we ask everyone about their reproductive health needs. "Do you want to talk about contraception or pregnancy prevention during your visit today?"

If no:

Clarification Prompt: "There are a lot of reasons why a person wouldn't talk about this, and you don't have to share anything you don't want. Do any of these apply to you?"

- I'm here for something else
- This question does not apply to me
- I prefer not to answer
- I am already using contraception (and what)
- I am unsure or don't want to use contraception
- I am hoping to become pregnant in the near future

Determine the need for services among female and male clients of reproductive age · Assess reason for visit · Assess source of primary care Assess reproductive life plan Reason for visit is related to Initial reason for visit is not preventing or achieving related to preventing or achieving pregnancy pregnancy Acute care · Chronic care management Preventive services Contraceptive Pregnancy Achievina Basic services testing and pregnancy infertility counseling services Assess need for services related If needed, to preventing or achieving provide pregnancy services If services are not needed at this Clients also should be Sexually Preconception visit, reassess at subsequent visits provided these transmitted health services, per disease services clinical recommendations services Related Clients also should be provided preventive or referred for these services, health per clinical recommendations services

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

References

Before, Between & Beyond Pregnancy. (2025). Reproductive life plan. https://beforeandbeyond.org/toolkit/reproductive-life-plan-assessment/

Centers for Disease Control and Prevention (CDC). (2016). Providing quality family planning services: Recommendations of the CDC and the U.S. Office of Population Affairs, 2015. MMWR, 65(9). https://www.cdc.gov/mmwr/volumes/65/wr/mm6509a3.htm

Shepherd, Jan. (2015). Ask the Expert: Reproductive Life Planning: Setting Goals for a Healthy Family. https://healthystart-tasc.org/wp-content/uploads/2024/03/2015-04-28-slides.pdf

Clinic Emergencies

- 1. Syncope
 - a. Symptoms (sudden onset of one or more of the following):

- i. Nausea and/or vomiting
- ii. Diaphoresis
- iii. Weakness
- iv. Dizziness
- v. Pallor

b. Clinical Signs:

- i. Weakness, Sweaty, Possible Decreased Level of Consciousness
- ii. Pulse < 60/min. or > 110
- iii. BP < 80 systolic

c. Laboratory:

- i. Consider checking hemoglobin (Hgb)/ hematocrit (Hct).
- ii. Consider finger stick glucose.

d. Plan:

- i. Check vital signs and perform physical examination.
- ii. Lay client flat with legs elevated.
- iii. Treat symptomatically, supportive care only.
 - a) Aromatic spirits of ammonia may be helpful (Do not use if patient is asthmatic).
 - b) Offer juice or cola with sugar for clients with hypoglycemic episode.
- iv. If cardiovascular collapse is suggested by examination activate EMS system and begin basic life support.

2. Anaphylactic Shock

- a. Symptoms (Sudden onset of one or more of the following):
 - i. Hives
 - ii. Pruritus
 - iii. Swelling
 - iv. Red, Watery Eyes
 - v. Rhinorrhea
 - vi. Dizziness or Syncope
 - vii. Change of Voice
 - viii. Coughing or Wheezing
 - ix. Throat Tightness or Closing

- x. Difficulty with Breathing or Swallowing
- xi. Sense of Doom
- xii. Change of Color

b. Plan

- i. If cardiovascular collapse, respiratory distress, or facial/oral swelling is suggested by examination, activate EMS system, and begin basic life support if needed.
- ii. Monitor vital signs frequently, every two to five (2-5) minutes.
- iii. Medications (below), as available:
 - a) If available, give aqueous epinephrine 1:1,000, 0.5mL subcutaneously, with a dose for adults of 0.01mL/kg up to a maximum dose of 0.2 to 0.5mL. Repeat every ten to fifteen (10-15) minutes as needed if available.
 - b) Administer oxygen by facial mask at 8-10liters/min if available.
 - c) Give Benadryl (diphenhydramine) 25-50mg intramuscular (IM).
 - d) If anaphylaxis is due to an injection, give aqueous epinephrine, 0.15-0.3mL, into injection site to inhibit further absorption.
- 3. Cardiopulmonary Arrest Basic Life Support (BLS) for Health Care Providers
 - a. Establish unresponsiveness.
 - i. Activate EMS or appropriate resuscitation team.
 - ii. Get automated external defibrillator (AED) and emergency equipment or send someone to do so. (All clinics and facilities should have an AED on the premises.)
 - b. Evaluate the airway and check for breathing.
 - i. Look, listen and feel.
 - ii. If unresponsive and not breathing, open the airway (the person needs to be in a supine position).
 - iii. Head tilt-chin lift or jaw thrust.
 - iv. If the victim is breathing or resumes effective breathing, place in the recovery position.
 - v. If the victim is not breathing, give two (2) slow breaths, one (1) second each while using a pocket mask or bag-mask. Allow for exhalation between breaths.
 - c. Check for signs of circulation (breathing, coughing, movement), including pulse. (carotid).
 - i. If signs of circulation/pulse are present but breathing is absent, provide rescue breathing one (1) breath every five (5) seconds for adult; ten to

- twelve (10-12) breaths per minute.
- ii. If signs of circulation/pulse are absent, begin chest compressions interposed with breaths.
 - a) Compression depth of at least two (2) inches in adults and at least one third (1/3) the anteroposterior (AP) dimension of the chest in infants and children.
 - b) Compression rate: 100-120 compression/minute.
 - c) Compression/Breath Ratio (1 Person): 30:2 5 cycles; about two (2) minutes.
 - d) Compression/Breath Ratio (2 people): 30:2 5 cycles; check pulse and switch roles every two (2) minutes.

4. Defibrillation

- a. If CPR is in progress, continue CPR until the AED is turned on, the AED pads are applied, and the AED is ready to analyze the heart rhythm.
- b. If you are alone and an AED is available, you should use it once you have determined the person in cardiac arrest.
- c. For an AED to be effective, you MUST use it properly by doing the following:
 - i. Turn it on first.
 - ii. Make sure the patient's chest is clearly exposed and dry.
 - a) Remove any medication patches with a gloved hand.
 - b) If necessary, remove or cut any undergarments that may be in the way. The pads need to be adhered to the skin for the shock to be delivered to the heart.
 - iii. Apply the appropriate-sized pads for the patient's age in the proper location on the bare chest.
 - a) Use adult pads for adults and children over the age of eight (8) years or over fifty-five (55) pounds.
 - b) Place one (1) pad on the upper right chest below the right clavicle to the right of the sternum; place the other pad on the left side of the chest on the mid-axillary line a few inches below the left armpit.
 - iv. Plug in the connector, and push the analyze button, if necessary. Most AEDs available today have their pads pre-connected and will automatically analyze once the pads are applied to the chest. Make sure you understand how the AED within your organization operates.
 - v. Tell everyone to "clear" while the AED is analyzing to ensure accurate analysis. Ensure no one is touching the patient during the analysis or shock.
 - vi. When "clear" is announced, have the rescuer performing the compressions

stop compressions and hover a few inches above the chest, but remain in position to resume compressions immediately after a shock is delivered or the AED advises that a shock is not indicated.

- vii. Observe the AED analysis and prepare for a shock to be delivered if advised.
 - a) Ensure that everyone is clear of the patient before the shock is delivered.
 - b) Remember that the AED delivers an electrical current that could injure anyone in contact with the patient.
 - c) Have the rescuer in the hover position ready to resume compressions immediately after a shock is delivered or the AED advises that a shock is not indicated.
- viii. Deliver the shock by pressing the shock button, if indicated.
 - ix. After the shock is delivered, immediately start compressions, and perform about two (2) minutes of CPR (about 5 cycles of 30:2) until the AED prompts that it is reanalyzing, the patient shows signs of return of spontaneous circulation, or you are instructed by the team leader or more advanced personnel to stop.
 - x. Do not wait for the AED to prompt to begin CPR after a shock or no shock advised message.

5. Shock/Hemorrhage

- a. Symptoms (sudden onset of one or more of the following):
 - i. Uncontrolled, Profuse Bleeding
 - ii. Pallor, Weakness, Diaphoresis, Fainting
- b. Clinical Signs:
 - i. Client may appear weak and may exhibit disorientation.
 - ii. Pulse may be weak, shallow, rapid, or slow.
 - iii. Blood pressure may decrease (hypotension).
 - iv. Skin may appear pale and cold.
- c. Plan:
 - i. Place client in Trendelenburg position.
 - ii. Activate EMS system.
 - iii. Monitor vitals as indicated.
 - iv. If able, start intravenous line and infusion.
 - v. If etiology identified, attempt to control bleeding.
- 6. General Emergency Information

- a. Staff should be trained in emergency procedures and must be familiar with emergency plans. All licensed medical staff should be trained in CPR and hold current certification.
 - i. All client medical emergencies requiring referral to another provider should have referral results documented in the client's record.
 - ii. If appropriate, copy pertinent records to send with emergency personnel.
 - iii. Staff should engage in periodic drills, if multiple use facility, coordinate drills with other personnel.
- b. After Hours Emergencies (all facilities must have in place at least one of the following for the management of afterhours contraceptive emergencies):
 - i. An answering service that can direct a client to either an on-call staff nurse or the nearest emergency department (ED).
 - ii. Message left on clinic phone with clear instructions to the nearest ED.
 - iii. Call-forwarding to the on-call staff nurse.
 - iv. In addition to the above, written instructions must be provided to every client during the initial and subsequent visits detailing the facilities' afterhour policies.
- c. Emergency Situations (fire, natural disaster, vandalism, power failure, harassment, bomb/terrorism, earthquake, and tornado) may occur at any time. All projects must therefore have written plans and procedures for the management of emergencies.
 - i. Disaster plans must be developed and made available to all staff.
 - ii. Staff must understand all the assigned emergency escape routes.
 - iii. Staff must complete training and understand their role in an emergency or natural disaster.
 - iv. All exits must be recognizable and free from barriers.

Latex

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

Subjective Data/Symptoms

History may include:

- Rash with latex exposure.
- Swollen lips like blowing up a latex balloon.

Symptoms may include:

- Itchy, stuffy, or runny nose
- Watery Eyes

- Scratchy Throat
- Hives or Swelling
- Nausea or Vomiting
- Dizziness, Confusion
- Wheezing, Cough, Chest Tightness, and Difficulty Breathing

Objective Data

Physical Findings:

- Rash or Redness
- Hives or Swelling
- Hypotension
- Confusion, Loss of Consciousness
- Weak or Rapid Pulse
- Cough
- Wheezing

Plan / Pharmacologic Treatment

Medication:

- If a person is having an anaphylactic reaction, the person needs an immediate injection of epinephrine.
- For less severe reactions, antihistamines or corticosteroids should control the reaction and relieve discomfort.

Latex Allergy Precautions

- Latex allergy precautions include:
- Remove all latex gloves from the area and replace them with:
 - Nonsterile latex free gloves, powder free, low protein, or vinyl gloves for nonsterile procedures.
 - Sterile latex free gloves for sterile procedures.
- Remove all items containing latex.
- A facility-wide strategy to manage latex allergies in the health care environment should be in place.
- Latex free materials should be readily available for those patients with allergies.

References

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

Healy, L. & Poole, D. (2021). Latex management of a patient at risk of or with a known latex allergy.

https://www.rch.org.au/rchcpg/hospital_clinical_guideline_index/Latex_management_of_a_patie_nt_at_risk_of_or_with_a_known_latex_allergy/

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

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

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

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

Custody of Records

The agency is the legal custodian of client records. It is responsible for the provision of a safe place for storage of client records to prevent disclosure to unauthorized persons.

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. Electronic medical records (EMR) must be password protected and should have an automatic time out when not in use. Users should lock the EMR when not in use to ensure against unauthorized access. Also, consider that portable laptops should not be left in a room with a client. An additional layer of security can be provided with the use of biometrics.

Confidentiality and HIPAA

Agencies must be compliant with HIPAA regulations. HIPAA covered entities are expected to have adequate administrative, technical, and physical safeguards in place to protect personal health information under its control.

- A summary of the HIPAA privacy rule is available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html
- A summary of the HIPAA security rule is available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html
- In January 2013, HHS announced a final rule that implements several provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act to strengthen the privacy and security protections for health information established under HIPAA. See http://www.hhs.gov/ocr/privacy/hipaa/administrative/omnibus/index.html for the press release and a link to the final rule.
- Clients must be informed of agency privacy practices and a signed acknowledgment of

receipt of the notice must be part of the medical record. Model notices of privacy practices that reflect 2013 regulatory changes are available at http://www.hhs.gov/ocr/privacy/hipaa/modelnotices.html

Some Considerations in Maintaining Confidentiality

- All staff must be oriented to the importance of safeguarding the confidential nature of the record and any other client information.
- Privacy and confidentiality in gathering client information by interview or any other means is essential.
- Office and clinic facilities should be such that client information is not inadvertently revealed to people in the waiting room or any place else.
- Use discretion in engaging a client in discussion in his home or on the street while neighbors, relatives, or other people are present.
- Electronic email exchanges with clients should be encrypted.

Accessibility of Medical Records

- The records must be systematically organized to facilitate retrieval and compiling of information.
- Funding agencies, such as HHS, have the right to review charts of those individuals whose care is supported by their funds.
- The original medical record is the property of the clinic. However, the client or her/his attorney, upon presentation of appropriate documentation, is entitled to copies of the record.

Retention of Records

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

Destruction of Records

• When materials no longer need to be retained, 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.

Content of Client Record

The medical record must contain sufficient information to identify the client, justify the diagnosis or clinical impression, and warrant the treatment and end results.

The record should contain the following:

Personal Data

- o Client identification.
- o Name, address, and telephone number.
- Name of someone who may be contacted to reach client.
- Name, address, telephone number, and relationship to client of a person who may be contacted in the event of a medical emergency. For the client under eighteen (18), the parent or guardian should be listed.
- o Dates of visits.
- Identification of other sources of medical care.

Clinical data

- Medical history, which must be updated at least annually or more often as indicated.
- Documentation of physical examination.
- o Documentation of laboratory tests ordered, results, and follow-up.
- Diagnostic and therapeutic orders, observations, clinical findings, and action taken.
 - o Indication of treatments and/or medications given, observations, and action taken.
 - o Progress notes.
 - o Special instructions.
 - o Follow-up contact when applicable.
- Any telephone calls to or from a client regarding medical problems.
 - o Referral forms.
 - o Follow-up of referrals.
 - o Whenever possible, a summary of relevant health-related encounters in other health facilities should be included in the client's family planning medical record.

Record Audit

- Internal record audits should be performed at least monthly, to determine completeness of records, e.g., blanks filled in, releases and consent signed appropriately, physician and staff signatures, etc.
- Chart audits for the Title X funding should be completed twice a year.

SECTION 5

Psychosocial

Human Trafficking

Human trafficking is a form of modern-day slavery that is widespread throughout the U.S. today. Human trafficking is the recruitment, transportation, transfer, harboring, or receipt of persons by means of force, fraud, or coercion for the purpose of exploitation. The following information summarizes key issues in human trafficking.

- 1. Three (3) Categories of Human Trafficking include:
 - a. Those eighteen (18) or over involved in commercial sex via force, fraud, or coercion.
 - b. Minors involved in commercial sex.
 - c. Adults or minors in forced labor, services or involuntary servitude via force, fraud, or coercion.
- 2. Since Title X clinics provide low/no cost reproductive health care to uninsured populations, providers may encounter victims of human trafficking. It is essential for clinic staff to recognize the signs and symptoms of human trafficking.
- 3. According to the legal definition trafficking does not require:
 - a. Transportation across state or national borders.
 - b. Physical restraint. Psychological means of control can be sufficient elements of crime.
 - c. Consent prior to an act of force, fraud, or coercion (or if the victim is a minor with sex trafficking) is not relevant, nor is payment.
 - d. Relatives can be traffickers.
- 4. Potential red flags/indicators for human trafficking include individuals who:
 - a. Are under eighteen (18) and provide commercial sex acts or trade sex for something of value.
 - b. Are inconsistent in their story or claim of "just visiting" coupled with inability to clarify their addresses.
 - c. Are in demeanor: fearful, anxious, submissive, tense, or nervous.
 - d. Are not in control of their own identification documents.
 - e. Are not in control of their own money.
 - f. Have few or no personal possessions/financial records.
 - g. Have excessively long working hours or odd tasks at odd hours.
 - h. Have jobs that do not pay or pay very little.
 - i. Have large debt and cannot pay it off.
 - j. Have restricted, mediated, or controlled communication by third parties (have. someone speaking for her/him).
 - k. Have an unusually high number of sexual partners for his/her age.
 - 1. Have signs of malnourishment, general lack of health care, physical abuse/restraint, confinement, torture, branding, sexual abuse or untreated STIs.
 - m. Lack of freedom to leave living/working conditions.
 - n. Lack of knowledge of a given community/whereabouts, frequent movement.
- 5. Additional questions to consider, each question taken individually can imply a trafficking

situation. Questions are not intended to be cumulative in nature:

- a. Was the person recruited? Were they promised anything?
- b. How did the person find out about the job? What are the working conditions?
- c. Is the person being paid? Is the person free to leave?
- d. Are there incidences of physical and/or sexual assault?
- e. Has the person been threatened? What are the threats?
- f. Is the person in control of their own identification documents?
- g. How many hours does the person work each day?
- h. What are the person's living conditions?
- i. Is the person being held against their will?
- i. Is the person afraid to discuss her or himself in the presence of others?
- 6. If you think you have come across a case of trafficking and/or have identified a victim of trafficking.
 - a. Document screening findings in patient electronic medical record.
 - b. In the case of a minor, call the Nevada Child Protective Services.
 - c. For non-minors, only if the patient allows you to make a report and disclose their confidential Information, may you contact law enforcement to make a report.

7. Mandated Reporting

Title X projects shall comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking (collectively, "State notification laws") (42 CFR 59.17(a)(b)(1)(2)).

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

- c. Conduct a preliminary screening of any minor who presents with a sexually transmitted disease (STD), pregnancy, or any suspicion of abuse, to rule out victimization of a minor.
- d. Projects are permitted to diagnose, test for, and treat STDs.
- e. Maintain records to demonstrate compliance with each of the requirements, including which:
 - i. Indicate the age of minor clients.
 - ii. Indicate the age of the minor client's sexual partners if such age is an element of a state notification law under which a report is required.
 - iii. Document each notification or report made pursuant to such Nevada notification laws.
- f. Refer to Minor Consent, Confidentiality, and Reporting Child Sexual Abuse: A Guide for Title X Family Planning Providers in Nevada for full details and procedures.
 - i. R. Gudeman, Minor Consent, Confidentiality and Reporting Child Sexual Abuse: A Guide for Title X Family Planning Providers in Nevada (National Center for Youth Law, Oakland, 4th ed. 2021).

What is mandated reporting?

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

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

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

Who are mandated reporters?

Nevada law specifies the persons or professions that are required to report child abuse or neglect. Nevada mandatory reporters are listed in Nev. Rev. Stat §432B.220.

Mandatory reporters include (selected sample):

- Physician, Physician Assistant
- Dentist
- Podiatrist
- Registered Nurse, Licensed Practical Nurse

- Other Healthcare Professional
- A person engages in social work or the practice of professional counseling.
- Pharmacists
- Or other person providing medical services licensed or certified in the state of Nevada.

How is a report made?

- Mandated reporters should report the abuse or neglect of the child to an agency which provides child welfare services or to a law enforcement agency. The report goes to law enforcement if the suspected abuse involves acts by a person working for a public or private home, institution of facility where the child is receiving childcare outside the home for a portion of the day. If the alleged abuse is at the hands of someone who works for a child welfare of law enforcement agency, the report must go to any agency other than the alleged one (Nev. Rev. Stat § 432B.220).
- Mandated reporters must make a report as soon as reasonably practicable but not later than twenty-four (24) hours after the person knows or has reasonable cause to believe that the child has been abused or neglected. (Nev. Rev. Stat § 432B.220) A person may make a report by telephone or, in light of all the surrounding facts and circumstances which are known or which reasonable should be known to the person at the time, by any other means or oral, written or electronic communication that a reasonable person would believe, under those circumstances, is a reliable and swift means of communication information to the person who received the report. If the report is made orally, the person who receives the report must reduce it to writing as soon as reasonably practicable. (Nev. Rev. Stat § 432B.230).

What information should be included in a mandatory report?

- The names, address, age, and sex of the child.
- The name and address of the child's parents or other person responsible for the care of the child.
- The nature and extent of the abuse, the effect of a fetal alcohol spectrum disorder or prenatal substance abuse on the newborn infant of the nature of the withdrawal symptoms resulting from prenatal drug exposure of the newborn infant.
- Any evidence of previously known or suspected abuse.
 - o Abuse or neglect of the child or the child's siblings.
 - Effects of a fetal alcohol spectrum disorder or prenatal drug exposure of the newborn infant.
- The name, address, and relationship, if known, of the person who is alleged to have abused or neglected the child.
- Any other information known to the person making the report that the agency which provides child welfare services considers necessary. Nev Rev. Stat § 432B.230.

When must abuse be reported?

- A mandated reporter must report when the reporter, in their "professional or occupational capacity, knows or has reasonable cause to believe that a child has been abused or neglected" Nev. Rev. § 432B.220.
- Confirmation of abuse is not required. Reporters must report whenever they have "reasonable cause to believe" that abuse has occurred. State law defines "reasonable cause to believe" to mean that if, considering all the surrounding facts and circumstances which are known or which reasonable should be known to the person at the time, a reasonable person would believe, under those facts and circumstances, that an act, transaction, event, situation, or conditions exists, is occurring or has occurred. Nev. Rev. § 432B.121.

What sexual activity must be reported?

Nevada law defines "abuse or neglect of a child" to include:

- "Physical or mental injury of a nonaccidental nature"
- "Sexual abuse or sexual exploitation"
- "Negligent treatment or maltreatment of a child" causes or allowed by a person responsible for the welfare of the child under circumstances which indicate that the child's health or welfare is harmed or threatened with harm. For this purpose, "allow" means to do nothing to prevent or stop the abuse or neglect of a child in circumstances where the person known or has reason to know that a child is abused or neglected. Nev. Rev. Stat. § 432B.020.

In addition, reporters must report any reasonable suspicion of activity that falls into the categories:

- Incest
- Lewdness with a Child
- Sado-masochistic Abuse
- Sexual Assault
- Open or Gross Lewdness
- Mutilation of the Genitalia of a Female Child

Am I ever required to report a minor's consensual sexual activity as child abuse?

Consensual acts that must be reported as child abuse include:

- There are a few circumstances in which sexual activity with a minor is deemed sexual abuse and must be reported based on age of parties alone. This includes:
 - O Any sexual penetration, including sexual intercourse, anal intercourse, cunnilingus, fellatio, or any intrusion in a genital or anal opening commutes by a person eighteen (18) years of age or older with a person fourteen or fifteen (14 or 15) and at least four (4) years younger than the perpetrator.
 - O Any sexual penetration, including sexual intercourse, cunnilingus, fellatio, or any intrusion in a genital or anal opening, upon or with a child under the age of fourteen (14) years, irrespective of the age of the other person.

- O Any lewd or lascivious act upon or with the body, or any part or member thereof, of a child under the age of sixteen (16) committed willfully and lewdly by a person eighteen (18) years of age or older with the intent of arousing, appealing to, or gratifying the lust of passions or sexual desires of either of the persons.
- O Any lewd or lascivious act upon or with the body, or any part or member thereof, of a child under the age of fourteen (14) years, with the intent of arousing, appealing to, or gratifying the list or passions or sexual desires of that person or that child, irrespective of the age of the other person. Nev. Rev. Stat. §§ 200.364, 200.368, 201.230.
- For this purpose, "sexual penetration" means cunnilingus, fellatio, or any intrusion, however slight, of any part of a person's body or any object manipulated or inserted by a person into the genital or anal openings of the body or another, including sexual intercourse in its ordinary meaning" Nev. Rev. Stat §§ 200.364, 200.368, 201.230.

In general, the following consensual acts do not require reporting:

Mandated reports are not require for:

- Sexual activity between minors who are fourteen (14), fifteen (15), sixteen (16), or seventeen (17) years of age and there is no reasonable suspicion that one person is subjected or forces the other person to engage in that activity and there is no reasonable suspicion that one person was mentally or physically incapable or resisting or understanding the nature of the conduct.
- Sexual activity between a minor who is age sixteen (16) or older and a partner aged sixteen (16) or older and there is no reasonable suspicion that one person subjected or forced the other person and no reasonable suspicion that one person was mentally or physically incapable of resisting or understanding the nature of the conduct.

What is abuse or neglect?

Nevada law defines "abuse or neglect of a child" to include:

- "Physical or mental injury of a nonaccidental nature"
- "Sexual abuse or sexual exploitation;"
- "Negligent treatment or maltreatment of a child" caused or allowed by a person responsible for the welfare of the child under circumstances which indicate that the child's health or welfare is harmed or threatened with hard. For this purpose, "allow" means to do nothing to prevent or stop the abuse or neglect of a child in circumstances where the person knows or has reason to know that a child is abused or neglected." Nev. Rev. Stat. § 432B.020.

Nevada law states that "negligent treatment or maltreatment of a child" occurs is a child has been subjected to harmful behavior that is terrorizing, degrading, painful or emotionally traumatic, has been abandoned, is without proper care, control of supervision or lacks the subsistence, education, shelter, medical care or other care responsible for the well-being of the child because of the faults or habits of the person responsible for the welfare of the child or the neglect or refusal of the person to provide them when able to do so. Nev. Rev. Stat § 432B.140.

Nevada law requires reporting, "sexual abuse" and defines "sexual abuse" to include acts upon a child constituting:

- Incest under NRS.201.180
- Lewdness with a child under NRS 201.230
- Sado-masochistic abuse under NRS 201.262
- Sexual assault under NRS 200.366
- Statutory sexual seduction under NRS 200.368
- Open or gross lewdness under NRS 200.368
- Mutilation of the genitalia of a female child, aiding, abetting, encouraging, or participating in the mutilation of the genitalia of a female child, or removal of a female child from this State for the purpose of mutilating the genitalia of the child under NRS 200.5082. Nev. Rev. Stat § 432B.100.

When mandated reports in Nevada must report consensual sexual activity as child?

If a minor engages in consensual sexual conduct with an older (or younger) partner, is a reported mandated.

Age∙of∙Partner⇒¤	12¤	13¤	14¤	15¤	16¤	17¤	18¤	1 9 ¤	20¤	21¤	22¤	3
Age·of·Patient·↓□									3			
11¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	3
12¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	3
13¤	Υ¤	N¤	N¤	Nα	Nα	N¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	3
1 4 ¤	Υ¤	N \square	Y¤	Y¤	Y¤	Υ¤	Y¤	3				
15¤	Υ¤	N¤	N¤	Nα	Nα	Nα	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	3
16¤	Υ¤	N¤	N¤	Nα	Nα	Nα	Nα	N¤	N¤	N¤	N¤	}
17¤	Y¤	N¤	N¤	N¤	N¤	N¤	N¤	N¤	N¤	N¤	N¤	}
18¤	Υ¤	Υ¤	Υ¤	Υ¤	N¤	N¤	N¤	N¤	Nα	Nα	N¤	}

If a minor engages in sexual contact is a report required.

Age·of·Partner⇒¤	12¤	13¤	1 4 ¤	15¤	16¤	17¤	18⊏	19¤	20□	21¤	22¤
Age·of·Patient·↓□											
11¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Y¤
12¤	Υ¤	Y¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Υ¤	Y¤
13¤	Υ¤	Nα	Nα	Nα	N¤	N¤	Υ¤	Υ¤	Υ¤	Υ¤	Y¤
14¤	Υ¤	Nα	Nα	N¤	N¤	N¤	Υ¤	Υ¤	Υ¤	Υ¤	Y¤
15¤	Υ¤	Nα	Nα	N¤	N¤	N¤	Nα	Υ¤	Υ¤	Υ¤	Y¤
16¤	Υ¤	Nα	N¤	N¤	N¤	N¤	N¤	N¤	N¤	N¤	N¤
17¤	Υ¤	N¤	N¤	N¤	N¤	N¤	N¤	N¤	N¤	N¤	N¤
18¤	Υ¤	Y¤	Υ¤	N¤	N¤	N¤	Nα	N¤	N¤	Nα	N¤

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

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

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

References

Gudeman, R. (2019). Minor Consent, Confidentiality, and Child Abuse Reporting in Title X Funded Family Planning Settings in Nevada. (3rd· ed.). National Center for Youth Law. Oakland: CA.

What is family and intimate partner violence?

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

IPV is abuse or aggression that occurs in a close relationship. "Intimate partner" refers to both current and former spouses and dating partners. IPV can vary in how often it happens and how severe it is. It can range from one (1) episode of violence that could have lasting impact to chronic and severe episodes over multiple years. IPV includes four types of behavior:

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

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

Screening

ACOG recommends that physicians screen ALL patients for intimate partner violence. Be sure to inform patients of any legal reporting requirements prior to screening. For women who are not pregnant, screening should occur:

- At routine obstetrics/gynecological (OB/GYN) visit
- At FP visits
- At pre-pregnancy visits

SNCHC utilizes Hurt, Insult, Threaten and Scream (HITS) tool for IPV by asking: How often does your partner?

- Physically hurt you.
- Insult or talk down to you.
- Threaten you with harm.
- Scream or curse at you.

Each item is scored from one to five (1-5). Range between four to twenty (4-20). A score greater than ten (10) signifies, client is at risk of domestic violence abuse and should seek counseling or help from a domestic violence resource center.

If Abuse is Denied:

If abuse is denied and no indicators of abuse are present, document the findings in the medical record and offer referral information for future reference.

What to do if a patient says "no"

- Respect her/his response.
- Let the patient know that you are available should the situation ever change.

- Assess again at regular intervals as an indication that it is safe to disclose to you.
- Display information and resources in exam and waiting rooms, or bathrooms.
- If patient says "no" but you believe she/he may be at risk, discuss the specific risk factors and offer information and resources.
- Let the patient know that experts and help are available. Offer a crisis card/safety card. Tell them that even if they don't need it that they can give it to a friend or family member who might use it. Discuss possible repercussions if their partner finds the card.
- Do not write any domestic violence referral on discharge papers that will be taken home with the patient.

If a patient has obvious or suspected abuse but cannot communicate to acknowledge abuse (i.e., unconscious, or impaired), schedule a follow-up appointment or initiate appropriate social work consult to ensure follow up.

If Abuse is Identified:

If a patient discloses that they are currently being abused, at a minimum their immediate safety should be assessed. This could include asking:

- Are you in immediate danger?
- Is your partner in the facility now?
- Has the violence escalated or gotten worse over the past year?
- Has your partner threatened to kill you or your children?
- Does your partner have access to guns or other deadly weapons?

If the patient answers yes to any of these, encourage her/him to speak with a domestic violence advocate to develop a safety plan even if the patient does not intend to leave her/his abuser.

Provide a phone and a safe place for her/him to contact an advocate. Offer to make a call for them if they would prefer that. Be mindful that your phone may be the only link a survivor has to a domestic violence advocate since cell phones and land lines are easily traceable.

Resources

- National Domestic Violence Hotline
 Call 1-800-799-7233 and TTY 1-800-787-3224
- <u>Love is Respect National Teen Dating Abuse Helpline</u> Call 1-866-331-9474 or TTY 1-866-331-8453
- Rape, Abuse & Incest National Network's (RAINN) National Sexual Assault Hotline Call 800-656-HOPE (4673) to be connected with a trained staff member from a sexual assault service provider in your area.
- National Resource Center on Domestic Violence
- Nevada Coalition to End Domestic and Sexual Violence
 Has created a network healthcare provider to have resources available for survivors.

Indicators

General signs and symptoms of family and intimate partner violence.

- Conditions such as chronic fatigue or headaches, abdominal and/or pelvic pain, frequent use of pain medication, sexual dysfunction, frequent vague complaints of physical discomfort, or gastrointestinal problems.
- Drug and alcohol abuse by the patient or her partner.
- History or signs of depression or anxiety, or use of sedatives and/or tranquilizers.
- Attempts or thoughts of suicide.
- Self-injury.
- Signs of post-traumatic stress disorder.
- Suspicious injuries that are explained in ways that are inconsistent with the type or severity of the injury.
- Multiple sites of injury and/or a pattern of repeated injury.
- Delay in seeking medical care including delayed prenatal care.
- Description of a partner as jealous, controlling or domineering, prone to anger, and/or frustrated with the patient and/or children.

Sample Safety Planning Guide for a Patient

We are concerned about your safety and strongly encourage you to talk to an advocate who can help you devise a safety plan. In the meantime, here are some steps you can take to prepare for emergencies and reduce your risk of injury.

- Prepare an emergency kit containing items you will need if you must leave suddenly. You may wish to include:
 - o Identification for you and your children.
 - o Money, credit cards, checkbook, and bankbook.
 - o Green card, custody papers, restraining orders, car registration, health insurance card, and any other important papers.
 - Keys, medications, address book, and a change of clothes. It may be helpful to keep a packed bag at a friend's house.
- Let neighbors know you want them to call 911 when they hear an argument. Set a code phrase you can use with a friend to signal that you are asking for help.
- Teach your children what to do if you and your partner are fighting. You should tell your children to stay out of the argument and arrange for them to have a safe, nearby place where they can go in an emergency.
- Plan for a place where you can stay if you must leave home.
- Design and practice escape routes from the house with your children in case of an emergency.

- Make sure weapons are not easily accessible. Knives should be removed from the kitchen counter and guns should be kept in a locked box separate from ammunition.
- During an argument, you should stay in an area where you can quickly exit. Stay away from the kitchen (where there are knives) and the bathroom (where you can hit your head easily).

Additional steps if separating from a potentially violent partner:

- Put a safety plan in place before discussing your desire to separate. Discuss your plan with your children.
- Change the locks on your doors and install locks on windows.
- Get the police and court system involved. If possible, obtain a protective order (e.g., restraining order). Always keep a copy with you and give a copy to someone that you trust. Call the police immediately if your partner violates the protective order.
- Inform others, your neighbors, especially that you have a restraining order in effect and encourage them to call the police for you if your partner violates it. Provide a picture of your partner if necessary.
- Make sure that your children's caregivers know who has permission to pick them up.

References

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

What is Substance Abuse?

HHS reports provide the tools necessary for the inclusion of substance abuse disorder screening into family planning services offered by Title X applicants as a key issue.

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

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

General Screening

- Clinic staff should utilize face-to-face time with proven screening instruments.
- Agencies need to have policies and procedures in place to assist the client when further assessment is indicated.
- Agencies should consult their legal counsel for processes when a minor warrants referral for a professional substance abuse assessment.

Drug Abuse

To screen patients, first use a statement like the following:

• "Substance use is so common in our society that I now ask all my patients, what, if any

substances they are using?"

Then, ask questions from a tool or provide them with a tool.

Assessment Tools examples

- Car, Relax, Alone, Forget, Friends, Trouble (<u>CRAFFT</u>) screening tool for adolescent aged fourteen and older.
 - Have you ever ridden in a car driven by someone (including yourself) who was high or had been using alcohol or drugs?
 - o Do you ever use alcohol or drugs to relax, feel better about yourself, or fit in?
 - o Do you ever use alcohol or drugs while you are by yourself or alone?
 - o Do you ever forget things you did while using alcohol or drugs?
 - Do your family or friends ever tell you that you should cut down on your drinking or drug use?
 - o Have you ever gotten into trouble while you were using drugs or alcohol?
- Cut, Annoyed, Guilty, Eye Opener (<u>CAGE AID</u>) to screen for drug and alcohol use
 - o Have you ever felt you ought to cut down on your drinking or drug use?
 - o Have people annoyed you by criticizing your drinking or drug use?
 - o Have you ever felt bad or guilty about your drinking or drug use?
 - Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover?
- Screening, Brief Intervention and Referral to Treatment (<u>SBIRT</u>) screening for the severity of substance use and identified appropriate level of treatment.
 - o How often do you have a drink containing alcohol?
 - o How many standard drinks containing alcohol do you have on a typical day?
 - How often do you have six (6) or more drinks on one occasion?
 - How many times in the past year have you used an illegal drug or used prescription medication for non-medical reasons?
 - o Alcohol Interpretation: three (3) or greater for women; four (4) or greater for men would be positive; anything less would be negative.
 - o Drug Interpretation:

Negative: 0

• Positive: 1 or more

SBIRT

- With a positive screening, the provider should provide a brief intervention and be prepared to make a referral.
- Brief interventions are evidence-based practices designed to motivate individuals at risk of

substance abuse and related health problems to change their behavior by helping them understand how their substance use puts them at risk and to reduce or give up their substance use.

- Healthcare providers can also use brief interventions to encourage those with more serious dependence to accept more intensive treatment within the primary care setting or a referral to a specialized alcohol and drug treatment agency.
- Brief interventions last from five (5) minutes of brief advice to fifteen to thirty (15-30) minutes of brief counseling.
- The two most common behavioral therapies used in SBIRT programs are brief versions of cognitive behavioral therapy and motivational interviewing, or some combination of the two (2).

Create Resource Area

- Ideal location in each program's waiting room and screening room.
- Feature publications on substance abuse and family violence.
- Post names of local counseling centers: mental health, drug-specific, alcohol specific. Include pamphlets/magnets for the public from these agencies.
- Post meeting schedules from Alcoholics Anonymous (AA) and Narcotics Anonymous (NA).
- Post directory of domestic violence shelters and related local resources.

Tobacco Use

Ask-Advise-Connect (AAC) uses electronic health record to systematically assess all patients for tobacco use, advise patients to quit using tobacco, and electronically connect the patient to the Nevada Tobacco Quit Line. It is recommended by CDC and North American Quit Line Consortium.

- Ask Systematically identify all smokers at every visit.
- Advise strongly urge all tobacco users to quit.
- Connect directly send patient information to Quitline through EMR. Quitline proactively calls patients within forty-eight (48) hours make five (5) attempts.

Resources:

- Nevada Tobacco Quitline provides free health coaching, and some patients may qualify for nicotine replacement therapy (NRT). Services are available to all Nevadans twenty-four (24) hours a day, seven (7) days a week. Translation services in one hundred and forty (140) languages. With special programs for pregnancy, youth, American Indian and young adult.
- Individuals can enroll by:
 - o Phone (English): 1-800-QUITNOW
 - o Phone (Spanish): 1-855-DEJELO YA

Online: nevadatobaccoquitline.com

National Resource

Substance Abuse and Mental Health Services Administration (SAMHSA)

- SAMHSA's National Helpline, <u>1-800-662-HELP (4357)</u>, (also known as the Treatment Referral Routing Service) or TTY: <u>1-800-487-4889</u> is a confidential, free, twenty-four (24) hour-a-day, three hundred sixty-five (365) day-a-year, information service, in English and Spanish, for individuals and family members facing mental and/or substance use disorders.
- This service provides referrals to local treatment facilities, support groups, and community-based organizations. Callers can also order free publications and other information.

References

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

SAMHSA. (2025). Screening and Assessment Tools Chart. https://www.samhsa.gov/resource/dbhis/screening-assessment-tools-chart.

SECTION 6

Contraception

What is abstinence or sexual risk avoidance?

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

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

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

Protocol

SNCHC trained clinical staff may provide abstinence counseling and education for adolescents, eighteen (18) and younger, who request birth control at their first visit. Education and information on abstinence may also be provided to any client who requests this method. There are no U.S. MEC risk conditions for using abstinence as a birth control method.

Procedure

Provide client-centered care through quality counseling and education using the five (5) key principles:

- Establish and maintain rapport with the client.
- Assess the client's needs and personalize discussions accordingly.
- Work with the client interactively to establish a plan.
- Provide information that can be understood and retained by the client.
- Confirm the client's understanding using a technique such as the teach-back method.

Review medical history:

- Significant illness
- Allergies
- Current medications, prescriptive and over the counter (OTC).
- Use of Tobacco, Alcohol, and Other Drugs
- Immunization and Rubella status
- Contraceptive

- Menstrual History
- Sexual History including risk for STIs.
- Obstetrical History
- Gynecological and PAP test history
- Surgical history
- Hospitalizations
- Family History
- Reproductive Life Plan

Review last menstrual period (LMP) and compliance with contraceptive method (if applicable). Assess the risk of current pregnancy. Offer pregnancy test if indicated.

- A health care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets the following:
 - o Is \leq 7 days after the start of normal menses.
 - o Has not had sexual intercourse since the start of last normal menses.
 - o Has been correctly and consistently using a reliable method of contraception.
 - o Is ≤ 7 days after spontaneous or induced abortion.
 - o Is within four (4) weeks postpartum.
 - o Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrhoeic, and < 6 months postpartum.

Assess recent sexual activity where intercourse was unprotected and offer emergency contraception (EC) for immediate use if indicated.

• Note that if Ella® is the EC formulation is administered, a reliable barrier method of contraception should be used with subsequent acts of intercourse that occur within the next fourteen (14) days. Because Ella® and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effect. After using Ella® if a woman wishes to use hormonal contraception, she should do so no sooner than five (5) days after the intake of Ella®.

Blood Pressure:

- Among patients with BP (blood pressure) < 120/80, screen for high blood pressure yearly and encourage a healthy lifestyle to maintain a normal blood pressure.
- Among patients with systolic BP (SBP) 120-129 and diastolic BP (DBP) less than 80, recommend healthy lifestyle changes and rescreen for high blood pressure in three to six (3-6) months.
- Screen adolescents for high blood pressure every year; refer clients with blood pressure reading ≥ 130 systolic or ≥ 80 diastolic refer to a primary care provider for further evaluation and treatment.

Weight/Height: obtain BMI.

Screen for STIs (if the client has not been screened) according to STI screening guidelines (see Section 9: STI Screening Policies and Procedures).

Discuss client's reproductive life plan about becoming pregnant by asking:

- Do you have children now?
- Do you want to have (more) children?
- How many (more) children would you like to have and when?
 - o If the client does not want a child now and is sexually active, then offer contraceptive services.
 - o If the client desires pregnancy testing, then provide pregnancy testing and preconception counseling.
 - If the client wants to have a child now, then provide services to help the client achieve pregnancy and provide preconception counseling.
 - o If the client wants to have a child and is having trouble conceiving, then provide basic infertility services.

Present all birth control method options for which the client has no U.S. MEC category 4 risk conditions.

Each client will receive client instructions regarding warning signs, common side effects, risks, use of method, alternative methods, use of secondary method and clinic follow-up schedule. Document the client's education and understanding of the method of choice.

Plan

- Abstinence can be initiated at any time in the menstrual cycle and at any time in the client's life.
- Abstinence requires the cooperation of both partners and staff will encourage partner involvement if indicated.
- Have a backup plan and supplies in case the method fails (e.g., condoms, EC).
- Review the client's history and access to recommended health screenings.
- Offer and schedule a reproductive health well visit if the client has not been screened appropriately within the past twelve (12) months or if an earlier assessment is clinically indicated.
- Offer and provide condoms for use as a back-up method and for STI protection.
- The decision to offer and dispense future use EC should be made on an individualized basis and should include shared decision making between the provider and the client. Clients requesting (those that self-identify that they need or want) EC for future use and those using less reliable methods of birth control (tier 3 methods) might benefit most from having future use EC made available.
 - o Instruct client to wait five (5) days after the administration of Ella® before

initiating hormonal contraceptives. Recommend the use of a barrier method of contraception with all subsequent acts of intercourse that occur within the next seven (7) days.

Routine Follow-up

The recommendations listed below address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women and men. Although routine follow-up is not necessary for the use of abstinence as a birth control method, recommendations for follow-up might vary for different users and different situations.

Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple conditions may benefit from more frequent follow-up visits.

- Advise the client to return at any time to discuss their birth control method, or if the client wants to change the method being used.
- At other routine visits, healthcare providers should do the following:
 - Assess the client's satisfaction with the contraceptive method and whether the client has any concerns about method use; and
 - Assess any changes in health status that would change the appropriateness of the birth control method.

Client Education

- All women who are planning or capable of pregnancy should be counseled to take a daily supplement containing 0.4 to 0.8 milligrams (400 to 800 μg) of folic acid.
- Advise the client that abstinence is always an option and can be initiated at any time even if she/he has already had sex.
- Provide information to the client on all birth control methods; it is important that the client understands all options available if/when they decide to have sexual intercourse.
- Abstinence alone does not prevent HIV/AIDS, hepatitis B and hepatitis C. Provide risk reduction counseling.
- Encourage the client to determine in advance what sexual activities are okay and discuss these with their partner.
- Provide the client with information on how to resist sexual coercion.
- Encourage family involvement for clients seventeen (17) and younger.

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What are combined oral contraceptives?

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

Protocol

SNCHC clinical providers may provide COCs to any client who requests this method and has no U.S. MEC category 4 risk conditions.

- Category 4 risk conditions (risk of use outweighs the benefits of pregnancy prevention):
 - Current breast cancer
 - Severe cirrhosis: (decompensated)
 - o Deep venous thrombosis/pulmonary embolism (DVT/PE): History of DVT/PE, not on anticoagulant therapy: higher risk for recurrent DVT/PE
 - Acute DVT/PE
 - DVT/PE and established on anticoagulant therapy for at least three (3) months with higher risk for recurrent DVT/PE
 - Major surgery with prolonged immobilization
 - o Diabetes mellitus with nephropathy/retinopathy/neuropathy
 - O Diabetes mellitus: other vascular disease or diabetes of > 20 years' duration
 - o Migraines with aura, any age
 - Hypertension: systolic ≥ 160 or diastolic ≥ 100
 - Hypertension with vascular disease
 - o Ischemic heart disease: current and history
 - o Benign liver tumors: hepatocellular adenoma
 - Malignant liver tumors
 - o Multiple risk factors for arterial cardiovascular disease (such as older age [> 35 years of age], smoking, diabetes, and hypertension).
 - Peripartum cardiomyopathy: normal or mildly impaired cardiac function < 6 months
 - o Peripartum cardiomyopathy: moderately or severely impaired cardiac function
 - o Postpartum < 21 days
 - o Smoking: age ≥ 35 , ≥ 15 cigarettes/day
 - Solid organ transplantation: complicated
 - o Stroke: history of cerebrovascular accident

- O Systemic lupus erythematosus: positive (or unknown) antiphospholipid antibodies
- o Thrombogenic mutations
- Valvular heart disease: complicated
- O Viral hepatitis: acute or flare for initiation of method.
- SNCHC clinical providers may consider providing COCs to any client who requests this method and with U.S. MEC category 3 risk conditions, but other methods should be strongly considered because the theoretical or proven risk may outweigh the advantages of using the method):
 - o Breast cancer: past and no evidence of current disease for five (5) years.
 - Breastfeeding 21 to <30 days postpartum with and without other factors for DVT/PE.
 - o Breastfeeding 30-42 days postpartum with other risk factors for DVT/PE.
 - o Non-breastfeeding 21-42 days postpartum with other risk factors for DVT/PE.
 - o Deep venous thrombosis/pulmonary embolism: History of DVT/PE, not on anticoagulant therapy with lower risk for recurrent DVT/PE.
 - o DVT/PE and established on anticoagulant therapy for at least three (3) months with lower risk for recurrent DVT/PE.
 - o Superficial venous thrombosis (acute or history).
 - o Diabetes mellitus: nephropathy/retinopathy/neuropathy.
 - o Diabetes mellitus: other vascular disease or diabetes of > 20 years duration.
 - o Gallbladder disease: medically treated.
 - o Gallbladder disease: current.
 - o History of cholestasis with past combined oral contraceptives related.
 - o Hypertension: adequately controlled.
 - Hypertension: elevated blood pressure levels with systolic 140-159 or diastolic 90-99.
 - o Inflammatory bowel disease: ulcerative colitis, Crohn's disease.
 - Multiple risk factors for arterial cardiovascular disease for initiation of method.
 - o Multiple Sclerosis with prolonged immobility.
 - o Peripartum cardiomyopathy ≥ 6 months.
 - Smoking: age ≥ 35 , < 15 cigarettes/day.
 - O Viral hepatitis: acute or flare for initiation of method.
 - Antiretroviral therapy protease inhibitors without ritonavir Fosamprenavir.
 - Anticonvulsant medications phenytoin, carbamazepine, barbiturates, primidone, topiramate, and oxcarbazepine.

- o Lamotrigine.
- o Antimicrobial therapy Rifampicin or rifabutin therapy.
- Clients with category 1 and 2 risk conditions are candidates for using this method.

Procedure

Provide client-centered care through quality counseling and education using the five (5) key principles:

- Establish and maintain rapport with the client,
- Assess the client's needs and personalize discussions accordingly,
- Work with the client interactively to establish a plan,
- Provide information that can be understood and retained by the client; and
- Confirm the client's understanding using a technique such as the teach-back method.

Review medical history:

- Significant illness
- Allergies
- Current medications prescriptive and OTC
- Use of Tobacco, Alcohol, and Other Drugs
- Immunization and Rubella status
- Contraceptive Use
- Menstrual History
- Sexual History including risk for STIs.
- Obstetrical History
- Gynecological and PAP test history
- Surgical History
- Hospitalizations
- Family History
- Reproductive Life Plan

Review last menstrual period (LMP) and compliance with contraceptive method (if applicable). Assess the risk of current pregnancy. Offer pregnancy test if indicated.

- A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets the following:
 - o Is ≤ 7 days after the start of normal menses.
 - o Has not had sexual intercourse since the start of last normal menses.
 - Has been correctly and consistently using a reliable method of contraception.

- o Is ≤ 7 days after spontaneous or induced abortion.
- Is within four (4) weeks postpartum.
- o Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority $[\geq 85\%]$ of feeds are breastfeeds), amenorrhoeic, and < 6 months postpartum.
- Assess recent sexual activity where intercourse was unprotected and offer emergency contraception (EC) for immediate use if indicated.
 - O Note that if Ella® is the EC formulation is administered, a reliable barrier method of contraception should be used with subsequent acts of intercourse that occur within the next seven (7) days. Because Ella® and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effect. After using Ella® if a woman wishes to use hormonal contraception, she should do so no sooner than five (5) days after the intake of Ella®.
- Blood Pressure: normal < 120/80; refer clients with blood pressure reading ≥ 140 systolic or > 90 diastolic to a primary care provider for further evaluation.
- Weight/Height: obtain BMI.
- Screen for STIs (if the client has not been screened) according to STI screening guidelines (see Section 9: STI Screening Policies and Procedures).
- Discuss the client's reproductive life plan about becoming pregnant by asking:
 - o Do you have children now?
 - o Do you want to have (more) children?
 - o How many (more) children would you like to have and when?
 - If the client does not want a child currently and is sexually active, then offer contraceptive services.
 - o If the client desires pregnancy testing, then provide pregnancy testing and preconception counseling.
 - o If the client wants to have a child now, then provide services to help the client achieve pregnancy and provide preconception counseling.
 - If the client wants to have a child and is having trouble conceiving, then provide basic infertility services.
- Present all birth control method options for which the client has no U.S. MEC category 3 or 4 risk conditions.
- Selection of contraceptive type based on U.S. MEC:
 - O Prescribing providers, after having a discussion with the client regarding risk versus benefit of a method, may initiate a method for which the client has a category 3 risk condition only if the benefit or pregnancy prevention outweighs the risks and the client finds other lower risk methods unacceptable.
 - o Clients requesting a method for which they have a category 4 risk condition will be

offered lower risk methods and referred to an OB/GYN or specialist provider.

• Each client will receive client instructions regarding warning signs, common side effects, risks, method of use, alternative methods, use of secondary method, and clinic follow-up schedule. Document client education and understanding of the method of choice.

Plan

Initiating combined oral contraceptives:

- COCs can be initiated at any time if it is reasonably certain that the client is not pregnant.
 - o If started within the first five (5) days since menstrual bleeding started, no additional contraceptive protection is needed.
 - If COCs are started > 5 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days.

When the initial start of the method occurs within a visit with NP, PA, or MD the provider will write a prescription for up to one (1) year supply and may dispense this amount depending on the client's preference and anticipated use.

- If the initial start of the method occurred within a visit with the RN, the RN.
- must obtain an order from the provider for the COCs.
- A method re-visit appointment may be scheduled with the prescribing provider in three (3) months. The purpose of this visit is for the prescribing provider to review the client's health history, discuss the method, and address any concerns or issues.
 - o Pill pick-ups do not count as client visits.
 - Schedule the client for reproductive health well visits if the client has not been screened appropriately within the past twelve (12) months or if an earlier assessment is clinically indicated.

Special Considerations

Amenorrhea (not postpartum):

- COCs can be started at any time if it is reasonably certain the client is not pregnant.
- The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days.

Postpartum (breastfeeding):

- COCs can be started when the client is medically eligible to use the method and if it is reasonably certain that she is not pregnant.
- Postpartum clients who are breastfeeding should not use COCs during the first three (3) weeks after delivery (category 4) because of concerns of increased risk for venous thromboembolism and generally should not use COCs during the fourth (4th) week postpartum (category 3) because of concerns about potential effects on breastfeeding.
- If the client is < 6 months postpartum, amenorrhoeic, and fully or nearly fully

- breastfeeding (exclusively breastfeeding or the vast majority [\geq 85 %] of feeds are breastfeeds), no additional contraceptive protection is needed.
- A client who is < 21 days postpartum, no additional contraceptive protection is needed.
- A client who is ≥ 21 days postpartum and has not experienced a return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days.
- If a client's menstrual cycle has returned and it has been > 5 days since menstrual bleeding started, the client will need to abstain from intercourse or use additional contraceptive protection for the next seven (7) days.

Postpartum (not breastfeeding):

- COCs can be started when the client is medically eligible and if it is reasonably certain that the client is not pregnant.
 - Postpartum clients should not use COCs during the first three (3) weeks after delivery (category 4) because of concerns of increased risk for venous thromboembolism.
 - o Postpartum clients with other risk factors for venous thromboembolism generally should not use COCs three to six (3-6) weeks after delivery (category 3).
- A client who is ≥ 21 days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days.
- If a client's menstrual cycle has returned, and it has been > 5 days since the menstrual bleeding began, the client will need to abstain from sexual intercourse or use additional contraceptive protection for next seven (7) days.

Post abortion (spontaneous or induced):

- COCs can be started within the first seven (7) days after first or second (1st of 2nd) trimester abortion, including immediately post-abortion (category 1).
- The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days unless COCs are started at the time of the surgical abortion.

Switching from Another Contraceptive Method

COCs can be started immediately if it is reasonably certain that the client is not pregnant. Waiting for the next menstrual period is not necessary.

• If it has been > 5 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days.

Switching from an IUD/ to Intrauterine System (IUS):

• If the client has had sexual intercourse since the start of her current menstrual cycle and it has been > 5 days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract. A healthcare provider may consider any of the following options:

- o Advise the client to retain the IUD/IUS for at least seven (7) days after combined hormonal contraceptives are initiated and return for IUD/IUS removal.
- O Advise the client to abstain from sexual intercourse or use barrier contraceptive for seven (7) days before removing the IUD/IUS and switching to the new method; advise the client to use ECPs at the time of IUD removal.
- Ocombined hormonal contraceptive can be started immediately after use of ECPs (except for Ella®).
- Ocombined hormonal contraceptives can be started no sooner than five (5) days after use of Ella®).
- Offer and provide condoms for use as a back-up method and for STI protection.
- The decision to offer and dispense future-use EC should be made on an individualized basis and should include shared decision making between the provider and the client.
 - Clients requesting (those that self-identify that they need or want) EC for future use and those using less reliable methods of birth control (tier 3 methods) might benefit most from having future use EC made available.
 - o Instruct the client to wait five (5) days after the administration of Ella® before initiating combined oral contraceptives. Recommend the use of a barrier method of contraception with all subsequent acts of intercourse that occur within the next seven (7) days.

Routine Follow-up

The recommendations listed below address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women and men.

Although routine follow-up is not necessary for the use of COCs, recommendations might vary for different users and different situations. Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple conditions may benefit from more frequent follow-up visits.

- Advise the client to return at any time to discuss side effects or other problems or if the client wants to change the method being used.
- At other routine visits, healthcare providers should do the following:
 - Assess the client's satisfaction with the contraceptive method and whether the client has any concerns about method use,
 - Assess any changes in health status, including medications that would change the appropriateness of combined hormonal methods' safe and effective use based on U.S. MEC,
 - o Assess blood pressure,
 - o Consider assessing weight changes and counsel clients who are concerned with any weight changes perceived to be due to contraceptive method; and
 - Provide up to the maximum number of refills of the birth control method under a current prescription from SNCHC prescribing provider.

Patient Education

- All women who are planning or capable of pregnancy should be counseled to take a daily supplement containing 0.4 to 0.8 milligrams (400 to 800 μg) of folic acid.
- Advise the client that combined hormonal contraceptive may change their periods; the client may have spotting or irregular bleeding for the first few months.
- Advise the client of common side effects. If the client has nausea from the COCs, suggest taking the pill with the evening meal or with food at bedtime. May consider a lower dose estrogen pill, progestin only pill, or nonhormonal method.
- Advise the client to call the clinic if she has any questions or concerns regarding the birth control method.
- Advise the client to use condoms for protection against STIs.
- Inform the client that any signs or symptoms of complications should be reported to the clinic; if the clinic is not open, clients should call 911 or go to the emergency room.
- Advise client with the warning signs of ACHES (client should be informed to seek immediate care if any warning signs are noted):
 - Abdominal pain
 - o Chest pain
 - Headaches
 - Eye problems
 - o Severe leg pain.

Late or Missed Dose

Recommendations for late or missed COCs:

- If one (1) hormonal pill is <u>late</u> (< 24 hours since a pill should have been taken), or if one (1) hormonal pill has been missed (24 to < 48 hours since a pill should have been taken):
 - o Take the late or missed pill as soon as possible,
 - Continue taking the remaining pills at the usual time (even if it means taking two
 (2) pills on the same day),
 - No additional contraceptive protection is needed; and
 - EC is not usually needed but can be considered (except for Ella®) if hormonal pills were missed earlier in the cycle or in the last week of the previous cycle.
- If two or more consecutive hormonal pills have been missed (> 48 hours since a pill should have been taken):
 - Take the most recent missed pill as soon as possible (any other missed pills should be discarded).
 - Continue taking the remaining pills at the usual time (even if it means taking two
 (2) pills on the same day.

- Use back-up contraception or avoid sexual intercourse until hormonal pills have been taken for seven (7) consecutive days.
- o If pills were missed in the last week of hormonal pills, days fifteen to twenty-one (15-21) for 28-day pill pack.
 - Omit the hormone-free interval by finishing the hormonal pills in the current pack and starting a new pack the next day.
 - If unable to start a new pack immediately, use back-up contraception or avoid sexual intercourse until hormonal pills from a new pack have taken for seven (7) consecutive days.
- EC should be considered (except for Ella®) if hormonal pills were missed during the first (1st) week and unprotected sexual intercourse occurred in the previous five (5) days.
- o EC may also be considered (except for Ella®) at other times as appropriate.

Vomiting or Severe Diarrhea

Recommendations for vomiting or diarrhea (for any reason, for any duration) that occurs within twenty-four (24) hours after taking a hormonal pill, or vomiting or diarrhea, for any reason, continuing for 24 to < 48 hours after taking any hormonal pill:

- Taking another hormonal pill (re-dose) is unnecessary.
- Continue taking pills daily at the usual time (if possible, despite discomfort).
- No additional contraceptive protection is needed.
- EC is not usually needed but can be considered (except for Ella®) as appropriate.

Recommendations for vomiting or diarrhea, for any reason, continuing for \geq 48 hours after taking any hormonal pill:

- Continue taking pills daily at the usual time (if possible, despite discomfort).
- Use back-up contraception or avoid sexual intercourse until hormonal pills have been taken for seven (7) consecutive days after vomiting or diarrhea has resolved.
- If vomiting or diarrhea occurred in the last week of hormonal pills, days fifteen to twenty-one (15-21) for 28-day pill packs.
 - Omit the hormone-free interval by finishing the hormonal pills in the current pack and starting a new pack the next day.
 - o If unable to start a new pack immediately, use back-up contraception or avoid sexual intercourse until hormonal pills from a new pack have been taken for seven (7) consecutive days.
- EC should be considered (except for Ella®) if vomiting or diarrhea occurred within the first week of a new pill pack and unprotected sexual intercourse occurred in the previous five (5) days.
- EC may also be considered (except for Ella®) at other times as appropriate.

Extended / Continuous Use of COCs

Unscheduled Bleeding

- Extended contraceptive use is defined as a planned hormone-free interval after at least two (2) contiguous cycles.
- Continuous contraceptive use is defined as uninterrupted use of hormonal contraception without a hormone-free interval.
- Before initiation of combined oral contraceptives, provide counseling about potential changes in bleeding patterns during extended or continuous use.
 - Unscheduled spotting or bleeding is common during the first three to six (3-6) months of extended or continuous combined hormonal use. It is not harmful and typically decreases with continued use.
 - o If clinically indicated, consider an underlying gynecological problem (e.g., STI, pregnancy or new pathologic uterine conditions). Refer to the prescribing provider/primary care provider for evaluation.
 - o If an underlying gynecological problem is not found and the client wants treatment, the following treatment option can be considered:
 - Advise the client to discontinue combined hormonal contraceptive use for three to four (3-4) consecutive days. A hormone-free interval is not recommended during the first twenty-one (21) days of using the continuous or extended combined hormonal contraceptive method. A hormone-free interval also is not recommended more than once per month because contraceptive effectiveness might be reduced.
 - If unscheduled spotting or bleeding persists and the client finds it unacceptable, counsel client on alternative contraceptive methods, and offer another method if it is desired.

Discontinuing the COCs

- Combined hormonal contraceptives may be stopped at any time.
- Fertility will return rapidly.
- If the client does not want to be pregnant, advise the client to begin a new contraceptive method immediately.
- If client desires to be pregnant:
 - o Provide the client with preconception counseling.
 - Advise client to begin taking a daily prenatal vitamin with 0.4 to 0.8 milligrams of folic acid at least thirty (30) days before trying to become pregnant.

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What is emergency contraception?

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

Emergency contraception (EC) consists of several different formulations which can be used by women to prevent pregnancy after unprotected sexual intercourse, or a known or suspected contraceptive failure.

Emergency contraceptive pills (ECPs) prevent pregnancy primarily by delaying or inhibiting ovulation and inhibiting fertilization. The best available evidence indicates that the ability of Levonorgestrel and Ulipristal acetate ECPs to prevent pregnancy can be fully accounted for by mechanisms that do not involve interference with post-fertilization events.

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

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

Formulations: There are four (4) options of EC available in the U.S., including:

- Cu-IUD for immediate use.
- Levonorgestrel formulations for immediate and future use are available in a 1.5 mg single dose tablet.
- Ulipristal acetate (Ella®) for both immediate and future use is available in a 30-mg single dose tablet.
- Combined estrogen and progestin or the Yuzpe formulation (for immediate use) is available in a two (2) dose regimen. (Yuzpe regimen includes one (1) dose of 100 µg of ethinyl estradiol plus 0.5 mg of levonorgestrel followed by a second (2nd) dose of 100 µg of ethinyl estradiol plus 0.5 mg of levonorgestrel twelve (12) hours later.)

Protocol

SNCHC clinical providers may write a prescription or provide EC to any client who requests this method and has no U.S. MEC category 4 risk conditions. RNs may provide the EC if there is a prescription. Only prescribing providers trained in the insertion of the Cu-IUD may perform the insertion of this method of EC.

Cu-IUD: Intrauterine contraceptives are among the safest and most effective methods of contraception available today. The Cu-IUD can be inserted for use as EC within five (5) days of unprotected sexual intercourse; if the day of ovulation can be estimated, the Cu-IUD can be inserted beyond five (5) days after sexual intercourse if insertion does not occur > 5 days after ovulation.

- Effectiveness of the Cu-IUD is not affected by weight or BMI.
- Category 4 risk conditions (risk of use outweighs the benefits of pregnancy prevention):
 - o Anatomic abnormalities: distorted uterine cavity,
 - o Cervical cancer: awaiting treatment for initiation of method,
 - o Endometrial cancer for initiation of method,
 - O Gestational trophoblastic disease: persistently elevated β-hCG levels,
 - o Current pelvic inflammatory disease for initiation of method,
 - o Post abortion: immediately post-septic abortion,
 - o Postpartum: puerperal sepsis,
 - Current pregnancy,
 - o STIs: current purulent cervicitis or CT/GC infection for initiation of method,
 - o Pelvic Tuberculosis for initiation of method; or
 - Unexplained vaginal bleeding with suspicion for serious condition (before evaluation) for initiation of method.
- Category 3 risk conditions (must consult with prescribing provider prior to initiation as the theoretical or proven risk may outweigh the advantages of using the method:
 - O Solid organ transplantation: complicated for initiation of method
 - O Systemic lupus erythematosus: severe thrombocytopenia for initiation of method
 - o Pelvic Tuberculosis for continuation of method.

Levonorgestrel EC: Progestin-only emergency contraceptive pill (ECP) (Plan B one step and its generic forms Take Action, Next Choice one dose and My Way) are available OTC for males and females of any age. It is recommended that women take levonorgestrel EC as soon as possible but within seventy-two (72) hours of unprotected intercourse (UPI).

Levonorgestrel may be taken up to one hundred twenty (120) hours after UPI, however, recent evidence suggests that it may not be effective if taken more than ninety-six (96) hours after UPI. Women with a BMI \geq 25 should be informed that the effectiveness of levonorgestrel may be decreased.

• According to the U.S. MEC, there are no category 3 or 4 risk conditions for the use of

progestin only EC given that the duration of use is less than that of regular use and would be expected to have less clinical impact. Recurrent EC use is an indication that the woman requires further counseling about other contraceptive options. Recurrent use may be harmful for women with U.S. MEC conditions classified as 2, 3, or 4 for progestin only pills.

- Contraindications (There are no U.S. MEC category 3 or 4 risks conditions):
 - o Pregnancy: Use of levonorgestrel EC once a pregnancy has been established is not harmful to the pregnancy but simply provides no benefit.

Ulipristal acetate (Ella®): Ulipristal acetate (Ella®), a selective progesterone receptor modulator, is a more recently approved option for EC. Ella® should not be taken if pregnancy is suspected or known. A pregnancy test should be performed to rule out pregnancy. Ella® does not interrupt an existing pregnancy. It is not recommended to use Ella® for breastfeeding women as it is not known if any active metabolites are excreted into the breast milk. Breastfeeding women should be informed not to breastfeed for one (1) week, rather they should express and discard the breast milk to maintain lactation. Ella® is available by prescription only. Ella® should be administered as soon as possible and within one hundred twenty (120) hours of UPI. Studies have shown no significant reduction in effectiveness with increasing time between UPI and taking Ella® (up to one hundred twenty (120) hours). Some limited data suggest Ella® could be less effective for women with a BMI over thirty-five (35). Recent studies looking at repeated use of Ella® within the same menstrual cycle showed no safety concerns, indicating Ella® can safely be used more than once per cycle.

Ella[®] is an anti-progestin, with the progestin component of hormonal contraceptives and Ella[®] both binding to the progesterone receptor, using them together may decrease the ability of Ella[®] to delay ovulation. After using Ella[®] a woman should use a reliable barrier of contraception for the next fourteen (14) days. If a woman wishes to start using a hormonal contraception after using Ella[®], she should delay starting for at least five (5) days and use a reliable barrier method for the next fourteen (14) days.

- Contraindications (There are no U.S. MEC category 3 or 4 conditions):
 - o Pregnancy
 - Ella® is not recommended for use by breastfeeding women.
- Warnings and Precautions
 - o After use of Ella[®], a reliable barrier method of contraception should be used with subsequent acts of intercourse that occur within the next seven (7) days.
 - O Because Ella® and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effect. After using Ella® if a woman wishes to use hormonal contraception, she should do so no sooner than five (5) days after the intake of Ella®.

Yuzpe – ECP containing ethinyl estradiol and levonorgestrel: The Yuzpe method for EC has been in place since the mid 1970's but has been rarely used since the advent of levonorgestrel and ulipristal formulations. The standard dosage consists of ethinyl estradiol, 100 mg, and levonorgestrel, 0.5 mg, to be taken within seventy-two (72) hours of UPI and repeated twelve (12)

hours later. The Yuzpe method of EC has been shown to be about seventy-five percent (75%) effective and requires a prescription. At this point, there are no documented studies that evaluate the impact of weight or BMI on the effectiveness of this method.

- According to the U.S. MEC, there are no category 3 or 4 risk conditions for the use of combined oral contraceptives as EC given that the duration of use is less than that of regular use and would be expected to have less clinical impact. Recurrent EC use is an indication that the woman requires further counseling about other contraceptive options. Recurrent use may be harmful for women with U.S. MEC conditions classified as 2, 3, or 4 for combined oral contraceptive pill (COCP).
 - o Contraindications:
 - Pregnancy: Use of COCP once a pregnancy has been established it is not harmful to the pregnancy but simply provides no benefit.
 - No one should be denied or discouraged from using ECPs based on weight.
 Clients with higher body weights should be provided with information on the most effective form of EC for them.

Procedure

Provide client-centered care through quality counseling and education using the five (5) key principles:

- Establish and maintain rapport with the client,
- Assess the client's needs and personalize discussions accordingly,
- Work with the client interactively to establish a plan,
- Provide information that can be understood and retained by the client; and
- Confirm the client's understanding using a technique such as the teach-back method.

Screen client for appropriateness to receive EC:

- Last normal menstrual period,
- Date and time of unprotected intercourse,
- Current contraceptive method,
- Ensure that the client is not wanting to be pregnant,
- Assess need for future use EC,
- Rule out contraindications per U.S. MEC category 3 and 4 risk conditions: and
- Obtain weight/BMI to offer the most effective EC formulation.

Review medical history:

- Significant Illness,
- Allergies,
- Current medications, prescriptive and OTC,

- Use of Tobacco, Alcohol, and Other Drugs,
- Immunization and Rubella Status,
- Contraceptive Use,
- Menstrual History,
- Sexual History including risk for STIs,
- Obstetrical History,
- Gynecological and PAP test history,
- Surgical History,
- Hospitalizations,
- Family History; and
- Reproductive Life Plan.

Review LMP and compliance with contraceptive method (if applicable). Assess the risk of current pregnancy. Offer pregnancy test if indicated.

- A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets the following:
 - o Is \leq 7 days after the start of normal menses.
 - o Has not had sexual intercourse since the start of last normal menses.
 - o Has been correctly and consistently using a reliable method of contraception.
 - o Is \leq 7 days after spontaneous or induced abortion.
 - o Is within four (4) weeks postpartum.
 - o Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥ 85%] of feeds are breastfeeds), amenorrhoeic, and < 6 months postpartum.

Blood Pressure: normal < 120/80; refer clients with blood pressure reading ≥ 140 systolic or ≥ 90 diastolic to a primary care provider for further evaluation and treatment.

Weight/Height: obtain BMI.

Screen for STIs (if the client has not been screened) according to STI screening guidelines (see Section 9: STI Screening Policies and Procedures).

Discuss client's reproductive life plan about becoming pregnant by asking:

- Do you have children now?
- Do you want to have (more) children?
- How many (more) children would you like to have and when?
 - If the client does not want a child currently and is sexually active, then offer contraceptive services.

- If the client desires pregnancy testing, then provide pregnancy testing and preconception counseling.
- o If the client wants to have a child now, then provide services to help the client achieve pregnancy and provide preconception counseling.
- o If the client wants to have a child and is having trouble conceiving, then provide basic infertility services.

Discuss EC options available for the individual client incorporating information regarding effects of weight/BMI on efficacy of EC of formulation.

Plan

Administer/provide selected EC formulation (see below).

- Cu-IUD:
 - o Scheduling:
 - RN/MA will schedule clients with clinical service providers for insertion the same day if possible, and within one hundred twenty (120) hours of UPI.
 - Insertion:
 - Clinical Service Providers (CSP) will follow the IUD policy and procedures (Section 6) for insertion of the device.
 - Client education:
 - Follow the client education steps outlined in the intrauterine contraception IUD/IUS policies and procedures (Section 6).
 - Instruct the client to return to the clinic for a pregnancy test if no menses occurs within the next three (3) weeks.
- Levonorgestrel EC:
 - Administration:
 - Administer levonorgestrel EC tablet as soon as possible (ASAP) while the client is in the office; otherwise instruct the client to take the pill ASAP within one hundred twenty (120) hours after UPI.
 - If a two (2) pill formulation of levonorgestrel is used, administer both pills together as a single dose.
 - Advise the client to eat or drink something, if possible, prior to administration to prevent nausea.
 - If vomiting occurs within one hour of taking the dose, the client should repeat the dose. May use OTC anti-nausea drugs:
 - Dramamine 50 mg one to two (1-2) tablets by mouth every four to six (4-6) hours.
 - Benadryl 25 mg one to two (1-2) tablets by mouth every four to six

(4-6) hours.

Dispensing for future use:

The decision to offer and dispense future-use EC should be made on an individualized basis and should include shared decision making between the provider and the client. The practice of offering and dispensing future use EC to all clients has had no impact on unplanned pregnancy rates. Data shows that clients who had EC available at the time of unprotected intercourse either didn't take it at all or took it incorrectly, and the practice of providing EC to all clients represents a significant cost to the agency with no measurable impact. Clients requesting (those that self-identify that they need or want) EC for future-use and those using less reliable methods of birth control (tier 3 methods) might benefit most from having future use EC made available.

Client education:

- Give client a copy of EC information/fact sheet.
- When a two (2) pill formulation is used, instruct the client to take both pills together as a single dose.
- Counsel the client on the effects of weight on efficacy of EC.
- Levonorgestrel EC is not contraindicated for those with a BMI ≥ 25; it just might not be effective.
- Instruct the client to abstain or to use a barrier or hormonal contraception until their next menses, as this EC formulation will not provide pregnancy protection for future acts of UPI.
- Any contraceptive method may be started immediately after the use of levonorgestrel EC.
- Discuss and facilitate plans for future contraception, beginning with the most effective methods.
- Recommend the use of condoms for protection from STIs/HIV offer/dispense condoms.
- Provide counseling on the contraceptive method currently used or initiated at this visit.
- Offer and schedule all clients for a prescription visit with the clinic's prescribing provider to obtain a written prescription for continuation of the birth control method.
- Schedule the client for reproductive health well visits if the client has not been screened appropriately within the past twelve (12) months or if an earlier assessment is clinically indicated.
- Advise the client to call the clinic if she has any questions or concerns regarding this contraceptive method.
- Inform the client that any signs or symptoms of complications should be

- reported to the clinic; if the clinic is not open, the client should call 911 or go to the ED.
- Over-the-counter EC formulations may be made available to clients as a supply pick-up when the client has previously received complete counseling and written information on the EC formulation.

• Ulipristal acetate (Ella®)

o Administration:

- Administer Ella® tablet ASAP while client is in the office; otherwise instruct the client to take the pill ASAP within one hundred twenty (120) hours after UPI.
- The prescription may be called into a local pharmacy for an established client.
- Advise the client to eat or drink something, if possible, prior to administration to prevent nausea.
- If vomiting occurs within one hour of taking the dose, the client should repeat the dose. May use OTC anti-nausea drugs:
 - Dramamine 50 mg one to two (1-2) tablets by mouth every four or six (4-6) hours.
 - Benadryl 25 mg one to two (1-2) tablets by mouth every four to six (4-6) hours.
- Because Ella® and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effect. After using Ella®, if a woman wishes to use hormonal contraception, she should do so no sooner than five (5) days after the intake of Ella®, and she should use a reliable barrier method for the next seven (7) days.

• Dispensing for future use:

The decision to offer and dispense future use EC should be made on an individualized basis and should include shared decision making between the provider and the client. The practice of offering and dispensing future use EC to all clients has had no impact on unplanned pregnancy rates. Data shows that clients who had EC available at the time of unprotected intercourse either didn't take it at all or took it incorrectly, and the practice of providing EC to all clients represents a significant cost to the agency with no measurable impact. Clients requesting (those that self-identify that they need or want) EC for future use and those using less reliable methods of birth control (tier 3 methods) might benefit most from having future use EC made available.

Client education:

- Give the client a copy of the EC information/fact sheet.
- Counsel the client on the effects of weight on efficacy of EC.

- Ella® is not contraindicated for those weighing over one hundred ninety-three (193) pounds or with a BMI over thirty-five (35); it just might not be effective.
- Instruct the client to abstain, use a barrier method, or hormonal contraception to prevent pregnancy. If she is currently using a hormonal method (pill, patch, or ring), or plans on using a hormonal method, the client should suspend use of the method until at least five (5) days after taking Ella[®]. Instruct the client to use condoms as a back-up method for the next seven (7) days.
- Discuss and facilitate plans for future contraception, beginning with the most effective method.
- Advise the client to use condoms for protection from STIs/HIV offer/dispense condoms.
- Provide counseling on contraceptive methods currently used or initiated at this visit.
- Offer and schedule all clients for a prescription visit with the clinic's prescribing provider to obtain a written prescription for continuation of the birth control method.
- Schedule the client for reproductive health well visits if the client has not been screened appropriately within the past twelve (12) months or if an earlier assessment is clinically indicated.
- Advise the client to call the clinic if she has any questions or concerns regarding this contraceptive method.
- Inform the client that any signs and symptoms of complications should be reported to the clinic, if the clinic is not open, the client should call 911 or go to the emergency room.

Yuzpe

Administration:

- When administering EC to clients presenting to the clinic for care, other formulations are preferable to the Yuzpe method, simply because they are better tolerated by the client. Therefore, most often the Yuzpe method will be utilized by clients in need of EC who have no future-use EC at hand or are unable to obtain EC from a pharmacy, are unable to return to the clinic and have COCP on hand.
- Determine the type of COCP on hand by referring to the Yuzpe chart for the number and color of pills needed for each dose. (See Section 6: Emergency Contraceptive Dosages)
- Consult with the prescribing provider for written or verbal orders for EC dosage.
- Advise the client to eat or drink something, if possible, prior to

administration to prevent nausea.

- May use OTC anti-nausea drugs:
 - Dramamine 50 mg one to two (1-2) tabs by mouth every four to six (4-6) hours.
 - Benadryl 25 mg one to two (1-2) tabs by mouth every four to six (4-6) hours.

Client education:

- Give the client a copy of the EC information/fact sheet.
- Instruct the client to abstain or use barrier or hormonal contraception to prevent pregnancy. If already using a hormonal method but incorrectly or inconsistently, instruct the client to use condoms as a back-up method until their next menses.
- Discuss and facilitate plans for future contraception, beginning with the most effective methods.
- Provide counseling on contraceptive methods currently used or initiated at this visit.
- Offer and schedule all clients for a prescription visit, if indicated, with the clinic's prescribing provider to obtain a written prescription for continuation of the birth control method.
- Schedule the client for reproductive health well visits if the client has not been screened appropriately within the past twelve (12) months or if an earlier assessment is clinically indicated.
- Advise the client to call the clinic if she has any questions or concerns regarding this contraceptive method.
- Inform the client that any signs and symptoms of complications should be reported to the clinic, if the clinic is not open the client should call 911 or go to the emergency room.

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ATTACHMENT 1: EC and Oral Contraceptive Dosages

Brand	Manufacturer	Pills per Dose	Ethinyl Estradiol per Dose (mcg)	Levonorgestrel per Dose (mg)					
Dedicated emergency contraception (take one dose)									
Plan B One- Step TM	Teva	1 white pill	0	1.5					
Next Choice®	Watson	2 peach pills	0	1.5					
Ella [®]	Watson	1 white pill	0	0					
Combined progestin and estrogen pills (take two does 12 hours apart)									
Aviane TM	Teva	5 orange pills	100	0.50					
Cryselle	Teva	4 white pills	120	0.60					
Enpresse	Teva	4 orange pills	120	0.50					
Jolessa	Teva	4 pink pills	120	0.60					
Lessina®	Teva	5 pink pills	100	0.50					
Levora	Actavis	4 white pills	120	0.60					
LoSeasonique®	Teva	5 orange pills	100	0.50					

Low-Ogestrel®	Actavis	4 white pills	120	0.60
Lutera	Actavis	5 white pills	100	0.50
Nordette®	Teva	4 light-orange pills	120	0.60
Portia®	Teva	4 pink pills	120	0.60
Quasense®	Actavis	4 white pills	120	0.60
Seasonale®	Teva	4 pink pills	120	0.60
Seasonique®	Teva	4 light-blue- green pills	120	0.60
Sronyx	Actavis	5 white pills	100	0.50
Trivora [®]	Actavis	4 pink pills	120	0.50

What is Depo Medroxyprogesterone Acetate (DMPA)?

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

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

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

With typical use, approximately four (4) out of one hundred (100) women will become pregnant in the first year of use. DMPA injections must be given every three (3) months. There are two (2) formulations, depo-subQ Provera 104 and Depo-Provera CI (IM injection).

DMPA does not protect against STIs.

Protocol

SNCHC CSP may provide DMPA to any client who requests this method and has no U.S. MEC category 4 risk conditions.

- Category 4 risk conditions (risk of use outweighs the benefits of pregnancy prevention):
 - o Current breast cancer.
- Category 3 risk conditions (must consult with prescribing provider prior to initiation as the theoretical or proven risk may outweigh the advantages of using the method):
 - o Breast cancer; past and no evidence of current disease for five (5) years.
 - o Cirrhosis; severe (decompensated).
 - o Diabetes mellitus: nephropathy/retinopathy/neuropathy.
 - o Diabetes mellitus: other vascular disease or diabetes of > 20 years' duration
 - Hypertension: systolic ≥ 160 or diastolic ≥ 100 .
 - Hypertension with vascular disease.
 - o Ischemic heart disease: current and history of; benign liver tumors: hepatocellular adenoma; malignant liver tumors.
 - Multiple risk factors for arterial cardiovascular disease: (old age, smoking, diabetes, and hypertension).
 - Rheumatoid arthritis: receiving long-term corticosteroid therapy with a history of, or risk factors for, non-traumatic fractures.
 - O Stroke: history of cerebrovascular accident.
 - O Systemic lupus erythematosus: positive (or unknown) antiphospholipid antibodies.
 - Systemic lupus erythematosus: severe thrombocytopenia for initiation of method.
 - Unexplained vaginal bleeding (suspicious for serious condition) before evaluation.
- Clients with category 1 and 2 risk condition are candidates for DMPA.
 - o RN/MA must have a prescription order, to provide DMPA to clients.

Procedure

Provide client-centered care through quality counseling and education using the five (5) key principles:

- Establish and maintain rapport with the client,
- Assess the client's needs and personalize discussions accordingly,
- Work with the client interactively to establish a plan,
- Provide information that can be understood and retained by the client; and
- Confirm the client's understanding using a technique such as the teach-back method.

Review medical history:

• Significant illness,

- Allergies,
- Current medications, prescriptive and OTC,
- Use of Tobacco, Alcohol, and Other Drugs,
- Immunization and Rubella status,
- Contraceptive Use,
- Menstrual History,
- Sexual History including risk for STIs,
- Obstetrical History,
- Gynecological and PAP test history,
- Surgical History,
- Hospitalizations; and
- Family History,
- Reproductive Life Plan.

Review LMP and compliance with contraceptive method (if applicable). Assess the risk of current pregnancy. Offer pregnancy test if indicated.

- A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets the following:
 - o Is \leq 7 days after the start of normal menses.
 - o Has not had sexual intercourse since the start of last normal menses.
 - o Has been correctly and consistently using a reliable method of contraception.
 - Is \leq 7 days after spontaneous or induced abortion.
 - o Is within four (4) weeks postpartum.
 - o Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥ 85%] of feeds are breastfeeds), amenorrhoeic, and < 6 months postpartum.

Assess recent sexual activity where intercourse was unprotected and offer emergency contraception (EC) for immediate use if indicated.

• Note that if Ella® is the EC formulation administered, a reliable barrier method of contraception should be used with subsequent acts of intercourse that occur within the next seven (7) days. Because Ella® and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effect. After using Ella® if a woman wishes to use hormonal contraception, she should do so no sooner than five (5) days after the intake of Ella®.

Blood Pressure: normal < 120/80; refer clients with blood pressure reading ≥ 140 systolic or ≥ 90 diastolic to a primary care provider for further evaluation and treatment.

Weight/Height: obtain BMI.

Screen for STIs (if the client has not been screened) according to STI screening guidelines.

Discuss the client's RLP about becoming pregnant by asking:

- Do you have children now?
- Do you want to have (more) children?
- How many (more) children would you like to have and when?
- If the client does not want a child now and is sexually active, then offer contraceptive services.
- If the client desires pregnancy testing, then provide pregnancy testing and preconception counseling.
- If the client wants to have a child now, then provide services to help the client achieve pregnancy and provide preconception counseling.
- If the client wants to have a child and is having trouble conceiving, then provide basic infertility services.

Present all birth control method options for which the client has no U.S. MEC category 3 or 4 risk conditions.

Selection of contraceptive type based on U.S. MEC:

- Prescribing providers, after having a discussion with the client regarding risk versus benefit of a method, may initiate a method for which the client has a category 3 risk condition only if the benefit of pregnancy prevention outweighs the risks and the client finds other lower risk methods unacceptable.
- Clients requesting a method for which they have a category 4 risk condition will be offered lower risk methods and referred to an OB/GYN or specialist provider.

Each client will receive client instructions regarding warning signs, common side effects, risks, use of method, alternative methods, use of secondary method, and clinic follow-up schedule. Document the client's education and understanding of the method of choice.

Administration

• Depo-Provera CI injection dose is 150 mg (shake vial vigorously prior to use). Administer it as a deep IM injection using a 21-23-gauge needle in the deltoid (using at least a 1-inch needle) or upper outer quadrant of the gluteal muscle (use a 1.5 inch or longer needle at this site). Do not massage the area.

OR

• Depo-sub—Q Provera 104 dose is 104mg/0.65 mL (shake the prefilled syringe vigorously) and is stored at room temperature. It is given by subcutaneous injection to the anterior thigh or abdomen, using a 26-gauge needle, once every twelve to fourteen (12-14) weeks.

Provide the client with a reminder card for when the next injection appointment is due.

Plan

Initiating DMPA:

- The first DMPA injection can be given at any time if it is reasonably certain that the client is not pregnant.
- If DMPA is started within seven (7) days since menstrual bleeding started, no additional contraceptive protection is needed.
- If DMPA is started > 7 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days.

When the initial start of the method occurs within a visit with provider. CSP will write a prescription for up to one (1) year supply.

- A method revisit appointment will be scheduled with the RN in three (3) months. The purpose of this visit is to review the client's health history, discuss the method, and address any concerns or issues.
 - o DMPA injections do count as client visits.
 - O Schedule the client for reproductive health well visits if the client has not been screened appropriately within the past twelve (12) months or if an earlier assessment is clinically indicated.

Special considerations:

- Use of Ella®:
 - The administration of DMPA should be delayed for five (5) days after use of Ella® to prevent the reduction of contraceptive effects of either.
 - A reliable barrier method of contraception should be used with subsequent acts of intercourse for the next seven (7) days.
- Amenorrhea (not postpartum):
 - The first DMPA injection can be given at any time if it is reasonably certain that the client is not pregnant.
 - The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days.
- Postpartum (breastfeeding):
 - The first DMPA injection can be given at any time, including immediately postpartum (U.S. MEC 2 if < 1 month postpartum and U.S. MEC category 1 if \geq 1 month postpartum) if it is reasonably certain that the client is not pregnant.
 - o If the client is < 6 months postpartum, amenorrhoeic, and fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [85%] of feeds are breastfeeding), no additional contraceptive protection is needed.
 - A client who is ≥ 21 days postpartum and has not experienced the return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days.
 - \circ If the client's menstrual cycles have returned and it has been > 7 days since

menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days.

• Postpartum (not breastfeeding):

- The first DMPA injection can be given at any time, including immediately postpartum (U.S. MEC category 1) if it reasonably certain the client is not pregnant.
- A client who is < 21 days postpartum, no additional contraceptive protection is needed.
- A client who is ≥ 21 days postpartum and has not experienced the return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days.
- If a client's menstrual cycles have returned and it has been > 7 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days.

• Post abortion:

- The first DMPA injection can be given within the first seven (7) days, including immediately post-abortion.
- The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days unless the injection is given at the time of a surgical abortion.

Switching from another method:

- The first DMPA injection can be given immediately if it is reasonably certain that the client is not pregnant. Waiting for the next menstrual cycle is unnecessary.
 - o If it has been > 7 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days.

• Switching from an IUD/IUS:

- o If the client is switching from an IUD/IUS and has had sexual intercourse since the start of the current menstrual cycle and it has been > 5 days since menstrual bleeding started, residual sperm might be in the genital tract, a healthcare provider may consider any of the following options:
 - Advise client to retain the IUD/IUS for at least seven (7) days after the injection and return for IUD removal.
 - Advise the client to abstain from sexual intercourse or use barrier contraception for seven (7) days before removing the IUD/IUS and switching to the new method; advise the client to use ECPs at the time of IUD removal.
- If uncertain whether the client might be pregnant, the benefits of starting DMPA likely exceed any risk; therefore, starting DMPA should be considered at any time, with a

follow-up pregnancy test in two to four (2-4) weeks.

• If a client needs to use additional contraceptive protection when switching to DMPA from another contraceptive method, consider continuing her previous method for seven (7) days after DMPA injection.

Offer and provide condoms for use as a back-up method and for STI protection.

The decision to offer and dispense future-use EC should be made on an individualized basis and should include shared decision making between the provider and the client. Clients requesting (those that self-identify that they need or want) EC for future use and those using less reliable methods of birth control (tier 3 methods) might benefit most from having future use EC made available.

Continuing DMPA:

- Repeat Depo-Provera IM injections every three (3) months (eleven to thirteen (11-13) weeks):
 - o The repeat DMPA injection can be given early when necessary (there are no time limits on early injections).
 - The repeat DMPA injection can be given up to two (2) weeks late (fifteen (15) weeks from the last injection) without requiring additional contraceptive protection.
 - O If the client is > 2 weeks late (> 15 weeks from the last injection) for a repeat DMPA injection, the client can have the injection if it is reasonably certain that the client is not pregnant. The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days. Consider the use of EC (except for Ella®), if appropriate.
- Repeat Depo-sub-Q Provera 104 injections every twelve to fourteen (12-14) weeks:
 - o If more than fourteen (14) weeks elapse between injections, confirm the patient is not pregnant before the next injection.
 - o If the patient does not receive the next injections within twelve to fourteen (12-14) weeks, another contraceptive method should be used until the next depo-sub-Q Provera 104 injection.

Routine Follow-Up

The recommendations listed below address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women and men.

Although routine follow-up is not necessary for the use of DMPA, recommendations might vary for different users and different situations. Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple conditions may benefit from more frequent follow-up visits.

- Advise the client to return at any time to discuss side effects or other problems, if the client wants to change the method being used, and when it is time for reinjection.
- At other routine visits, healthcare providers should do the following:

- O Assess the client's satisfaction with the contraceptive method and whether the client has any concerns about the method use,
- Assess any changes in health status, including medications that would change the appropriateness of the injectable for safe and effective continued use based on U.S. MEC,
- Consider assessing weight changes and counsel clients who are concerned about weight changes perceived to be associated with their contraceptive method; and
- Consider continuing to administer DMPA every three (3) months with a current prescription from SNCHC prescribing provider.

Management of DMPA Side Effects

Prior to initiation provide counseling about potential changes in bleeding patterns:

- Amenorrhea,
- Unscheduled spotting,
- Light bleeding; and
- Heavy or prolonged bleeding.
- These irregularities are not harmful and may decrease with continued use.

Unscheduled Spotting or Light Bleeding:

- If clinically indicated, consider an underlying gynecological problem (e.g., STI, pregnancy or new pathologic uterine conditions). Schedule with prescribing provider/primary care provider for evaluation.
- If an underlying condition is not found, consider nonsteroidal anti-inflammatory drugs (NSAIDs) for short term treatment five to seven (5-7) days during the days of bleeding.
- If unscheduled spotting or light bleeding persists and the client finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if desired.

Heavy or Prolonged Bleeding:

- If clinically indicated, consider an underlying gynecological problem (e.g., STI, pregnancy or new pathologic uterine conditions). Refer to the prescribing provider/primary care provider for evaluation.
- If an underlying condition is not found, consider the following treatment option during the days of bleeding:
 - o NSAIDs for short term treatment five to seven (5-7) days; or
 - o Hormonal treatment (if medically eligible) with one or more cycles of combined oral contraceptives or estrogen for ten to twenty (10-20) days.
- If heavy or prolonged bleeding persists and the client finds it unacceptable, counsel the client on alternative contraceptive methods, and offer another method if it is desired.

Stopping DMPA

DMPA may be stopped at any time.

If the client does not want to become pregnant, advise the client to start using the new contraceptive thirteen (13) weeks after her last injection. The client may start birth control pills, have a contraceptive implant or IUD placed, or use another contraceptive before it is time for the next injection.

If the client desires to be pregnant:

- Advise client that pregnancy may not occur for up to six to twelve (6-12) months after stopping DMPA,
- Provide the client with preconception counseling; and
- Advise the client to begin taking a daily prenatal vitamin with 0.4 to 0.8 milligrams of folic acid at least thirty (30) days before trying to become pregnant.

Client Education

- All women who are planning or capable of pregnancy should be counseled to take a daily supplement containing 0.4 to 0.8 milligrams (400 to 800 µg) of folic acid.
- Advise the client there may be changes in periods (e.g., irregular bleeding, spotting, heavy bleeding, or no periods).
- Advise the client that prolonged use of DMPA may put her at risk for osteoporosis and decreased bone mass.
- Advise the client using DMPA to have adequate intake of calcium and vitamin D, engage in regular exercise, and avoid cigarette smoking and excessive alcohol consumption to maximize bone health.
- Advise client that there may be a delay in the return to ovulation and fertility is likely to be delayed after having several doses of DMPA.
- Advise the client to use condoms for protection against STIs.
- Inform the client to call the clinic if she has any questions or concerns regarding the birth control method.
- Inform the clients that any signs or symptoms of complications should be reported to the clinic; if the clinic is not open, clients should call 911 or go to the emergency room.
- Discuss DMPA warning signs that indicate the need for medical evaluation (client should be informed to seek immediate care if any warning signs are noted):
 - o Repeated, very painful headaches,
 - Heavy bleeding,
 - o Depression,
 - o Severe, lower abdominal pain (may be sign of pregnancy); and/or
 - Pus, prolonged pain, redness, itching or bleeding at injection site (may be sign of infection).

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What is a subdermal implant (Nexplanon)?

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

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

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

The implant does not protect against STIs.

Protocol

SNCHC CSP may provide Nexplanon[™] to any client who requests this method and has no U.S. MEC, 2010 category 4 risk conditions. RNs may provide counseling and education related to the subdermal implant.

- Category 4 risk conditions (risk of use outweighs the benefits of pregnancy prevention):
 - o Current breast cancer.
- Category 3 risk conditions (must consult with prescribing provider prior to initiation as the theoretical or proven risk may outweigh the advantages of using the method):
 - o Breast cancer: past and no evidence of current disease for five (5) years.
 - o Cirrhosis: severe (decompensated).

- o Ischemic heart disease: current and history of for continuation of method.
- o Benign liver tumors: hepatocellular adenoma.
- o Malignant liver tumors.
- o Stroke: history of cerebrovascular accident for continuation of method.
- O Systemic lupus erythematosus: positive (or unknown) antiphospholipid antibodies.
- o Unexplained vaginal bleeding (suspicious for serious condition before evaluation).
- Clients with Category 1 and 2 risk conditions are candidates for using this method.

Procedure

Provide client-centered care through quality counseling and education using the five (5) key principles:

- Establish and maintain rapport with the client,
- Assess the client's needs and personalize discussions accordingly,
- Work with the client interactively to establish a plan,
- Provide information that can be understood and retained by the client; and
- Confirm the client's understanding using a technique such as the teach-back method.

Review medical history:

- Significant illness,
- Allergies,
- Current medications, prescriptive and OTC,
- Use of Tobacco, Alcohol, and Other Drugs,
- Immunization and Rubella status,
- Contraceptive Use,
- Menstrual History,
- Sexual History including risk for STIs,
- Obstetrical History,
- Gynecological and PAP test history,
- Surgical History,
- Hospitalizations,
- Family History; and
- Reproductive Life Plan

Review LMP and compliance with contraceptive method (if applicable). Assess the risk of current pregnancy. Offer pregnancy test if indicated.

- A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets the following:
 - o Is \leq 7 days after the start of normal menses.
 - Has not had sexual intercourse since the start of last normal menses.
 - o Has been correctly and consistently using a reliable method of contraception.
 - o Is ≤ 7 days after spontaneous or induced abortion.
 - o Is within four (4) weeks postpartum.
 - o Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥ 85%] of feeds are breastfeeds), amenorrhoeic, and < 6 months postpartum.

Assess recent sexual activity where intercourse was unprotected and offer EC for immediate use if indicated.

• Note that if Ella® is the EC formulation administered, a reliable barrier method of contraception should be used with subsequent acts of intercourse that occur within the next seven (7) days. Because Ella® and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effect. After using Ella® if a woman wishes to use hormonal contraception, she should do so no sooner than five (5) days after the intake of Ella®.

Blood Pressure: normal < 120/80; refer clients with blood pressure reading ≥ 140 systolic or ≥ 90 diastolic to a primary care provider for further evaluation and treatment.

Weight/Height: obtain BMI.

Screen for STIs (if the client has not been screened) according to STI screening guidelines.

Discuss the client's reproductive life plan about becoming pregnant by asking:

- Do you have children now?
- Do you want to have (more) children?
- How many (more) children would you like to have and when?
 - o If the client does not want a child now and is sexually active, then offer contraceptive services.
 - o If the client desires pregnancy testing, then provide pregnancy testing and preconception counseling.
 - o If the client wants to have a child now, then provide services to help the client achieve pregnancy and provide preconception counseling.
 - o If the client wants to have a child and is having trouble conceiving, then provide basic infertility services.

Selection of contraceptive type based on U.S. MEC:

• Prescribing providers, after having a discussion with the client regarding risk versus benefit of a method, may initiate a method for which the client has a category 3 risk

- condition only if the benefit of pregnancy prevention outweighs the risks and the client finds other lower risk methods unacceptable.
- Clients requesting a method for which they have a category 4 risk condition will be offered lower risk methods and referred to an OB/GYN or specialist provider.

Each client will receive client instructions regarding warning signs, common side effects, risks, use of method, alternative methods, use of secondary method, and clinic follow-up schedule. Document the client's education and understanding of the method of choice.

Plan

Initiation of the implant:

- The implant can be inserted at any time if it is reasonably certain that the client is not pregnant:
 - o If the implant is inserted within the first five (5) days since menstrual bleeding started, no additional contraceptive protection is needed.
- If the implant is inserted > 5 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days. Instruct the client of the need to wait five (5) days after the administration of Ella® before having the implant inserted. Schedule the insertion as soon as possible after the recommended five (5) day period and recommend the use of a barrier method of contraception with all subsequent acts of intercourse that occur within the next seven (7) days.

Insertion Procedure:

- Only clinicians who have received certification by undergoing approved training by the manufacturer and have demonstrated skill in successful Nexplanon[™] insertion and removal, shall insert the implant.
 - Obtain consent for the procedure and for use of the device using the manufacturer's consent form.
 - o Insert the device; the manufacturer's instructions MUST be followed.
 - Provider and client should palpate the arm to check for placement.
 - o Apply a small adhesive bandage over the insertion site.
 - The clinician and client must be able to palpate the device under the skin immediately after the insertion. If it cannot be palpated, the client must be advised to use a non-hormonal birth control method until placement is verified.
 - o Apply a pressure bandage with sterile gauze to minimize bruising.
 - Instruct the client to remove the pressure bandage in twenty-four (24) hours and the small adhesive bandage over the insertion site in five to seven (5-7) days.
 Instruct the client to keep the area dry for twenty-four (24) hours to prevent infection.
 - o Document the procedure in the client's medical record including:

- Date of procedure,
- Site of the procedure,
- The lot number of the implant; and
- The clinician and client confirmed placement by palpating the implant after insertion.
- Ocomplete the "User Card" supplied by the manufacturer and give it to the client to keep.
- Because the device is inserted and retained, it is recommended that the lot number and expiration date is documented in the client's medical record in addition to the pharmacy dispensing log.

Implant Removal:

- Only clinicians who have received certification by undergoing a training course approved by the manufacturer and have demonstrated skill in successful NexplanonTM insertion and removal, shall remove implants.
 - o Implants must be removed by the end of the third year of use. Manufacturer recommends use up to three (3) years. However, scholarly evidence supports effectiveness of device up to five (5) years. Patients may be offered extensions, if desired.
 - Unless pregnancy is desired, an alternative method of contraception should be offered.
 - Another NexplanonTM may be inserted immediately after removal through the same incision and in a track parallel to the one removed.
 - If pregnancy is desired, provide preconception counseling and advise client to begin taking a daily prenatal vitamin with 0.4 milligrams of folic acid at least thirty (30) days before trying to become pregnant.
 - o Obtain consent for the procedure.
 - o Remove the device; the manufacturer's instructions MUST be followed.
 - o After removal, close the incision with wound closure strips.
 - Apply a pressure bandage with sterile gauze to minimize bruising.

Special insertion considerations:

- Amenorrhea (Not Postpartum):
 - The implant can be inserted at any time if it is reasonably certain that the client is not pregnant.
 - The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days.
- Postpartum (breastfeeding):
 - \circ The implant can be inserted at any time (U.S. MEC category 2 if < 1 month

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

Switching from another contraceptive method

- The implant can be inserted immediately if it is reasonably certain that the client is not pregnant. Waiting for her next menstrual period is unnecessary.
 - o If it has been > 5 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven (7) days after insertion.

Switching from an IUD/IUS:

- If the client has had sexual intercourse since the start of her current menstrual cycle and it has been > 5 days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract. A healthcare provider may consider any of the following options:
 - O Advise the client to retain the IUD/IUS for at least seven (7) days after the implant is inserted and return for IUD/IUS removal.
 - o Advise the client to abstain from sexual intercourse or use barrier contraception

for seven (7) days before removing the IUD/IUS and switching to the new method, OR

- o If the client cannot return for IUD removal and has not abstained from sexual intercourse or used barrier contraception for seven (7) days, advise the client to use EC pills (except for Ella®) at the time of IUD/IUS removal.
- Offer and provide condoms.

Routine Follow-up

The recommendations listed below address when routine follow-up is needed for safe and effective continued use of contraception for healthy women. These recommendations refer to general situations and might vary for different users and different situations. Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions may benefit from more frequent follow-up visits.

- Advise client to return at any time to discuss side effects or other problems, if she wants
 to change her method, or when it is time to remove or replace the implant. No routine
 follow-up is required.
- At other routine visits, healthcare providers should do the following:
 - Assess a client's satisfaction with the implant and whether she has any concerns about the method use,
 - Assess any changes in health status, including medications that would change the appropriateness of the implant for safe and effective continued use based on U.S. MEC (e.g., category 3 or 4 conditions or characteristics); and
 - Consider assessing weight changes and counseling women who are concerned about weight changes perceived to be due to contraceptive method.

Management of Bleeding Irregularities

Prior to implant insertion, provide counseling about potential changes in bleeding patterns during implant use. Unscheduled spotting or light bleeding is common with implant use, and some women experience amenorrhea. This bleeding is not harmful and may or may not decrease with continued use.

• Heavy or unusually prolonged bleeding is uncommon with implant use.

Irregular bleeding (spotting, light bleeding or heavy or prolonged bleeding):

- If clinically indicated, consider underlying gynecological problems such as interaction with other medications, STIs, pregnancy, or new pathologic uterine conditions.
 - Refer to the prescribing provider/ PCP for evaluation.
- If any underlying condition is not found and the client wants treatment, the following treatment options during days of bleeding can be considered:
 - o NSAIDS for short term treatment five to seven (5-7) days; or
 - O Hormonal treatment (if medically eligible) with monophasic combined oral contraceptives for short-term treatment; daily for fourteen (14) days or longer term

(cyclic or extended use).

• If irregular bleeding persists and the client finds it unacceptable, counsel her on alternative methods, and offer another method if it is desired.

Amenorrhea:

- Amenorrhea does not require any medical treatment. Provide reassurance.
 - o If a client's regular bleeding pattern changes abruptly to amenorrhea, consider ruling out pregnancy if clinically indicated.
 - o If amenorrhea persists and the client finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

Client Education

All women who are planning or capable of pregnancy should be counseled to take a daily supplement containing 0.4 to 0.8 milligrams (400 to 800 μ g) of folic acid (USPSTF, Grade A recommendation; January 2017).

Ensure that the client is aware of all contraceptive choices and has received information that meets the criteria for informed consent.

Review care of insertion or removal site.

Instruct client to return to clinic if a significant NexplanonTM related problem is suspected and/or if any of the following occur:

- Unable to palpate rod or it feels bent (use back-up birth control until evaluated),
- Expulsion (use back-up birth control until she can return to the clinic),
- Very heavy vaginal bleeding or bleeding that lasts longer than fourteen (14) days,
- Delayed menses after a long interval of regular cycles,
- Concern about a possible pregnancy,
- Arm pain; pus, redness, or bleeding at the insertion site,
- Onset or worsening of episodes of migraine, aura, or severe headache; or
- Client desires to remove the implant. Advise the client to use condoms for protection against STIs.

Advise the client to contact the clinic whenever she has questions about her contraceptive method.

Client shall be informed that any signs or symptoms of complications should be reported to the clinic; if the clinic is not open, clients should call 911 or go to the emergency room.

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What is a diaphragm?

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

Diaphragms provide contraception by blocking sperms' entry into the cervix by both a barrier effect and by spermicidal activity from the spermicides used with the diaphragm/cervical cap. These contraceptive devices are used with a spermicidal agent in front of the cervix to kill the sperm. In typical use, twelve (12) out of one hundred (100) women will experience an unintended pregnancy within the first year.

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

Diaphragms do not protect against STIs.

Protocol

SNCHC CSP may provide a diaphragm to any client who requests this contraceptive method and has no U.S. MEC category 4 risk conditions. RNs may provide counseling and education related to the diaphragm/cervical cap.

- Category 4 risk conditions (risk of use outweighs the benefits of pregnancy prevention):
 - o High risk for HIV (related to the association between increased risk for HIV infection and use of nonoxynol-9 (N-9) spermicides).
 - < 6 weeks postpartum (diaphragm and cap use are unsuitable until uterine involution is complete).</p>
- Category 3 risk conditions (must consult with prescribing provider prior to initiation as the theoretical or proven risk may outweigh the advantages of using method):
 - o HIV infections
 - o AIDS
 - History of Toxic Shock Syndrome.

- Antiretroviral (ARV) therapy: nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), ritonavir-boosted protease inhibitors
- Allergic to latex (does not apply to plastic diaphragms).
- Clients with category 1 and 2 risk condition are candidates for using this method.

Procedure

Provide client-centered care through quality counseling and education using the five (5) key principles:

- Establish and maintain rapport with the client,
- Assess the client's needs and personalize discussions accordingly,
- Work with the client interactively to establish a plan,
- Provide information that can be understood and retained by the client; and
- Confirm the client's understanding using a technique such as the teach-back method.

Review medical history:

- Significant illness,
- Allergies,
- Current medications, prescriptive and OTC,
- Use of Tobacco, Alcohol, and Other Drugs,
- Immunization and Rubella status.
- Contraceptive Use,
- Menstrual History,
- Sexual History including risk for STIs,
- Obstetrical History,
- Gynecological and PAP test history,
- Surgical History,
- Hospitalizations,
- Family History; and
- Reproductive Life Plan

Review LMP and compliance with contraceptive method (if applicable). Assess the risk of current pregnancy. Offer pregnancy test if indicated.

- A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets the following:
 - o Is \leq 7 days after the start of normal menses.

- Has not had sexual intercourse since the start of last normal menses.
- o Has been correctly and consistently using a reliable method of contraception.
- o Is ≤ 7 days after spontaneous or induced abortion.
- o Is within four (4) weeks postpartum.
- o Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥ 85%] of feeds are breastfeeds), amenorrhoeic, and < 6 months postpartum.

Assess recent sexual activity where intercourse was unprotected and offer EC for immediate use if indicated.

Blood Pressure: normal < 120/80; refer clients with blood pressure reading ≥ 140 systolic or ≥ 90 diastolic to a primary care provider for further treatment and evaluation.

Weight/Height: obtain BMI.

Perform pelvic examination and fitting for diaphragm/cervical cap to ensure proper size and placement.

Screen for STIs (if the client has not been screened) according to STI screening guidelines.

Discuss the client's reproductive life plan about becoming pregnant by asking:

- Do you have children now?
- Do you want to have (more) children?
- How many (more) children would you like to have and when?
- If the client does not want a child now and is sexually active, then offer contraceptive services.
- If the client desires pregnancy testing, then provide pregnancy testing and preconception counseling.
- If the client wants to have a child now, then provide services to help the client achieve pregnancy and provide preconception counseling.
- If the client wants to have a child and is having trouble conceiving, then provide basic infertility services.

Selection of contraceptive type based on U.S. MEC:

- Prescribing providers, after having a discussion with the client regarding risk versus benefit of a method, may initiate a method for which the client has a category 3 risk condition only if the benefit of pregnancy prevention outweighs the risks and the client finds other lower risk methods unacceptable.
- Clients requesting a method for which they have a category 4 risk condition will be offered lower risk methods and referred to an OB/GYN or specialist provider.

Each client will receive client instructions regarding warning signs, common side effects, risks, use of method, alternative methods, use of secondary method, and clinic follow-up schedule. Document the client's education and understanding of the method of choice.

Plan

- Diaphragms may be initiated at any time. Allow the client to practice insertion and removal.
- Provide the client with spermicides.
- Review the client's history and access to recommended health screenings. Send a release of records for past health screenings, if performed elsewhere.
- Schedule the client for reproductive health well visits if the client has not been screened appropriately within the past twelve (12) months or if an earlier assessment is clinically indicated.
- Offer and provide condoms for use as a back-up method and for STI protection.
- The decision to offer and dispense future-use EC should be made on an individualized basis and should include shared decision making between the provider and the client. Clients requesting (those that self-identify that they need or want) EC for future use and those using less reliable methods of birth control (tier 3 methods) might benefit most from having future-use EC made available.

Routine Follow-Up

These recommendations address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women. Although routine follow-up is not necessary for the use of the diaphragm, recommendations might vary for different users and different situations. Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple conditions may benefit from more frequent follow-up visits.

- Advise the client to return at any time to discuss side effects or other problems if she wants to change the method being used.
- At other routine visits, healthcare providers should do the following:
 - Assess the client's satisfaction with the contraceptive method and whether the client has any concerns about method use.
 - o Assess any changes in health status that would change the appropriateness of the vaginal barrier for safe and effective continued use based on U.S. MEC.
 - Assess any significant weight changes (gain or loss of ten (10) or more pounds) or recent pregnancy which may affect the fitting of the diaphragm.
 - o Diaphragms should be replaced every two (2) years or sooner if there is visible deterioration or damage.

Managing Problems

Recurrent vaginal or vulvar irritation, without sign of infection, may indicate an allergy or sensitivity to the product; may suggest client try another contraceptive method.

• If symptoms persist after discontinuing the method, reevaluate for other etiology (e.g., STI exposure, yeast vaginitis, or bacterial vaginitis).

Counsel the client that recurrent urinary tract infections (UTI) may occur the client should contact

the prescribing provider for a possible refitting with smaller diaphragm size or an alternative rim style if needed.

Client Education

All women who are planning or capable of pregnancy should be counseled to take a daily supplement containing 0.4 to 0.8 milligrams (400 to 800 μ g) of folic acid.

Advise the client to use the diaphragm every time vaginal intercourse occurs; ensure the diaphragm is in proper place before the penis enters the vagina.

Advise the client if unsure about the proper fit or placement of the diaphragm, use an alternative method until evaluated by a medical provider.

Instruct the client on the use of the diaphragm:

- Ideally it is inserted into the vagina less than or up to two (2) hours before sexual intercourse.
- Place one tablespoon of spermicide into the dome and along rim.
- Place an additional applicator of spermicide in the vagina.
- If the diaphragm is placed three to six (3-6) hours before intercourse, another applicator full of spermicides needs to be inserted into the vagina prior to sexual intercourse.
- Each new episode of intercourse while the diaphragm is in place should be preceded by the insertion of fresh spermicide, and the diaphragm should remain in place for at least six (6) hours after the last episode of intercourse to maximize effectiveness.
- For the cervical cap, once it is in place, it is not necessary to use more spermicide with each vaginal intercourse.
- Label the case with the first use date to ensure it gets replaced in two (2) years.
- Instruct the client to remove the diaphragm within twenty-four (24) hours to minimize the risk of vaginal irritation, cystitis and, rarely, toxic shock.

Counsel the client on their individual risk of STI acquisition or transmission; when using N-9 spermicides more than three (3) applications per day, the risk of HIV is increased compared to a placebo.

Instruct the client when using the diaphragm to avoid lubricants such as mineral oil, baby oil, suntan oil, vegetable oil, butter; and vaginal cream such as Femstat cream, Monistat cream, estrogen cream, and Vagisil.

Inform the client that she may use contraceptive jelly or water-soluble lubricant intended for use with condoms for lubrication, if needed.

Advise the client that douching after intercourse is not recommended.

Advise the client to store the diaphragm/cervical cap in a location that is clean, cool, and out of the sunlight.

Instruct the client to wash diaphragm and spermicide inserter after each use with plain soap and water. Dry gently with a soft, clean cloth or let it air dry.

Instruct the client to check diaphragm before each use to make sure there are no holes, thin spots, or tears and that the device is not damaged and that the spring rim is fully enclosed by silicon rubber. Store in case not in use. It can be reused for up to two (2) years.

Advise the client to use condoms for protection against STIs.

Inform the client of signs and symptoms of TSS (clients should be informed to seek immediate care if any warning signs are noted):

- Sudden high fever
- Chills
- Vomiting
- Diarrhea
- Muscle aches: or
- Sunburn-like rash.

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Explaining How to Use the Diaphragm

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

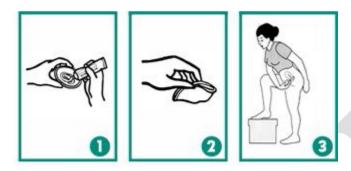
Explain the Five (5) Basic Steps to Using a Diaphragm

Basic Steps

Step 1. Squeeze a spoonful of spermicidal cream, jelly, or foam into the diaphragm and around the rim.

- Wash your hands with mild soap and clean water, if possible.
- Check the diaphragm for holes, cracks, or tears by holding it up to the light.
- Check the expiration date of the spermicide and avoid using anything beyond its expiration date.
- Insert the diaphragm less than six (6) hours before having sex.

- Step 2. Press the rim together; push into the vagina as far as it goes.
 - Choose a position that is comfortable for insertion -- squatting, raising one leg, sitting, or lying down.
- Step 3. Feel diaphragm to make sure it covers the cervix.
 - Through the dome of the diaphragm, the cervix feels like the tip of the nose.
 - If the diaphragm feels uncomfortable, take it out and insert it again.



Step 4. Keep in place for at least six (6) hours after sex.

- Keep the diaphragm in place at least six (6) hours after having sex but no longer than twenty-four (24) hours.
- Leaving the diaphragm in place for more than one day may increase the risk of toxic shock syndrome. It can also cause a bad odor and vaginal discharge. Odor and discharge may go away after the diaphragm is removed.).
- For multiple acts of sex, make sure that the diaphragm is in the correct position and insert additional spermicide in front of the diaphragm before each act of sex.
- Step 5. To remove, slide a finger under the rim of the diaphragm to pull it down and out.
 - Wash your hands with mild soap and clean water, if possible.
 - Insert a finger into the vagina until the rim of the diaphragm is felt.
 - Gently slide a finger under the rim and pull the diaphragm down and out. Use care not to tear the diaphragm with a fingernail.
 - Wash the diaphragm with mild soap and clean water and dry it after each use.

What is intrauterine contraception?

An IUD is tier 1, the most effective method of contraception and falls into the LARC category. SNCHC follows manufacturer recommendation based on FDA approval on length of use.

Objective Data

History and Physical exam

Laboratory tests may include:

- Cervical cancer screening within the normal screening interval for the client. Cervical intraepithelial neoplasia (CIN) is listed as a category 2 (a condition for which the advantages of using the method generally outweigh the theoretical or proven risk) for Mirena, and a category 1 (a condition for which there is no restriction for the use of the contraceptive method) for ParaGard. An IUD 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.
- Gonorrhea and chlamydia tests according to national screening guidelines and within the normal screening interval for the client. Screening may be provided at the time of IUD insertion if screening has not previously been done.
- Pregnancy testing should be done prior to insertion.

Assessment and Plan

Client Education/Informed Consent

- Have client read the FDA approved client brochure for the IUD hat she is to have inserted.
- Provide anticipatory counseling and reinforce the effects of the IUD on the menstrual cycle.
- The client must sign an IUD procedure consent and IUD package insert must be provided to the client.

Pre-insertion Management

- Prophylactic antibiotics are generally not recommended for IUD insertion.
- Sub-bacterial endocarditis (SBE) prophylaxis prior to IUD insertion is not recommended. Routine administration of prophylactic antibiotics solely to prevent endocarditis is not recommended for clients undergoing genitourinary tract procedures. Routine antibiotic prophylaxis to prevent pelvic infection is not recommended before IUD insertion.
- For pre-insertion pain management, clients may be given a NSAID one (1) hour prior to insertion. According to U.S. Selected Practice Recommendations (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 in women with a recent failed insertion.
- 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 one (1) minute before proceeding with the IUD insertion, or 3) inject 1 ml of local anesthetic to cervical lip into which the tenaculum will be placed.

Initiation of IUD follow manufacturer's instructions for insertion of IUD device.

Insertion

- Document baseline pulse and blood pressure prior to insertion.
- Document pelvic exam done prior to insertion as to uterine position, size, cervix and discharge appearance and any abnormalities.

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

Post-insertion of the IUD -- Vasovagal observation

- If signs of vasovagal response noted following procedure, record BP and pulse frequently; every five to fifteen (5-15) minutes.
- Client should not be allowed to leave the clinic until stable.
- Clients with persistent vasovagal symptoms should be evaluated for perforation, abdominal bleeding, etc.

Post-IUD Insertion Education

- Client should be instructed on the expiration period for the IUD.
 - o ParaGard is approved for ten (10) years.
 - o Mirena is approved for up to eight (8) years, and for up to five (5) years in women with heavy periods, who choose IUD for birth control.
 - o Kyleena is approved for up to five (5) years.
 - O Skyla is approved for up to three (3) years.
 - o Liletta is currently approved for eight (8) years.
- Need for back up contraception, if indicated
- Reinforce the signs and symptoms of possible IUD complications. Instruct the client to call the clinic for any of the following:
- Late or missed period if using ParaGard; abnormal spotting or bleeding; signs or symptoms of pregnancy.
- Pelvic or lower abdominal pain; pain with intercourse
- Exposure to STIs; abnormal vaginal discharge
- Not feeling well -- fever or chills
- Inability to locate IUD string, changes in string length.
- Known partial or full expulsion.
- Inform the client if she wishes to discontinue the use of her IUD to make an appointment with her provider to have it removed. If she does not wish to become pregnant, she must start a new method on or before the day she has her IUD removed.

Follow-up Visits

- The scheduling of follow-up visits is at the provider's discretion. Consider a six (6) week IUD string check to confirm placement. Routine follow-up visits after IUD insertion are not required unless the provider feels that the client would benefit (e.g., adolescents, certain medical conditions).
 - Advise women to return at any time to discuss side effects or other problems or if she wants to change her method.

- 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 U.S. MEC), consider exam for IUD string check.
- o Hemoglobin/Hematocrit if indicated.
- o Review of IUD danger signs.
- Reinforce the importance of an annual visit and cervical cancer screening according to screening guidelines.

Management of Complications / Side Effects

Client diagnosed with pelvic inflammatory disease (PID)

- Treatment 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." Close clinical follow up is required.
- Inform the client to seek care immediately if her symptoms do not improve or worsen. Reassess in forty-eight (48) to seventy-two (72) hours. If there is no improvement, consider IUD removal. Continue antibiotics and refer for care.
- If the IUD is removed, contraceptive counseling is necessary.
 - o If the client is mid-cycle, and has recently had intercourse, inform her of the risk of removing the IUD and possible subsequent pregnancy. Offer EC, if the client decides she does not want removal, documentation must exist of discussion of need for close clinical follow up.
 - o If IUD is removed, be certain the client leaves the clinic with an alternative method of birth control.

Actinomyces on PAP test -- Symptomatic of PID

- Client must receive/be referred for intensive antibiotic therapy, along with the removal of the IUD, as this bacterium prefers to grow on foreign bodies.
- Clients must be counseled on the use of a different method of contraception.

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. With this in mind, provider will manage and determine the approach to be used for actinomyces on PAP test in an asymptomatic IUD user.
 - The IUD does not have to be removed, but the client should be informed and questioned about any symptoms suggestive of PID. If she is asymptomatic, nothing more is required.
 - 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.

 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.

Spotting, Bleeding

- o Rule out pregnancy, infection or partial expulsion and manage appropriately.
- o If the client complains of excess bleeding within the first three (3) months after insertion.
 - Reassure that it is likely to get better in subsequent cycles,
 - Check Hct or Hgb and give iron supplement, if indicated,
 - For Cu-IUD: U.S. SPR recommends short term NSAIDs for five to seven (5-7) days.
 - Rule out other pathology related to vaginal bleeding.

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 ten to fifteen (10-15) minutes.

- Pain with sounding of the uterus during insertion
 - o Go slowly, consider smaller sound.
 - o If severe, check alignment of uterine cavity on bimanual exam, and consider using a paracervical block before proceeding.
- Pain at the time of insertion persists, with signs of abdominal tenderness.
 - o If the string is present, treat it as pelvic infection.
 - o If the string is absent, consider the possibility of perforation, migration, expulsion, or pregnancy and refer to physician or emergency room.
 - o If severe: rule out perforation, pregnancy, or infection. Check blood pressure and pulse. Consider removing the IUD if indicated.
 - o If mild: recommend a mild analgesic such as Ibuprofen.

Severe post-insertion reaction, such as syncope

- If placement is questionable, remove the IUD. An IUD can be re-inserted now or later.
- If the IUD is properly placed, and pulse < 60 beats/min, consider the use of ammonium capsules (smelling salts).
- Call 911 for emergency services.
- Remove the IUD if necessary.

Partial expulsion of IUD

• Without signs of infection, remove IUD and another IUD may be inserted if reasonably certain woman is not pregnant and urine pregnancy test is negative.

- With PID or question of PID, treat with antibiotics and remove the partially expelled IUD. Provide alternative contraception. Another IUD may be inserted after three (3) cycles.
- Consider EC

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.

- Do highly sensitive pregnancy test and pelvic exam.
- If the client is pregnant and the IUD string is visible, the patient should be referred to an obstetrician as soon as possible.
 - o Counsel the client that an ectopic pregnancy, SAB, or sepsis is a possibility and review signs and symptoms of each.
 - o Refer the client for health care services.
 - o If the client chooses to keep the IUD, advise her to seek care promptly and especially with heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.
- If the client is pregnant and the string is not visible, explain the risks of ectopic pregnancy, spontaneous abortion (SAB) and sepsis with an IUD in situ during pregnancy.
 - o Review the warning signs of infection, SAB, and ectopic pregnancy, including where to seek emergency care.
 - o Refer to physician immediately for follow-up.
- Ectopic pregnancy
 - o IUD significantly reduces a woman's risk of an ectopic pregnancy, because the IUD prevents all types of pregnancies. Should a pregnancy occur with an IUD in place, the ratio of ectopic to intrauterine pregnancies may be increased.

Absent IUD Strings

- If menses have not been missed and there is no abdominal pain:
 - After ruling out pregnancy, attempt to determine if the IUD is in the uterus by gently exploring the cervix for the strings.
 - o If the strings are located, bring them to their appropriate place.
- If the strings are not found, the clinician may elect to discuss and provide an alternative method of contraception with the client and have her return with the next menses to check again for the string OR obtain a pelvic ultrasound to determine if the IUD is in the uterus.
 - If the IUD is seen on ultrasound, clarify the location to rule out perforation. If the IUD is in the uterus, nothing else needs to be done.
 - 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.

- If menses have been missed and/or there are signs and symptoms of infection:
 - o Rule out pregnancy.
 - o See management of pregnancy with IUD in situ or PID with IUD.

IUD Removal

Subjective Data

- LMP and previous menstrual period
- Medical history update
- History of recent intercourse if client not menstruating
- Reason for IUD removal

Objective Data

- Physical exam/pelvic exam as indicated.
- Laboratory as indicated. Perform pregnancy testing with removal and same day insertion and when indicated.

Assessment and Plan

- Client requesting reinsertion of IUD:
 - Reinsertion may be done at the same visit except when pregnancy test is positive, refer to OB/GYN.
- Client requesting change in contraceptive method.
 - Counsel regarding other methods of birth control. Hormonal methods may be initiated before the IUD is removed.
 - Remove IUD. If the client is not menstruating, counsel on risks of pregnancy. Consider ECP.
 - o Provide interim method of birth control, as indicated.
 - o If pregnancy is desired, preconception counseling, including the benefits of folic acid, should be provided.
- Client symptomatic of PID.

Resources

The Contraceptive Choice Project for resources regarding counseling, training, troubleshooting and forms: http://www.choiceproject.wustl.edu/

 $ACOG\ LARC\ resources: \underline{http://www.acog.org/more-info/increasinglarc}\ and \underline{https://www.acog.org/About-ACOG/ACOG-Departments/Long-Acting-Reversible-Contraception}$

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Introduction / What are progestin-only pills (POP)?

POP contraceptives are tier 2 contraceptives and are moderately effective. U.S MEC categories of MEC for contraceptive use to use when assessing the safety of a contraceptive method for women with specific medical conditions or characteristics.

Management of Women with Special Conditions Requiring Further Evaluation

Drug Interactions

- Anti-seizure medications: Concurrent use of anti-seizure drugs that induce hepatic enzymes may reduce effective plasma steroid levels in oral contraceptive users. These medications include phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine.
- Gabapentin (Neurontin®), vigabatrin, ethosuximide and lamotrigine (Lamictal®) have no effect on this enzyme system and do not interfere with contraceptive effectiveness. Valproate/ Valproic Acid (Depakote®) and felbamate (Felbatol®) do not increase breakdown of hormones and may even increase hormone levels. No drug interactions have been reported among epileptic women taking lamotrigine and using POPs.
- Rifampin increases hepatic clearance of estrogen and progestin; it is recommended that clinicians not prescribe hormonal contraceptives for women on this drug.
- Use of broad-spectrum antibiotics, antifungals, and antiparasitic with POPs is category 1.
- The FDA has alerted providers that the use of St. John's Wart may decrease the therapeutic effect of combined hormonal methods.
- 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.

• Most studies suggest no association between use of hormonal contraception and progression of HIV, as measured by CD4+ count < 200 cells/mm3, initiation of antiviral therapy, or mortality.

Client Education / Informed Consent

- Fact sheet on all contraceptive options available if she is a new client or is undecided as to what method she wishes to use.
- Fact sheet on the client's chosen method.
- Instructions on correct use of the method,
- Information about the effectiveness of her method and that the effectiveness of hormonal contraception may be decreased by some medications,
- The importance of scheduled follow-up visits,
- Importance of informing other providers of their use of oral contraceptives,
- Information regarding discontinuation of her method. If she does not wish to get pregnant, she should start using another method before the day she was due to start her next cycle,
- Information regarding STIs, including counseling that hormonal contraceptives provide no protection. Use of either male or female condoms should be recommended for clients in need of protection from STIs,
- Non contraceptive benefits of the method,
- Possible side effects and how to manage side effects; and
- 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.

Medical Screening and Evaluation

- History
- Examination
- Laboratory

Provision of POPs

Follow U.S. SPR recommendations for initiation of POPs http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm

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.

Starting hormonal contraceptives should be considered at any time with a follow up pregnancy test in two to four (2-4) weeks POPs may be started in lactating and non-lactating women at any time postpartum. The U.S. MEC for contraceptive use lists POPs as a category 2 for breastfeeding women less than one (1) month postpartum.

A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is ≤ 7 days after the start of normal menses.
- has not had sexual intercourse since the start of last normal menses.
- has been correctly and consistently using a reliable method of contraception.
- is ≤ 7 days after spontaneous or induced abortion.
- is within four (4) weeks of postpartum.
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥ 85%] of feeds are breastfeeds), amenorrhoeic, and < 6 months postpartum.

A pregnancy that does occur in a woman taking mini pills is more likely to be ectopic. Some sources postulate that ten percent (10%) of pregnancies that occur to mini-pill users are ectopic.

POPs inhibit ovulation in about half of cycles, though rates vary widely by individual. Serum levels peak at two (2) hours after taking a POP and return to baseline at twenty-four (24) hours. Taking POPs at the same time each day is important. It takes forty-eight (48) hours to achieve the contraceptive effect on cervical mucus.

A blood pressure must be documented for all patients starting a hormonal method and then checked and documented periodically if the patient is using the method.

Provide or prescribe up to a one (1) year supply of the contraceptive method, e.g., thirteen (13), 28-day pill packs. The more cycles provide, the higher the continuation rates.

See U.S. SPR for instructions on missed POPs and vomiting or severe diarrhea that occurs within three (3) hours after taking a pill.

Follow-Up

Routine follow up is not recommended unless indicated. Provider recommendations for follow up visits are based on factors such as whether the woman has certain medical conditions or multiple medical conditions in need of monitoring.

Advise woman to return to the clinic at any time to discuss side effects, problems or if she wants to change her method.

At other routine visits the client should be assessed for her satisfaction with her method, changes in health status including medications that would impact the safe use of her method (e.g., category 3 and 4 conditions for the method), assess blood pressure, and consider assessing weight changes.

Monitor blood pressure as indicated or when client returns for annual visit.

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What is fertility awareness-based methods (FABM)?

This policy provides direction for reproductive health clinics to assist clients in their use of FABM as birth control.

FABM methods help couples understand how to avoid pregnancy or how to become pregnant. FAB methods are based on:

- identifying the fertile days of the menstrual cycle through monitoring the cycle days (e.g., Standard Days method and Calendar Rhythm method
- observing fertility signs such as cervical secretions, and basal body temperatures (e.g., Two-day Method, the Billings Ovulation Method, Symptothermal Method).

Approximately twenty-five percent (25%) of women using FABM methods will experience an unintended pregnancy during the first year of typical use. FABM methods are reversible and can be used by women of all ages.

FABM methods do not protect against STIs.

Protocol

SNCHC clinical staff may provide information and counseling to any client who requests FABM.

- No medical conditions become worse by using FABM.
- The U.S. MEC identifies several conditions which makes using FABM more complicated.
 - Delay (use of calendar or symptom-based methods until the following conditions are evaluated or corrected):
 - Breastfeeding < 6 weeks postpartum -- both methods,
 - Breastfeeding \geq 6 weeks -- calendar-based method,
 - Postpartum (in non-breastfeeding women) < 4 weeks -- both methods,
 - Postpartum (in non-breastfeeding women) ≥ 4 weeks -- calendar-based method (after completion of three (3) postpartum menses may begin calendar-based method),
 - Post abortion -- calendar-based method (the client can start calendar method after she has had at least one (1) post abortion menses; clients who before this pregnancy had most cycles of twenty-six to thirty-two (26-32) days can then use the Standard Days Method). May offer methods appropriate for the postpartum period before that time,
 - Current irregular vaginal bleeding -- both methods,
 - Current vaginal discharge -- symptom-based method until after treatment,
 - Use of drugs that affect cycle regularity, hormones, and/or fertility signs -both methods (the condition should be carefully evaluated, and a barrier method offered until the degree of effect has been determined or the drug is

- no longer being used); or
- Acute diseases that elevate body temperature: -- symptom-based method.
- Caution (method is normally provided in routine setting but with extra preparation and precautions e.g., special counseling to ensure correct usage):
 - Post menarche -- both methods,
 - Perimenopause -- both methods,
 - Breastfeeding ≥ 6 weeks -- symptom-based method,
 - Breastfeeding after menses returns -- both methods. After three (3) postpartum menses and cycles are regular, the client can use calendar method; after four (4) postpartum menses and if the most recent cycle lasted twenty-six to thirty-two (26-32) days the client can use the Standard Days Method. Offer a barrier method if the client plans to use a FABM later,
 - Post abortion -- symptom-based method,
 - Use of drugs that effect cycle regularity, hormones, and/or fertility signs -both methods (The condition should be carefully evaluated, and a barrier
 method offered until the degree of effect has been determined or the drug is
 no longer being used); or
 - Chronic diseases that elevate body temperature -- symptom-based method.
 Temperature based methods are not appropriate for women with
 chronically elevated temperatures. In addition, some chronic diseases
 interfere with cycle regularity, making calendar methods difficult to
 interpret.
- o Accept (no medical reason to deny the FABM in these circumstances):
 - Postpartum \geq 4 weeks -- symptom-based method,
 - Vaginal discharge -- calendar-based method; or
 - Chronic and acute diseases that elevate body temperature calendar-based method.
- Clients with conditions that make pregnancy an unacceptable risk should be advised that FABM methods may not be appropriate for them.

Procedure

Provide client-centered care through quality counseling and education using the five (5) key principles:

- Establish and maintain rapport with the client,
- Assess the client's needs and personalize discussions accordingly,
- Work with the client interactively to establish a plan,
- Provide information that can be understood and retained by the client; and

• Confirm the client's understanding using a technique such as the teach-back method.

Review medical history:

- Significant illness,
- Allergies,
- Current medications, prescriptive and OTC,
- Use of Tobacco, Alcohol, and Other Drugs,
- Immunization and Rubella status,
- Contraceptive Use,
- Menstrual History,
- Sexual history including risk for STIs,
- Obstetrical History,
- Gynecological and PAP test history,
- Surgical History,
- Hospitalizations,
- Family History; and
- Reproductive Life Plan

Review LMP and compliance with contraceptive method (if applicable). Assess the risk of current pregnancy. Offer pregnancy test if indicated.

- A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets the following:
 - o Is \leq 7 days after the start of normal menses.
 - o Has not had sexual intercourse since the start of last normal menses.
 - o Has been correctly and consistently using a reliable method of contraception.
 - o Is ≤ 7 days after spontaneous or induced abortion.
 - o Is within four (4) weeks postpartum.
 - o Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority $[\ge 85\%]$ of feeds are breastfeeds), amenorrhoeic, and < 6 months postpartum.

Assess recent sexual activity where intercourse was unprotected and offer EC for immediate use if indicated.

Blood Pressure: normal < 120/80; refer clients with blood pressure reading ≥ 140 systolic or ≥ 90 diastolic to a primary care provider for further evaluation.

Weight/Height: obtain BMI.

Screen for STIs (if the client has not been screened) according to STI screening guidelines (see Section 9: STI Screening Policies and Procedures).

Discuss the client's reproductive life plan about becoming pregnant by asking:

- Do you have children now?
- Do you want to have (more) children?
- How many (more) children would you like to have and when?
 - o If the client does not want a child currently and is sexually active, then offer contraceptive services.
 - o If the client desires pregnancy testing, then provide pregnancy testing and preconception counseling.
 - o If the client wants to have a child now, then provide services to help the client achieve pregnancy and provide preconception counseling.
 - o If the client wants to have a child and is having trouble conceiving, then provide basic infertility services.

Present all birth control method options for which the client has no U.S. MEC category 3 or 4 risk conditions.

Each client will receive client instructions regarding warning signs, common side effects, risks, method of use, alternative methods, use of secondary method, and clinic follow-up schedule. Document client education and understanding of the method of choice.

Plan

Initiating the fertility awareness-based methods

- Standard Days Method (SDM):
 - o Clients must avoid unprotected sexual intercourse on days eight to nineteen (8-19) of the menstrual cycle.
 - O Clients with twenty-six to thirty-two (26-32)-day menstrual cycles may use this method.
 - Clients may use a barrier method of contraception, for pregnancy protection, on days eight to nineteen (8-19) if desired.
 - o If the client has unprotected sexual intercourse during days eight to nineteen (8-19), consider the use of EC, if appropriate.
 - Clients with two (2) or more menstrual cycles of < 26 or > 32 days within one (1) year of SDM use:
 - Advise the client that the method might not be appropriate because of higher risk of pregnancy.
 - Help the client to consider another method.
- Calendar Rhythm Method:
 - Prior to starting this method, the client must record the length of the previous six
 (6) menstrual cycles to identify the longest and shortest cycles.
 - o Calculate the fertile period by looking at the calendar.

- The first day of the fertile phase is found by subtracting eighteen (18) days from the length of the shortest cycle.
- The last day of the fertile phase is found by subtracting eleven (11) days from the longest cycle.
- Avoid pregnancy by abstaining from sexual intercourse from the first day of the fertile period to the last day of the fertile phase.

• Two Day Method

- Is based on assessing for the presence or absence of cervical secretions (the
 presence of secretions conforms sufficiently to the actual fertile window so that
 further evaluation of the secretions' characteristics is not necessary).
 - Clients are counseled to avoid unprotected sexual intercourse on all days there is the presence of secretions; AND on the first day following a day with secretions.
 - The mean length of the identified fertile period is thirteen (13) days.
- o Instruct the client in how to observe, record, and interpret their cervical secretions:
 - Color
 - Elasticity
 - Abundance and
 - Viscosity
- Counsel the client on how to recognize if they have secretions:
 - o By touching the vulva with the fingers, or using toilet paper to collect secretions and assess their characteristics,
 - o Noting secretions on underwear; or
 - o Simply feeling for wetness at the vulva.
- Advise the client to observe for secretions two (2) times per day (adjust observations according to the times they typically have intercourse):
 - o Once in the afternoon; and
 - o Once before going to bed at night.
 - Clients may start the method anytime during a cycle.
- Billings Ovulation Methods:
 - o Advise the client to observe cervical secretions several times each day.
 - o Instruct the client in how to observe, record and interpret their cervical secretions:
 - Color
 - Elasticity
 - Abundance; and

- Viscosity.
- o Advise the client to avoid unprotected sexual intercourse:
 - During menses (menstrual bleeding could obscure the presences of secretions),
 - On preovulatory days following days with intercourse (possible confusion with semen),
 - On all days with wet, slippery, transparent, or stretchy secretions; and
 - Until four (4) days past the last day with wet secretions.
- o Based on rules, clients should avoid unprotected intercourse for approximately fourteen to seventeen (14-17) days of each cycle.
- Symptothermal Method:
 - o Based on changes in cervical secretions and basal body temperature:
 - Requires client to observe and evaluate their cervical secretion several times each day.
 - Take their temperature each morning before rising (with basal body temperature thermometer).
 - Record and interpret their findings to determine whether the day is a fertile day.
 - Some may check the position and feel of the cervix (cervix rises to the top of the vagina, becomes softer and moister when approaching ovulation).
 - Clients need to abstain or avoid unprotected intercourse for approximately twelve to seventeen (12-17) days each cycle.
 - o Offer and provide condoms as a back-up method and for STI protection.

The decision to offer and dispense future-use EC should be made on an individualized basis and should include shared decision making between the provider and the client. Clients requesting (those that self-identify that they need or want) EC for future use and those using less reliable methods of birth control (tier 3 methods) might benefit most from having future-use EC made available.

• Instruct the client to wait five (5) days after the administration of Ella® before initiating hormonal contraceptives. Recommend the use of a barrier method of contraception with all subsequent acts of intercourse that occur within the next fourteen (14) days.

Routine Follow-Up

The recommendations listed below address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women and men. Although routine follow-up is not necessary for the use of fertility awareness based as a birth control method, recommendations for follow-up might vary for different users and different situations. Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple conditions may benefit from more frequent follow-up visits.

- Advise the client to return at any time to discuss any problems or concerns or if wanting to change the method being used. No routine return visit is required for this method of birth control.
- At other routine visits, healthcare providers should:
 - Assess the client's satisfaction with the contraceptive method and whether the client has any concerns about method use; and
 - Assess any changes in health status that would change the appropriateness of using the method.

Client Education

All women who are planning or capable of pregnancy should be counseled to take a daily supplement containing 0.4 to 0.8 milligrams (400 to 800 µg) of folic acid.

Provide the client information on all birth control methods; it is important that the client understands all options available to decrease risk of pregnancy.

Provide educational material or resources to assist the client in being successful in determining their fertile days.

Advise the client on the importance of her partner's cooperation to be successful in preventing an unintended pregnancy.

Advise the client to use condoms for protection against STIs.

Advise the client to call the clinic if she has any questions or concerns regarding birth control methods.

First year typical use failure rates for fertility awareness methods range from twelve to twenty-five percent (12 %-25%) (Zieman M, Hatcher RA. Managing Contraception. Tiger, Georgia: Bridging the Gap Foundation, 2015, pg. 53).

Criteria for Starting the Standard Days Method

Women whose menstrual cycles are usually between twenty-six to thirty-two (26-32) days.

- Date of last period known
 - Start immediately.
- Date of last period unknown
 - Start on the first day of next period.

Special circumstances

- Postpartum/breastfeeding
 - Wait for at least four (4) periods.
 - O Start after two (2) most recent periods are about a month apart.
- Three-month DMPA injection used for contraception.
 - Wait for at least ninety (90) days after the last injection.
- Start after two (2) most recent periods are about a month apart.

- Pill, patch, implant, EC, IUD, miscarriage, or abortion.
 - Cycles before using method or pregnancy were twenty-six to thirty-two (26-32) days long.
 - o Start on the first day of next period.

Resources

Two Day Method® http://irh.org/twoday-method/ <a href="http://irh.org/twoday-m

Standards Day Method® http://irh.org/standard-days-method/

Cycle Beads® Uses color coded beads (Cycle Beads) to monitor the days of a women's menstrual cycle http://www.cyclebeads.com/

References

Centers for Disease Control and Prevention. (2024). U.S. Medical Eligibility Criteria for Contraceptive Use, 2024. https://www.cdc.gov/mmwr/volumes/73/rr/pdfs/rr7304a1-H.pdf

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SECTION 7

Cervical Cancer Screening What is management of abnormal cervical cytology?

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

The cause of pre-invasive cervical lesions is an accumulation of DNA mutations in immature metaplastic cells because of persistent HPV. Genital HPV infections are transmitted by skin-to-skin contact during sexual intercourse. More than one hundred (100) DNA types of HPV have been identified; a limited number of these are associated with premalignant and malignant epithelial lesions of the lower genital tract. These high risk (HR) types can be identified through lab testing, often performed in conjunction with the PAP test. Types sixteen to eighteen (16-18) account for about seventy percent (70%) of CIN 2 or 3 lesions and cervical cancers, while the remaining thirty percent (30%) are due to HPV types 31, 33, 35, 39, 45, 51, 52, 56, and 58.

Infections due to HPV types 6 and 11, the cause of genital warts and most low-grade cervical lesions, are felt to exhibit no malignant potential.

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

MEC risk categories for contraceptive use for women in need of abnormal cervical cytology management.

Protocol

SNCHC clinical staff may provide clients with information on abnormal cervical cytology management. A referral to the client's provider of choice will be provided when the determination of follow-up falls outside the agency's scope of practice.

Procedure

Provide client-centered care through quality counseling and education using the five (5) key principles:

- Establish and maintain rapport with the client,
- Assess the client's needs and personalize discussions accordingly,
- Work with the client interactively to establish a plan,
- Provide information that can be understood and retained by the client; and
- Confirm the client's understanding using a technique such as the teach-back method.

All abnormal cervical cytology results will be reviewed by the clinical service providers and follow-up recommendations will be made based on the client's history and cytology results. The Medical Director should be consulted as needed for complex cases. Clients will be referred to an OB/GYN.

Review medical history: subjective information reported by the client when the PAP test was

performed, as well as records of prior testing/treatment should be reviewed to help determine appropriate follow-up of results. Items to review:

- Prior PAP screening history:
 - o Age screening began.
 - o Frequency of screening
 - Most recent screening/testing; and
 - o Any history of abnormalities.
- Prior history of + high risk (HR) HPV testing and results.
- Prior history of abnormal cervical cytology management:
 - o Colposcopy; and/or
 - o Treatment for dysplasia.
- Review of symptoms. Review any client reported symptoms at the time of screening/testing. Most cervical dysplasia and many cancers are asymptomatic, but red flags include unexplained chronic vaginal discharge, or unexplained bleeding or spotting, particularly if post-coital.
- History of vaccination against HPV

The mode and urgency of communicating abnormal results to the client depends on the severity of the abnormality.

- Clients who need immediate colposcopy or referral should be contacted by phone; if unable to contact by phone, a certified letter should be sent in seven (7) days.
- For clients who indicate they cannot be contacted, the agency must have a procedure in place to reach them. Patients should be able to access lab results through the patient portal.

All clients referred for abnormal cervical cytology management will receive verbal and/or written information on:

- HPV
- Abnormal cervical cytology; and
- The procedure for which they are being referred.
- Document the client education and the client's understanding of information that was provided.

Actively refer the client to the provider who will perform the cervical procedure including faxing medical records and scheduling the procedure.

Obtain a signed Release of Information (ROI) for communication with that provider (although a signed ROI is not required for a referral for on-going clinical management, this often facilitates the transfer of information).

Patients may be scheduled for a telehealth visit.

Pertinent records, including copies of PAP/HR HPV results and a cover letter, should be faxed to the provider's office, well before the day of the procedure. Assist the client as needed in making the appointment.

HPV Vaccination

Offer routine vaccinations to all unvaccinated or under vaccinated clients (males and females) ages nine to twenty-six (9-26).

- Ideally, HPV vaccinations should be offered and completed prior to potential exposure to HPV through sexual contact.
- The vaccine can be discussed with most adults aged twenty-seven to forty-five (27-45); however, based on history, some adults may benefit from the discussion and vaccine.
- For under-vaccinated women over age twenty-six (26) years, complete the series.

Women should be advised that the HPV vaccine will have no therapeutic effect on an existing HPV infection, genital warts, or current abnormal cervical cytology.

Refer to CDC immunization protocols.

Plan

Examine the patient's current results and history to determine the immediate CIN 3+ risk (recommend using the ASCCP phone or computer application). If the risk is $\geq 4\%$, then immediate management via colposcopy or treatment is indicated. If the immediate risk is < 4%, the five (5) year CIN 3+ risk is examined to determine whether patients should return in one (1), three (3), or five (5) years.

CIN 3+ Risk Thresholds for Management

Management Option/Clinical Action Threshold

• Expedited treatment preferred*

• Expedited treatment or colposcopy acceptable*

Colposcopy recommended.

• Repeat test in one (1) year.

$$\circ$$
 0.55% to < 4%‡

• Repeat test in three (3) years.

$$\circ$$
 0.15% to < 0.55%

• Return to routine screening at five (5) year intervals.

^{*}For nonpregnant patients twenty-five (25) years or older.

†Refers to immediate CIN 3+ risk.

‡Refers to five (5) year CIN 3+ risk.

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

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

- Squamous Cell Carcinoma (SCC),
- Atypical Glandular Cells (AGC),
- High-Grade Squamous Intraepithelial Lesion (HSIL),
- Atypical Squamous Cells Cannot Exclude High Grade Squamous Intraepithelial Lesion (ASC-H),
- ASC-H and HSIL in women twenty-one to twenty-four (21–24),
- Low-Grade Squamous Intraepithelial Lesion (LSIL) for women with no HPV test or + HR HPV,
- Atypical Squamous Cells of Undetermined Significance (ASCUS) with +HR HPV,
- Women aged thirty (30) and older with a negative cytology screening result and +HR HPV,
- Women aged thirty (30) and older with an unsatisfactory screening result and +HR HPV.

Referral to Colposcopy:

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

Routine Follow-Up

Follow-up after the procedure will be based on the findings from the procedure, recommendations from the provider performing the procedure, and following the ASCCP's recommendations (available at https://www.asccp.org/management-guidelines).

Results of the procedure will be recorded in the client's medical record. The client's medical record will be flagged indicating when/where next the follow-up will occur.

Client Education

All women who are planning or capable of pregnancy should be counseled to take a daily supplement containing 0.4 to 0.8 milligrams (400 to 800 μg) of folic acid.

Discuss and provide written information on abnormal cervical cytology results, the nature of HPV infections, and the procedure indicated.

Inform the client that the risk of acquiring cervical cancer (and associated sexually transmitted infections (STIs) such as HPV and HIV) can be reduced by (as appropriate to the individual):

- Completing the HPV vaccination series,
- Reducing the number of sexual partners,
- Using condoms,
- Being abstinent; and
- Delaying onset of sexual intercourse.

Educate women that smoking cessation, safer sex practices, and eating a diet rich in fruits and vegetables may also decrease the risk of cervical cancer.

Advise the client to contact the clinic if she has any questions or concerns.

• Provide information regarding the provider where the client is being referred. This will help decrease the patient's anxiety.

Reinforce importance of return for scheduled follow-up care.

References

American College of Obstetricians and Gynecologists. (2024). Updated guidelines for management of cervical cancer screening abnormalities. Practice Advisory. Available at https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/10/updated-guidelines-for-management-of-cervical-cancer-screening-abnormalities

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Cytology Screening Guidelines

Population	Recommended screening method	Management of screen results	Comments
< 21 years	No screening		HPV testing should NOT be used for screening or management of ASC-US in this age group
21-29 years	Cytology alone every 3 years	Examine the patient's current results <u>and</u> history to determine the immediate CIN 3+ risk. (Recommend using the ASCCP	HPV testing should NOT be used for screening in this age group
30-65 years	HPV <u>and</u> Cytology "Co-testing" every 5 years (Preferred)	phone or computer application.) If the risk is $\geq 4\%$, then immediate management via colposcopy or treatment is indicated.	Screening by HPV alone is not recommended for most clinical settings
	Cytology alone every 3 years (Acceptable)	5- year CIN 3+ risk is examined to determine whether patients should return in 1, 3, or 5 years.	
		All positive primary HPV screening tests, regardless of genotype, should have additional reflex triage testing performed from the same laboratory specimen (e.g., reflex cytology).	
> 65 years	No Screening following adequate negative prior screening		Women with a history of CIN2 or a more severe diagnosis should continue routine screening for at least 25 years.
After posttreatment management of histologic	Continued surveillance with HPV testing or cotesting at 3-year		Continued surveillance at 3- year intervals beyond 25 years is acceptable for as long as

HSIL, CIN 2, CIN 3, or AIS	intervals for at least 25 years are recommended after treatment		The patient's life expectancy and ability to be screened are not significantly compromised by serious health issues.
After Hysterectomy	No Screening		Applies to women without a cervix and without a history of CIN2 or a more severe diagnosis in the past 25 years or cervical cancer free
HPV	Follow age-specific recommendations (same as unvaccinated women)		

Reference

American Society for Colposcopy and Cervical Pathology. (2020). 2019 ASCCP risk-based management consensus guidelines for abnormal cervical cancer screening tests and cancer precursors. Journal of Lower Genital Tract Disease, 24(2). doi:10.1097/LGT.000000000000525

US Preventive Services Task Force. (2018). Screening for cervical cancer: US Preventive Services Task Force Recommendation Statement. Journal of the American Medical Association, 320(7). doi:10.1001/jama.2018.10897

What is Referral and Follow-up of Abnormal Findings?

The SNCHC FP shall refer and/or treat all clients with abnormal physical findings or laboratory results.

Clients of the SNCHC FP shall be provided with appropriate referral and/or treatment to expedite follow-up examination, treatment, and care.

Procedure

Follow-up procedure for Abnormal PAP Smear and/or Abnormal Physical Findings

- The clinician will document recommendations for follow-up and method of follow-up in the electronic health record.
- Client will be notified by method of choice as indicated in client record to make every attempt to assure client privacy.
- PAP log and electronic pap tracking will be utilized for pap follow up.
 - o Clients will be contacted with recommendations for follow-up.
 - o A minimum of two (2) attempts will be made to encourage compliance with recommended follow-up.

- o If no response or attempt for follow-up is made by the client, a certified letter will be sent, encouraging follow-up, and releasing the clinic from responsibility for adverse effects of not completing follow-up.
- Referrals for abnormal findings during an exam will have a ROI obtained from the patient requesting the report of findings and recommendations from physician.
- Staff follows contact algorithm protocol for PAP.

Colposcopy/provider referral

Indications for colposcopy/provider referral

- As indicated under Management of PAP Results
- Obvious or suspected cervical aberration.
- Clinician discretion
- What is preconception health?

SECTION 8

Special Conditions

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

Subjective Data

Medical history for females must include:

- Reproductive Life Plan
- Sexual Risk Assessment
- Reproductive History, including history of prior pregnancy outcomes and complications.
- Chronic Disease Management
- Gynecological History
- Environmental Exposures
- Medications
- Genetic Conditions
- Family History
- Intimate Partner Violence
- Social History/Risk Behaviors
- Immunizations
- Depression

Medical history of males must include:

- Reproductive Life Plan
- Sexual Health Assessment
- Past medical and surgical history that impairs reproductive health.
- Genetic Conditions
- History of reproductive failures, or conditions that can reduce sperm quality (obesity, diabetes, varicocele)
- Social History/Risk Behaviors
- Environmental Exposures

- Immunization Status
- Depression

Objective Data

Assessment must include:

- Height, weight, BMI (screen for obesity)
- Vital signs: temperature, heart rate, respiration rate, blood pressure, and pain
- BP (screen for hypertension)
 - o All clients screen yearly
 - o If BP < 120/80 -- screen yearly, continue yearly.
 - o If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit and if average BP > 140/90 recheck at next visit or in one (1) week and refer if sustained BP > 140/90.
- No physical exam is needed for preconception. Exams may be needed to evaluate problems raised by review of systems or complaints raised by the client.
- Provide education and counseling on healthy lifestyle.

Assessment

Laboratory testing must be recommended based on risk assessment. Options may include:

- Diabetes screening (for type 2 diabetes in asymptomatic male and female adults) with sustained BP (either treated or untreated) > 140/90.
- STD testing

Plan

Identify and modify biomedical, behavioral, and social risks to a woman's health or pregnancy outcomes through prevention and management.

- Develop an action plan on how to maintain and/or attain a healthy lifestyle to promote a positive planned pregnancy outcome in the future.
- Encourage the client to examine potential health risks (including chronic conditions) and make positive changes where indicated (see client education and referrals below).
- Facilitate contraceptive services if pregnancy is not desired.
- Provide client with listing of community resources.

Patient Education/Counseling

- Importance of regular preventive health care and chronic disease management.
- Some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (e.g., an obstetrician or midwife).
- Provide a daily supplement containing (400-800 mcg) of folic acid (or a prenatal vitamin).

- Avoid smoking, alcohol, and other drugs.
- Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish)
- Offer/Refer for any needed STD screening (including HIV)
- Refer for age-appropriate vaccinations, if indicated

Consultation/Referral

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

Resources

- CDC Show Your Love
- CDC Preconception Health
- CDC Vaccine Schedule
- FDA Fish in Pregnancy Advisory
- Reproductive Life Plan example
- Baby & Me, Tobacco Free
- Healthy Weight Program
- Folic Acid fact sheet

References

Centers for Disease Control and Prevention (CDC). (2016). Providing quality family planning services: Recommendations of the CDC and the U.S. Office of Population Affairs, 2015. MMWR, 65(9). https://www.cdc.gov/mmwr/volumes/65/wr/mm6509a3.htm

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

What is achieving pregnancy?

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

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

current standards of practice.

Subjective Data

History must include:

- Reproductive Life Plan (RLP)
 - o RLP may include:
 - When she/he/they want to get pregnant.
 - Length of time she/they have been trying to get pregnant.
 - History of pregnancies or infertility.
 - Partner involvement and support system issues. Support system issues may include family and community support, LGBTQ considerations, single parent considerations, cultural/familial considerations, financial concerns and awareness of other concerns or influences.
- Medical History
- Immunizations
- Medications
- Present infectious or chronic health conditions
- Genetic Conditions
- Environmental Exposures
- Social History/Risk Behaviors
- Sexual Health Assessment and Risk Assessment
- Mental Health

Include for Females:

- Reproductive History
- Obstetrical/gynecology History
- Family History
- Intimate Partner Violence

Include for Men:

- Past medical/surgical history that might impair reproductive health.
- Medical conditions associated with reproductive failure could reduce sperm quality.

Objective Data

Assessment must include:

- Height, weight, BMI (screen for obesity)
- BP (screen for hypertension)

- o All clients screen yearly
- o If BP < 120/80 -- screen yearly, continue yearly.
- o If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit and if average BP > 140/90 recheck at next visit or in one (1) week and refer if sustained BP > 140/90.
- No physical exam is needed for achieving pregnancy. Exams may be needed to evaluate problems raised by review of systems or complaints raised by the client.

Assessment

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

Lab testing may include, as indicated based on client medical and sexual history.

- STD testing
- Diabetic screening

Plan (also see Fertility Awareness)

While Fertility Awareness education is not required for clients who wish to achieve pregnancy, it can be very helpful (and interesting) for them to know:

- How pregnancy occurs, including the basics of male and female fertility, and
- When during the menstrual cycle a woman is most likely to get pregnant,
- Different ways to observe and keep track of naturally occurring signs of fertility,
- Tips for maximizing fertility while attempting conception, including how certain diet and lifestyle factors can enhance or reduce fertility.

Patient Education/Counseling (also see Preconception)

Remember to document counseling in the patient record.

- Importance of regular preventive health care and chronic disease management.
- Some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (e.g., an obstetrician or midwife).
- Encourage to take a daily supplement containing (400-800 mcg) of folic acid (or a prenatal vitamin) while attempting conception.
- Avoid smoking, alcohol, and other drugs.
- Nutritional counseling.
 - Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish)

- \circ Fertility rates are lower among women with BMI < 18.5 or > 25.
- o Limit caffeine to 200 mg per day.
- Offer/Refer for any needed STD screening (including HIV)
- Encourage males to avoid hot tubs.
- Many commercially available vaginal lubricants lower fertility rates and should be discouraged.
- Refer for age-appropriate vaccinations, if indicated
- Menstrual calendar, cycle beads, fertility awareness,
 - Providing education about peak days and signs of fertility (including the six (6) day interval ending on the day of ovulation that is characterized by slippery, stretchy cervical mucus and other possible signs of ovulation).
 - Advising that vaginal intercourse every one to two (1-2) days beginning soon after the menstrual period ends can increase the likelihood of becoming pregnant (women with regular menstrual cycles).
 - Educating on methods or devices designed to determine or predict the time of ovulation (e.g., over-the-counter ovulation kits, digital telephone applications, or cycle beads) should be discussed.

Consultation/Referral

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

Resources

- CDC Show Your Love
- CDC Preconception Health
- CDC Vaccine Schedule
- FDA Fish in Pregnancy Advisory
- Reproductive Life Plan example
- Baby & Me, Tobacco Free
- Healthy Weight Program
- Folic Acid fact sheet

References

Centers for Disease Control and Prevention (CDC). (2016). Providing quality family planning services: Recommendations of the CDC and the U.S. Office of Population Affairs, 2015. MMWR, 65(9). https://www.cdc.gov/mmwr/volumes/65/wr/mm6509a3.htm

What is pregnancy testing and counseling?

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

Standard

All clients receiving a pregnancy test will be offered information regarding their test results and, if pregnant, a referral to prenatal care.

Information may include the limitations of the test itself, prenatal care referral for a positive test result, and contraceptive choices, preconception counseling or infertility counseling for a negative test result.

Subjective Data

History may include:

- Menstrual History
 - o First day of last menstrual period
 - Was this a normal period, i.e., amount of flow, time of month?
 - o If not, when was last normal menstrual period?
 - Are periods usually regular? How often do periods come? How long do they last?
 Is the flow heavy, medium, scant?
 - o Has client missed a period(s) before?
- Symptoms of Pregnancy Other Than Amenorrhea
 - o Early
 - Breast tenderness
 - Nausea or vomiting
 - Urinary frequency
 - o Late
 - Enlargement of abdomen
 - Fetal movement
- Obstetrical History
 - Number of pregnancies (gravida)
 - Number of children (para)
 - Number of spontaneous abortions
 - Number of therapeutic abortions
 - History of ectopic pregnancies
- Birth Control History

- o Is the client consistently using a method of birth control? If not, how long has she been having unprotected intercourse?
- o If client is currently using birth control, what method, and is she using it correctly?
- o If client had been using birth control in the past, what method, when, and why did she discontinue its use?
- Sexual History
 - When was the last time that the client had intercourse?
- Determine if this is a planned/wanted pregnancy. How does she feel about being pregnant?

Objective Data

Physical exam, as indicated.

• Clients with a positive pregnancy test should be counseled to have a physical exam performed as early as possible.

Laboratory

- Urine HCG
- CT/GC testing
- Syphilis /HIV testing

Assessment and Plan

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

Counseling Results

Pregnant clients will be offered the opportunity to be provided information and counseling regarding each of the following options:

- Prenatal care and delivery
- Infant care, foster care, or adoption
- Pregnancy termination (42 CFR 59.5(a)(5)
- If requested to provide such information and counseling, staff at the service site will provide neutral, information and non-directive counseling on each of the options (except with respect to any option(s)about which the pregnant client indicates they do not wish to receive such information and counseling.)
- Referral for additional services (e.g., for prenatal care, delivery, infant care, foster care, adoption, or pregnancy termination) will be made upon request (42 CFR 59.5 (a) (5)

When a client requests a referral for pregnancy termination/abortion, they will be:

• Given a name, address, and telephone numbers. Staff will not take affirmative actions (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the client. (65 Fed. Reg., 41281 (July 3,2000)

• When a referral to another provider who might perform an abortion is medically indicated because of the client's condition or the condition of the fetus (such as where the woman's life would be endangered), such referral by a Title X project is not prohibited by section 1008 and is referred by 42 FR 59.5 (b) (1). The limitation on referrals does not apply in cases in which a referral is made for medical indications (65 Fed. Reg 41281) (July 3,2000)

Description of referral workflow for different types of referral (s)

- Patients opting to continue with a pregnancy will be referred for prenatal care. Referral will be generated through the electronic health record (EHR) system and assigned to the referral specialist. Encourage patients to start prenatal care and assess for any potentially teratogenic medications. Discuss alcohol, drug, and tobacco use.
- Patients wanting to terminate their pregnancy will be referred for abortion services. Provide name, address, and telephone number to patient. When asked, clinical staff may discuss differences between medication abortions and in-clinic abortions, review gestational age limits for each option.
- Undecided patients will be presented with the opportunity to discuss options and will be given information on a variety of options (continuation, termination and or adoption services).
- Staff will use clear, straightforward language, assess barriers to care and offer telehealth options (when appropriate).
- A referral packet that will include educational material, resources and up to date referral names and contact information will be provided to the patient during the visit.

Positive Results

- Positive test results
- Evaluate the client's support systems.
- Written referrals for primary or prenatal care must be given, referrals for counseling should be encouraged if deemed necessary by clinic staff.
- Workflow for sharing information about specific options:
- Staff will provide information consistent with the patient's choice.
- Information will be given without bias and sensitively offered to discuss all options when appropriate.
- Assess for reproductive coercion/intimate partner violence.
- Assessing support systems.
- Staff will use person-centered communication when sharing information about specific options.

Continuing the pregnancy

• 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.
- 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.
- Emphasize the dangers to the fetus of smoking, alcohol, and substance use (over the counter, prescription, and/or illicit drug use).
- Provide brochures regarding healthy behaviors during pregnancy and referrals to programs that help clients reduce or stop unhealthy behaviors.
- Review danger signs and symptoms of pregnancy.
- Counsel about the impact of diet on fetal development and appropriate nutrition information, particularly regarding folic acid supplementation.
- Counsel about the availability of prenatal care and give referral information. Give information about Medicaid eligibility if applicable. The client may also be referred to a Women, Infants and Children (WIC) provider if she meets the eligibility criteria for this program.
- Agencies are encouraged to follow-up with clients to determine if they are receiving prenatal care.
- Document counseling, referral and follow-up attempts in the client's record.
- Women should be counseled prenatally about the effective option of immediate postpartum LARC. Systems should be in place to ensure that women who desire LARC can receive it during a comprehensive postpartum visit if immediate postpartum placement is not provided.

Adoption

- Clinical service providers, including nurses, are permitted to provide nondirective pregnancy counseling and should be able to impart accurate information regarding adoption. This should include services offered by agencies, birth mother rights, a basic overview of the process, and appropriate referrals.
- Clients are made aware of adoption options including designated adoption and open adoption.
- Clients should understand that relinquishment is final and permanent, but that at any time up to the signing of the final orders, a woman can change her mind.
- Clients are made aware of counseling, financial assistance, housing, and other services that may be available through adoption agencies. In addition, the client is given appropriate referrals to reputable agencies that can provide more extensive, non-coercive counseling, as needed. Each family planning agency should explore the adoption agencies in its area and determine services provided and qualifications of staff (adoption agency professionals' education and professional credentials) and ensure coercion is not used.
- Basic prenatal education, discussion of pregnancy danger signs and referrals for prenatal care, Medicaid and Nurse Home Visitor program should always be offered as indicated

(see previous section).

Pregnancy Termination

If requested to provide such information and counseling, provide neutral, information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.

- Pregnant patients may be given a list of licensed, qualified, comprehensive primary health care providers including abortion providers.
- Basic information about the procedure may be provided by physicians or APRNs. As appropriate, explain medical abortion, vacuum aspiration, and amnio abortion procedures, time limitations, and consent requirements.
- Explain that there is no evidence of abortion affecting future conception.
- Emphasize that abortion is not a method of birth control and discuss methods of birth control that can be used afterwards.
- Document all test results, counseling, and follow-up in the client's record.

Negative Results

Negative Test Results

- Work with the client to determine other causes of delayed/missed menses including:
 - o Pregnancy, but with hormone levels too low for a positive test and/or testing done too soon after the last act of unprotected intercourse.
 - o Not pregnant, with delay or absence of ovulation.
 - Absence of menses due to medication, especially hormonal contraceptives, including Mirena IUD.
- If the client is not using birth control and desires pregnancy, the following information should be given:
 - Information about optimizing chances of conception (i.e., timing and frequency of intercourse).
 - The availability of infertility services, if client has been unable to conceive for one
 (1) year or more (six months if age > 35).
 - o The impact of diet on fetal development, specifically, folic acid supplementation.
 - o Preconception counseling
- If the client is not using birth control and does not want to become pregnant, provide the following information and services:
 - o Contraceptive services.
 - Offer emergency contraception and information about emergency contraception.
 - Optimally, offer same day contraceptive services. If this is not possible, the client

- should be encouraged to return for an express visit or comprehensive visit to obtain contraceptive services.
- If the client cannot be jump started on a hormonal method of birth control at the visit, an interim method of birth control should be made available (e.g., foam and condoms).
- o If the client desires to start a LARC method and the method cannot be provided on the day of her visit, offer, and provide a bridge method (e.g., OCs, DMPA, Ring, and Patch if no risk factors exist) until the client can return for a LARC method.

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

- Education, as appropriate, about her birth control method. Correct any misinformation leading to incorrect usage. If the client is not using her method correctly, consider providing emergency contraception as indicated.
- A referral to the family planning clinic as indicated. Reinforce the fact that all available information is confidential, and that the family planning clinic is available as a resource for emotional support, birth control information, and pregnancy determination.
- If appropriate, have the client return to clinic in two (2) weeks for a repeat pregnancy test if menses has not occurred or have her return ten to fourteen (10-14) days after the last act of unprotected intercourse.

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

Additional Information on Prohibition of Abortions

- Permissible abortion-related activities
 - o Information and counseling via a physician or APRN regarding options of pregnancy may be supplied to those clients who do not desire to continue their pregnancies and may be interested in obtaining abortions.
 - o Collection of statistical data and information regarding abortion is acceptable.
- Non-permissible activities related to abortion.
 - o "Pregnancy Counseling" in the sense of encouraging persons to obtain abortions is not allowed.
 - Abortion may not be the only option discussed.
 - o SNCHC staff may offer referral lists with provider types that offer prenatal services, family practice services, and abortion services.

What are basic infertility services?

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

Infertility visits to a family planning clinic focus on determining potential causes of the inability

to achieve pregnancy and making any needed referrals for specialist care.

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

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

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

Basic Infertility Care for Women

The infertility visit should focus on:

- Understanding the client's reproductive life plan and her difficulty in achieving pregnancy.
- The medical history must include:
 - Past Surgeries
 - o Previous Hospitalizations
 - Significant Illnesses or Injuries
 - Medical conditions associated with reproductive failure (e.g., thyroid disorders, hirsutism, or other endocrine disorders)
 - Childhood Disorders
 - o Cervical cancer screening results and any follow-up treatment
 - Medication
 - Allergies
 - Social History/Risk Behaviors
 - Family History of Reproductive Failures
 - Reproductive history (i.e., time trying to achieve pregnancy, coital frequency, and timing)
 - Level Of Fertility Awareness
 - Previous evaluation and treatment results; gravidity, parity, pregnancy outcome(s), and associated complications; age at menarche, cycle length and characteristics, and onset/severity of dysmenorrhea
 - Sexual History (pelvic inflammatory disease, history of/exposure to STDs)
 - Review of Systems (symptoms of thyroid disease, pelvic or abdominal pain, dyspareunia, galactorrhea, and hirsutism)

- A physical examination must be offered if clinically indicated:
 - o Height, weight, and BMI calculation
 - o Thyroid Examination (i.e., enlargement, nodule, or tenderness)
 - o CBE
 - o Signs Of Androgen Excess
 - A pelvic examination (i.e., pelvic, or abdominal tenderness, organ enlargement/mass; vaginal or cervical abnormality, secretions, discharge; uterine size, shape, position, and mobility; adnexal mass or tenderness; and cul-de-sac mass, tenderness, or nodularity).

Basic Infertility Care for Men

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

• Client's Reproductive Life Plan

Medical history must include:

- Reproductive History (methods of contraception, coital frequency, and timing; duration of infertility, prior fertility; sexual history; and gonadal toxin exposure, including heat).
- Medical illnesses (e.g., diabetes mellitus)
- Medications (prescription and nonprescription)
- Prior surgeries
- Past infections
- Allergies
- Lifestyle exposures
- Sexual Health Assessment. Including, female partners' history (PID, STDs, and problems with sexual dysfunction).

A physical examination must be offered if clinically indicated:

- 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 vas deferens and epididymis
- Presence of a varicocele
- Secondary sex characteristics

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

Plan

The following may be offered (female):

- If menstruating every twenty-one to thirty-five (21-35) days, may offer progesterone seven (7) days before the next menses.
- If age > 35, may offer or refer for cycle day three (3) FSH.
- If unexplained amenorrhea > 6 months, may offer or refer for FSH, Estradiol.
- If irregular cycling, may offer or refer for TSH, Prolactin.
- CT screening
- Obtain preconception labs (if have not been done in last year): (see Section 1: Protocol for Preconception Health).
- May offer Provera 5-10 mg tabs, 1 tab orally daily x 12 days if she has not had menses in last thirty-five (35) days and urine pregnancy test negative. Return to provider if no withdrawal bleeding within two (2) weeks after completing medication.

For male:

- CT screening
- Semen analysis

Infertility Counseling & Client Education

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

Prenatal vitamins or other sources of folic acid for three (3) months prior to conception (some clients may need more folate by prescription); consider condom use if client has not had three (3) months of folate supplementation.

Menstrual calendar, cycle beads.

Timed coitus every other day at least three (3) times starting two to three (2-3) days prior to ovulation. Ovulation may be calculated using prior cycle lengths, cycle beads or urine ovulation detection tests.

Nutritional counseling and recommend weight loss if client is overweight.

Consultation/Referral

• Clients (female and male) must be referred for further diagnosis and treatment if indicated or requested.

References

Centers for Disease Control and Prevention (CDC). (2016). Providing quality family planning services: Recommendations of the CDC and the U.S. Office of Population Affairs, 2015. MMWR, 65(9). https://www.cdc.gov/mmwr/volumes/65/wr/mm6509a3.htm

What are 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). Client confidentiality, including for adolescents, must be safeguarded. Adolescents are a priority population for Title X and adolescent services are addressed specifically in Providing Quality Family Planning Services (QFP) pgs. 38-40. Family planning programs should take steps to make services youth friendly. (QFP pg. 40)

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

Title X providers must provide counseling to adolescents on how to resist attempts to coerce them into engaging in sexual activities, sexual risk avoidance, contraception, safer sex practices, and encourage communication between the minor and the parents or guardians regarding seeking family planning services. In addition, Title X providers must offer confidential services to minors and adhere to all state mandated reporting laws regarding child abuse, neglect, and human trafficking.

While research shows most adolescent clients who come to a family planning program have been sexually active nine (9) months to one (1) year, some teenagers are seeking assistance in reaching a decision about sexual activity. Abstinence should be discussed with all teens as a valid and responsible option.

Family planning programs should take steps to make their services youth friendly.

Contraceptive Services

Adolescents seeking contraceptive services must be informed about all methods of contraception, including abstinence. Education should include an explanation that LARCs are a safe and effective method for women who have not been pregnant, including adolescents.

Adolescents should be offered information about basic female and male reproductive anatomy and physiology.

All counseling and education must be documented.

Confidentiality

Services provided to adolescents are confidential. Adolescents should be informed that contraceptive services are confidential and do not require parental consent.

Encourage family participation in the decision to seek family planning services; and, with respect to each minor patient, ensure that the records be maintained document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).

The family planning program recognizes the key role family members must play in teenagers' lives and ideally as primary sex educators.

Adolescents must understand that there are certain reportable situations (e.g., positive STI, child abuse, child molestation, sexual abuse, rape, or incest) that supersede confidentiality. See Section 5: Mandatory Reporting Policies and Procedures.

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 eighteen (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 eighteen to twenty-six (18-26) years old and covered under their parents' policy may contact their private insurance company and request that Explanation of Benefits (EOB) are only sent to the covered individual and not the policy holder.

Encouraging Family Involvement

Family involvement includes, but is not limited to, parental awareness of an adolescent's decision to seek family planning services, discussion of family planning options, and encouragement of responsible sexual decision-making. By integrating encouragement of family involvement into the family planning visit, the staff may help adolescents develop the interpersonal skills necessary to involve their families. Provide adolescents information about contraception, safer sex, abstinence, teen pregnancy, STIs, and HIV/AIDS. Adolescents often need to be introduced to the concept of responsible decision-making as regards their sexuality.

Title X providers must encourage communication between the minor and his or her parent(s) or guardian(s) about sexual and reproductive health and his or her decision to seek services, except that documentation of such encouragement is not to be required if the Title X provider has documented in the medical record:

That it suspects the minor to be the victim of child abuse or incest; and

That it has, consistent with, and if permitted or required by, applicable State or local law, reported the situation to the relevant authorities.

Motivating adolescents to involve family should include the following:

- 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.
- Stating it is the clinic policy to talk to all adolescents about family involvement.
- Asking whether the adolescent has ever talked to his/her parent about sex, birth control, or STIs.
- Being positive about the potential benefits of family involvement, while allaying any fears about requiring family involvement.
- 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.

Counseling on Resisting Sexual Coercion

Sexual coercion is the act of persuading or coercing a person, including an adolescent, into engaging in 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.

Education and counseling:

Information about sexual coercion must be provided to all new 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 pressure, intimidation, and threats; and it can be physical, emotional, psychological, or spiritual in nature.

Education should include, but not be limited to:

- an explanation of what coercion is.
- the right to refuse sex at any time without negative consequences.
- the right to set limits.
- 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.
- the importance of self-esteem and self-respect in avoiding coercive relationships.
- a list of any available community resources written information on the topic of sexual coercion that has been approved by your agency I & E committee.

Observe all relevant state laws and any legal obligations such as reporting child abuse, child molestation, sexual abuse, rape, incest, and human trafficking.

- Maintain records to demonstrate compliance with each of the requirements, including records which:
 - o Indicate the age of minor clients.
 - o Indicate the age of the minor client's sexual partners if such age is an element of a state notification law under which a report is required.
 - Document each notification or report made pursuant to such Nevada notification laws.

A preliminary screening will be conducted on any minor who presents with a STD, pregnancy, or any suspicion of abuse, to rule out victimization of a minor. Screenings are permitted to diagnose, test, and treat STDs.

Documentation on Education / Counseling

Education and counseling about family involvement and sexual coercion must be documented in the client chart. Document reasons family involvement counseling was not performed if it was not. Use of a check-off box is acceptable.

Documentation of abstinence counseling is required.

Document mandated state reporting and all compliance requirements. Please be sure that your education check-off list covers all the above topics.

References

Centers for Disease Control and Prevention (CDC). (2016). Providing quality family planning services: Recommendations of the CDC and the U.S. Office of Population Affairs, 2015. MMWR, 65(9). https://www.cdc.gov/mmwr/volumes/65/wr/mm6509a3.htm

What is breast cancer screening?

Breast cancer screening, a related preventive health service, is beneficial to reproductive health, is closely linked to family planning services, and is appropriate to deliver in the context of a family planning visit, but it does not contribute directly to achieving or preventing pregnancy. Providing QFP Clinics must stress the importance of and provide breast cancer screening as appropriate.

Prevention

ACOG recommendations, a screening clinical breast exam should be performed every one to three (1-3) years starting at twenty-five (25) years of age, and as indicated. ACOG recommends annual breast exams starting at forty (40) years of age.

Clients should be told about breast self-awareness and that any breast changes should be reported to their health care provider. The benefits and limitations of breast self-examination (BSE) should be explained. Clients choosing to do BSE should be given instruction and/or review on the technique for doing a BSE.

Screening Mammograms

Clients should be told about the benefits and limitations of routine mammograms.

- Under age 35
 - o Mammography is not indicated unless a woman has a first-degree relative diagnosed with breast cancer at age thirty-five (35) or younger. Clients should be referred for physician consultation and follow-up. There is evidence to support a mammogram ten (10) years before the age of diagnosis of the relative's breast cancer, but no sooner than the age of twenty-five (25) years.
- Age 35-39
 - Mammographic imaging should be limited to clients with a first-degree relative with a history of early breast cancer unless signs or symptoms are present. Clients with a personal history of breast cancer should receive a diagnostic mammogram, as well as other follow-up determined by the physician in charge of her breast cancer care.
- Women in their forties (40s) should have mammogram screening based on their individual risk and preferences. Mammography recommendations may also depend on physical exam findings or a radiologist's recommendations.
- Screening recommendations vary for women considered to be at average or high risk for breast cancer. Breast cancer risk can be calculated using a screening tool such as the Breast Cancer Risk Assessment Tool from the National Cancer Institute and based on the Gail Model http://www.cancer.gov/bcrisktool/Default.aspx
- See ACS recommendations for women at higher than-average risk for breast cancer https://www.cancer.org/cancer/types/breast-cancer/screening-tests-and-early-detection-of-breast-cancer.html
- National screening recommendations/guidelines

- ACOG recommends annual screening mammograms starting at age forty (40)
 http://www.acog.org/About-ACOG/News-Room/Statements/2015/ACOG-Statement-on-Recommendations-on-Breast-Cancer-Screening
- USPSTF screening mammogram recommendations (2016) for woman at average risk for breast cancer. See the following link for more in-depth information. http://www.uspreventiveservicestaskforce.org/BrowseRec/Search?s=breast+cancer
 - Women ages fifty to seventy-four (50-74) years -- biennial screening mammography (Grade B).
 - The decision to start screening mammography before the age of fifty (50) years should be an individual one.
 - Women who place a higher value on the potential harms may choose to begin biennial screening between the ages of forty to forty-nine (40-49).
 - Women with a parent, sibling or child with breast cancer are at higher risk for breast cancer and thus may benefit more than average risk women from beginning screening in their forties (40s).
- ACS Recommendations for woman at average risk for breast cancer (JAMA, 2015; 314(15): 1599-1614)
 - Women ages forty to forty-four (40-44) should have the choice to start annual screening mammograms if they wish to do so (qualified recommendation).
 - Women should start mammogram screening at age forty-five (45) (strong recommendation).
 - Women ages forty-five to fifty-four (45–54) should get a mammogram every year (qualified recommendation).
 - Women aged fifty-five (55) and older should switch to mammograms every two (2) years or have the choice to continue yearly screening (qualified recommendation).

Management

- Clients with a family history of first-degree relatives with premenopausal breast cancer should be encouraged to have a baseline evaluation with a specialist. These clients should be counseled regarding risks, benefits, and limitations of monthly BSE and the importance of annual clinical breast exams.
- Any breast pathology a lesion, mass, cyst, lump, breast pain, nipple discharge, change in appearance or deviation from the normal breast of an individual requires careful follow-up.
- Palpable mass/unusual or suspicious unilateral thickening:
 - O Document complete description of mass. The client must be given a written referral to a physician. In women under thirty (30) years of age with a well-circumscribed mass and no skin changes, it is acceptable to re-check the breast after the next menses for resolution of the mass.

- A negative mammogram in the presence of a palpable mass is NOT sufficient to rule out pathology.
- Follow-up contact, to document client compliance, should be made with the patient within two (2) weeks, according to agency tracking and follow-up guidelines.
- Nipple change or discharge:
 - o Women with skin breakdown on the nipple or areola or skin changes, such as dimpling, puckering, or peau d'orange (orange peel-like skin) should be referred.
 - o For women with nipple discharge, document the complete description and history, including use of any medications.
 - Bloody discharge, unilateral discharge, a palpable mass, or abnormal mammogram increases the suspicion of malignancy.
 - If spontaneous galactorrhea is present, serum prolactin levels/ thyroid function tests may be drawn.
 - Referral should be made either in house or to an outside provider for:
 - Galactorrhea with headaches, amenorrhea and/or involuntary infertility, or galactorrhea in the presence of an abnormal prolactin or thyroid function test result. Any non-milky discharge.
- Breast pain: If the clinical breast exam is negative, reassure the patient; suggest an analgesic and a supportive bra. A follow-up breast exam may be done in two (2) months. If conservative measures do not relieve symptoms, a referral is indicated. Any other undiagnosed, unilateral breast pain or non-cyclic breast pain should be referred.
- Clients may be followed on hormonal contraceptives or hormonal replacement therapy for up to three (3) months while the breast findings are investigated.
- Referrals for solitary breast masses are considered urgent, requiring follow-up within two (2) weeks.

Reference

Centers for Disease Control and Prevention (CDC). (2016). Providing quality family planning services: Recommendations of the CDC and the U.S. Office of Population Affairs, 2015. MMWR, 65(9). https://www.cdc.gov/mmwr/volumes/65/wr/mm6509a3.htm

What is menopause?

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

Menopause -- the cessation of ovarian ovulatory function evidenced by the cessation of menses for a period of one (1) year. Menopause may also be induced surgically (oophorectomy) or medically (chemotherapy or radiation treatment). The average age of menopause in the U.S. is

fifty-two (52). Smokers reach menopause 1.5 years earlier than non-smokers.

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

Perimenopausal / Menopausal Signs and Symptoms

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

- 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

Diagnosis

The diagnosis of menopause is usually made presumptively based on amenorrhea, at least twelve (12) months, and presence of menopausal symptoms in a woman at least forty (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.

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

- Artificial lubrication and/or vaginal moisturizers (e.g., Replens[®], Luvena[®]) can help alleviate vaginal symptoms and dyspareunia.
- Clinical trials generally demonstrate the 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.
- 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.

Counseling and Education

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

- Inquire about symptoms that may need to be addressed. Ask about sexual problems since the client may be uncomfortable bringing them up.
- Stress that the menopausal transition is an important time for women to implement behavioral changes to ensure healthy aging.
- 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 recommended daily allowance (RDA).
- Encourage regular exercise for heart health. Weight-bearing exercise also enhances bone density.
- Promote a healthy lifestyle.
- Maintain normal body weight.
- Stop smoking.
- Decrease alcohol consumption.
- 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, lipid, and diabetes screens.
- Discuss the importance of recommended immunizations, including a Tdap booster every ten (10) years, influenza immunization yearly, Shingrix shingles vaccine at age fifty (50), and pneumococcal vaccine at age sixty-five (65).
- Counsel regarding contraception if client has not experienced cessation of menses for one (1) year.
- Discuss issues pertinent to STI & HIV prevention as indicated.
- Refer to community and other supportive resources as needed for discussion of treatment options.
 - Assess client risk factors for osteoporosis, cardiovascular disease, breast cancer and other pertinent conditions.
 - o Menopause.org is an excellent internet site maintained by the North American Menopause Society providing information for both patients and providers.

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SECTION 9

Vaginal Infections and Sexually Transmitted Infections

What is Expedited Partner Therapy (EPT)?

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

Qualifications for expedited partner therapy

Nevada Physicians, advance practice registered nurses, and physician assistants are authorized to prescribe or personally furnish a drug for a sexual partner of a patient diagnosed with chlamydia, gonorrhea, or trichomoniasis, without examining the sexual partner, if all the following conditions are met:

- Partners to persons with a clinical diagnosis of chlamydia trachomatis or Neisseria gonorrhea, preferably confirmed with a laboratory test, who are unable or unlikely to seek a medical evaluation.
- Eligible Partners: Asymptomatic partners who were exposed within the previous sixty (60) days (or most recent sex partner if none in the previous sixty (60) days), and who are unable or unlikely to seek medical care.

The patient has been diagnosed with chlamydia, gonorrhea, or trichomoniasis; and

The patient reports to the prescriber that the sexual partner is unable or unlikely to be evaluated or treated by a health professional.

Prescription label

A prescription issued using EPT shall include the individual's name and address, if known. If the provider is unable to obtain the individual's name and address, the prescription shall include the patient's name and address and the words "expedited partner therapy" or the letters "EPT." A separate prescription should be issued for the patient's partner. This applies to paper and electronic prescriptions.

Number of prescriptions

A provider may prescribe or personally furnish a drug under this section for not more than a total of two individuals who are sexual partners of the provider's patient.

Requirements of the prescriber

For each drug prescribed or personally furnished under this section, the provider shall do all the following:

- Provide the patient with information concerning the drug for the purpose of sharing the information with the individual, including directions for use of the drug and any side effects, adverse reactions, or known contraindications associated with the drug.
- Recommend to the patient that the individual seek treatment from a health professional.
- Document all the following in the patient's record:

- o The name of the drug prescribed or furnished and its dosage.
- That information concerning the drug was provided to the patient for the purpose of sharing the information with the individual.
- o If known, any adverse reactions the individual experiences from treatment with the drug.

Providers contact the patient's partner.

Provider submits request to SNHD Pharmacy who will contact the individuals for whom they drug is intended.

- If the provider contacts the individual, the provider shall do all the following:
 - Inform the individual that the individual may have been exposed to chlamydia, gonorrhea, or trichomoniasis.
 - o Encourage the individual to seek treatment from a health professional.
 - Explain the treatment options available to the individual, including treatment
 with a prescription drug, directions for use of the drug, and any side effects,
 adverse reactions, or known contraindications associated with the drug.
 - o Document in the patient's record that the nurse contacted the individual.
- If the provider does not contact the individual, the provider shall document that fact in the patient's record.

Liability protections

Health care providers or pharmacists who dispense EPT in accordance with NAC 441A.200(2)(f) shall not be subject to liability or be deemed to have engaged in unprofessional conduct.

References

Nevada State Board of Pharmacy https://bop.nv.gov

What is Chlamydia?

Chlamydia is the most frequently reported STI in the U.S., and it is a leading cause of infertility in women. It is usually caused by sexual contact through oral, anal, or vaginal intercourse. Chlamydia infections are most diagnosed in persons aged fifteen to twenty-four (15-24) years.

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

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

Subjective Data/Symptoms

History may include:

- History of STDs, including chlamydia
- Sexual activity without condoms or condom failure
- Recent change in sex partner
- Partner with chlamydia symptoms
- Multiple sex partners or partner with concurrent partners

Symptoms may include:

- Dysuria
- Yellow mucopurulent discharge from urethra
- Vaginal discharge or abnormal vaginal bleeding
- Proctitis or rectal discharge
- Slow onset and progression of lower abdominal pain for women or unilateral pain and swelling of the scrotum for men.
- Fever
- No symptoms

Objective Data

Physical Findings:

- Women
 - Cervical friability
 - o Mucopurulent cervical, vaginal, or rectal discharge
 - Cervical motion tenderness
 - o Abdominal pain upon exam
- Men
 - o Mucopurulent urethral or rectal discharge
 - Urinary urgency or frequency
 - Scrotal swelling or epididymitis

Assessment

Lab testing:

NAAT

- First catch urine sample or collecting swab specimens
- Vaginal, cervical, pharyngeal, or rectal swab specimens done by clinical staff or selfcollected.

Persons who receive a diagnosis of chlamydia should also be tested for gonorrhea, syphilis, and HIV.

A pregnancy test for females with suspected chlamydial infection is recommended. Obtaining a pregnancy test helps with early diagnosis and guidance of treatment.

Because pregnancy is a contraindication for the use of doxycycline and ofloxacin, it is critical to obtain a pregnancy test before beginning treatment with these drugs.

Plan / Pharmacologic Treatment

Medication:

Single-dose, in-office treatment has been shown to improve compliance and confidentiality. Partner treatment is necessary to prevent reinfection from the same partner.

Recommended Regimens

- Doxycycline 100 mg orally twice a day for seven (7) days (preferred)
 OR
- Azithromycin 1 g orally in a single dose

Alternative Regimens

• Levofloxacin 500 mg orally once daily for seven (7) days

Partner notification:

Contact sexual partners within the previous sixty (60) days and most recent partner.

Management of sex partners:

- Sexual partner and any sexual contacts in the last sixty (60) days preceding onset of symptoms or diagnosis must be informed of possible infection and provide written materials about the importance of seeking evaluation for any symptoms suggestive of complications (e.g., testicular pain in men and pelvic or abdominal pain in women).
- Timely treatment of sex partners is essential for decreasing the risk for re-infection.
- Use EPT if necessary.
 - Use of EPT is not routinely recommended for MSM with chlamydia diagnoses because there is a high risk for coexisting infections among their partners.

Special Considerations

Pregnancy:

- Test of cure via NAAT three to four (3-4) weeks after treatment.
- If diagnosed with chlamydia in the first trimester, should be retested three (3) months after treatment.
- Women aged < 25 years and those at increased risk for chlamydia should be rescreened during the third trimester to prevent maternal postnatal complications and chlamydial infection in the infant.

- Doxycycline, ofloxacin, and levofloxacin are contraindicated in pregnancy.
- Treat with azithromycin 1 g orally in a single dose or amoxicillin 500 mg orally three (3) times a day for seven (7) days.

HIV infection:

• Persons who have chlamydia and HIV infection should receive the same treatment regimen as those who do not have HIV infection.

Patient Education/Counseling

- Implement behavioral counseling interventions to reduce the likelihood of acquiring additional STDs.
- Sexual contact should be avoided:
 - o for seven (7) days if take single-dose therapy, OR
 - o until completion of a seven (7) day regimen
 - o until all partners have been evaluated and/or treated
 - o and symptoms are resolved if they were present.
- Inform patients of long-term risks and complications, including the risk of infertility, of chlamydia and other STIs.
- Provide information to prevent reinfection. For example, proper use latex condoms.
- Chlamydia can be spread through unprotected vaginal, anal, or oral sex.
- Chlamydia can be spread to a baby during delivery.
- Chlamydia can be cured. Reinfection is common.
- Washing genitals, douching, or urinating after sex will not prevent chlamydia or other STDs.
- Provide medication information sheet, STD education and information, contraception information (if indicated), and offer STD testing.
- To prevent chlamydia, abstain from vaginal, oral, and anal sex or be in a long-term, mutually monogamous relationship with a partner who has been tested and is known to be uninfected.

Follow-up

- Test-of-cure to detect therapeutic failure is not advised for persons treated with the recommended or alterative regimens, unless therapeutic adherence is in question, symptoms persist, or reinfection is suspected.
- Men and women who have been treated for chlamydia should be retested approximately three (3) months after treatment.
- If retesting at three (3) months is not possible, clinicians should retest whenever persons next present for medical care in the twelve (12) month period following initial treatment.

Consultation/Referral

- Refer pregnant patients to primary or prenatal care.
- Refer clients with multiple incidents of reinfections, when appropriate.
- Offer PrEP and PEP services.

Screening

- Recommendations
 - o Annual screening of all sexually active women aged < 25.
 - o All pregnant women < 25 and older pregnant women who are at increased risk.
 - O Annual screening of women ≥ 25 that are at an increased risk for infection (e.g., new sex partner, more > 1 sex partner, sex partner with concurrent partners, or sex partner with a STI).
 - The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for chlamydia and gonorrhea in men.
 - The CDC recommends that clinicians consider screening for chlamydia in sexually active young men in high-prevalence settings.
 - o CDC recommends annual screening for chlamydia and gonorrhea in MSM, based on exposure history, with more frequent screening in populations at highest risk.

Reporting

• Mandated state reporting is required.

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What is Gonorrhea?

Gonorrhea is the second most common reportable sexually transmitted disease, and it has the highest prevalence rates among persons > 25 years. Neisseria gonorrhoeae is a gram-negative

diplococcal bacterium and causes gonorrhea, which is a purulent infection of mucus membrane surfaces. It may be spread through sexual contact or childbirth. According to the CDC, patients diagnosed with gonorrhea should also be treated for chlamydia.

Gonorrhea typically presents as urethritis, cervicitis, proctitis, salpingitis, pharyngitis or asymptomatic. Complications may include pelvic inflammatory disease, ectopic pregnancy, infertility, and chronic pelvic in women; prostatitis, epididymitis and proctitis in men; conjunctivitis or pharyngeal infection in men and women. Rarely, gonorrhea may also invade the bloodstream leading to disseminated gonococcal infection, which is characterized by arthritis and skin lesions. If gonorrhea is transmitted to the newborn, the neonatal conjunctiva, pharynx, respiratory tract, or anal canal may become infected and there is a risk of corneal perforation and blindness.

Subjective Data/Symptoms

History may include:

- Inconsistent or incorrect condom use
- Sexual contact outside of a mutually monogamous relationship
- Previous or coexisting STI
- Exchanging sex for money or drugs
- New or multiple sex partners
- Living in an urban area where gonorrhea prevalence is high.

Symptoms may include:

- Women
 - o Thin, purulent, mildly odorous vaginal discharge
 - o Dysuria
 - o Intermenstrual bleeding
 - Lower abdominal pain
 - o Dyspareunia
- Men
 - o Burning with urination with serous discharge
 - o Discharge that becomes more profuse, purulent, may be tinged with blood.
 - o Decreased or abnormal urine stream
 - Unilateral epididymitis with urethral exudate
 - o Rectal pain, pruritus, discharge, or tenesmus
- Disseminated gonococcal infection.
 - Joint or tendon pain
 - Rash or lesions

Objective Data

Physical Findings:

- Women
 - o Purulent or mucopurulent vaginal, urethral, or cervical discharge
 - Cervical friability
 - o Cervical motion tenderness upon exam
 - Abdominal pain upon exam
- Men
 - Mucopurulent or purulent urethral discharge
 - o Epididymitis
 - o Penile edema
 - o Urethral stricture

Assessment

Lab testing:

- NAAT can be used for
 - o endocervical swabs, vaginal swabs, urethral swabs (men), and urine (from both men and women)
 - o Collect specimens from anatomic sites of exposure for most accurate detection.
- Culture is available for detection of rectal, or opharyngeal, and conjunctival gonococcal infection.
- Should have other STD testing (chlamydia, syphilis, HIV) and, if female, a pregnancy test to guide further care and determination of which medications to use.

Plan / Pharmacologic Treatment

Medication:

Uncomplicated Gonorrhea of the Cervix, Urethra, Rectum and Pharynx

Recommended Regimens – for any anatomic site

Ceftriaxone 500 mg in a single intramuscular dose for persons weighing < 150 kg.

Ceftriaxone 1 g in a single intramuscular dose for persons weighing ≥ 150 kg.

*If chlamydial infection has not been excluded, treat for chlamydia with doxycycline 100 mg orally twice daily for seven (7) days

Alternative regimens:

If ceftriaxone is not available:

Gentamicin 240 mg in a single intramuscular dose, PLUS

Azithromycin 2 g orally in a single dose, OR

Cefixime 800 mg in a single oral dose

*If chlamydial infection has not been excluded, treat for chlamydia with doxycycline 100 mg orally twice daily for seven (7) days.

Partner notification:

- Sexual partner and any sexual contacts in the previous sixty (60) days preceding onset of symptoms and/or gonorrhea diagnosis must be informed and provided with written materials about the importance of seeking evaluation for any symptoms suggestive of complications.
- May use expedited partner treatment (EPT).

Management of sex partners:

- Persons having sexual contact with the infected patient within the sixty (60) days preceding onset of symptoms or gonorrhea diagnosis should be referred for evaluation, testing, and presumptive dual treatment.
- If the patient's last potential sexual exposure was > 60 days prior to onset of symptoms or diagnosis, the most recent sex partner should be treated.
- To avoid reinfection, sex partners should be instructed to abstain from unprotected sexual intercourse for seven (7) days after they and their sexual partner(s) have completed treatment.
- If there are concerns the sex partner will not seek prompt clinical evaluation, and based on the current CDC recommendations, the partner treatment would be a single dose of 800 mg oral cefixime plus oral doxycycline 100 mg 2 times/day for 7 days if chlamydia cannot be excluded. This can be delivered to the partner by the patient, a disease investigation specialist, or a collaborating pharmacy as permitted by law.

Special Considerations

Allergies:

- While allergic reactions to first generation cephalosporins occur in < 2.5% of persons with a history of penicillin allergy and are uncommon with third generation cephalosporins (e.g., ceftriaxone and Cefixime), use of ceftriaxone or cefixime is contraindicated in persons with a history of an IgE-mediated penicillin allergy.
- The following alternative treatment regimen may be considered when the patient has a history of such an allergy.
 - o <u>If patient is allergic to penicillin</u>:
 - Gentamicin 240 mg in a single intramuscular dose PLUS
 - Azithromycin 2 g orally in a single dose
- Providers treating people with cephalosporin or IgE-mediated penicillin allergy should consult an infectious-disease specialist.

Pregnancy:

• Pregnant women should be treated with the recommended dual therapy if CT has been

excluded.

- Pregnant women should not be treated with any fluoroquinolone or any tetracycline drug.
- Pregnant women who cannot tolerate a cephalosporin should be evaluated by an infectious disease specialist.

HIV infection:

• Should have gonorrhea screening at initial evaluation and at least annually thereafter. Collect samples from the anatomic sites of sexual exposure.

Patient Education/Counseling

- Abstain from sexual activity for seven (7) days after treatment and until all sex partners are adequately treated (seven (7) days after receiving treatment and resolution of symptoms if present).
- Inform patients of long-term risks and the importance of testing and treatment.
- Provide medication information sheet, STD education and information, contraception information (if indicated), and offer STD testing.
- Gonorrhea is spread via oral, vaginal, and anal sex, as well as from mother to baby during childbirth.
- Persons with gonorrhea are more likely to transmit and acquire HIV.
- Discuss prevention strategies such as abstinence, mutual monogamy with an uninfected partner, use of latex condoms, and limited the number of sex partner.
- Implement behavioral counseling interventions to reduce the likelihood of acquiring additional STDs.
- Offer PrEP and PEP services.

Follow-up

- A test-of-cure is not needed for persons who receive a diagnosis of uncomplicated urogenital or rectal gonorrhea who are treated with any of the recommended or alternative regimens.
- A test-of-cure is recommended for patients with pharyngeal gonorrhea.
- For all patients with gonorrhea, repeat testing should occur approximately three (3) months after treatment to identify recent reinfection.

Consultation/Referral

- Refer pregnant patients to primary or prenatal care.
- Refer clients with multiple reinfections or persistent symptoms.
- Refer patients with penicillin allergy to infectious disease specialist.

Screening

Annual screening for gonorrhea is recommended for all sexually active women aged.

- < 25 years and for older women at increased risk for infection (e.g., those who have a new sex partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has an STI).
- Pregnant women should be screened for gonorrhea at the first prenatal visit for women > 25 years or older if at increased risk for gonorrhea.
- Subgroups of MSM are at high risk for gonorrhea infection and should be screened at sites of exposure.

Reporting

• Mandated state reporting is required.

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Centers for Disease Control. (2021). Gonococcal infections. 2021 STD Treatment Guidelines. https://www.cdc.gov/std/treatment-guidelines/gonorrhea.htm

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What is Pelvic Inflammatory Disease (PID)?

PID is an infectious and inflammatory disorder of the upper female genital tract, including the uterus, fallopian tubes, and adjacent pelvic structures. PID can spread into the abdomen and perihepatic structures. Sexually transmitted organisms, especially N. gonorrhea and C. trachomatis, are implicated in many cases, but PID may also be caused by vaginal flora or cytomegalovirus (CMV), M. hominis.

U. urealyticum, and M. genitalium.

Many cases of PID go unrecognized. Some patients have few or no symptoms whereas others will present with acute, serious illness. There are several important differentials to consider including appendicitis, cervicitis, urinary tract infection, endometriosis, ectopic pregnancy, ovarian torsion, and adnexal tumors. Providers should use a low threshold for PID diagnosis due to the risk of infertility and damage to the reproductive health of women.

Subjective Data/Symptoms

History may include:

- Multiple sex partners
- Lives in an area with high prevalence of STDs
- Prior or current STDs
- Partner with STDs, current or present
- Age younger than twenty-five (25) years
- The age of first sexual intercourse was younger than sixteen (16) years.
- Use of non-barrier contraception

Symptoms may include:

- Lower abdominal pain
- Abnormal vaginal discharge
- Abnormal vaginal bleeding
- Dyspareunia
- Fever
- Dysuria

Objective Data

Physical Findings:

- Uterine, adnexal, or cervical motion tenderness upon exam
- Cervical friability
- Mucopurulent cervical discharge

Assessment

Presumptive treatment for PID should be initiated in sexually active young women and other women at risk for STDs if they are experiencing pelvic, or

lower abdominal pain, if no cause for the illness other than PID can be identified, and if <u>one (1) or</u> more of the following minimum clinical criteria are present of pelvic examination:

- Cervical motion tenderness
- Uterine tenderness
- Adnexal tenderness

Additional criteria to enhance the specificity of the minimum clinical criteria and support a diagnosis of PID:

- oral temperature > 101°F (> 38.3°C)
- abnormal cervical mucopurulent discharge or cervical friability
- presence of abundant numbers of white blood cell count (WBC) on saline microscopy of vaginal fluid

- elevated erythrocyte sedimentation rate
- elevated C-reactive protein
- laboratory documentation of cervical infection with N. gonorrhoeae or C. trachomatis.

Lab testing:

- Wet prep to look for white blood cells and other infections (e.g., bacterial vaginosis [BV], trichomoniasis)
- A pregnancy test for women of childbearing age who are presenting with lower abdominal pain to rule out ectopic pregnancy.
- Test for HIV
- Use NAAT to test for gonorrhea and chlamydia.

Plan / Pharmacologic Treatment

Medication:

For mild-to-moderately severe acute PID who do not fit any of the hospitalization criteria listed below

- Recommended Intramuscular/Oral Regimens
 - o Ceftriaxone 500 mg IM in a single dose PLUS
 - o Doxycycline 100 mg orally twice a day for fourteen (14) days WITH
 - o Metronidazole 500 mg orally twice a day for fourteen (14) days

OR

• Cefoxitin 2 g IM in a single dose and Probenecid, 1 g orally administered concurrently in a single dose.

PLUS

- Doxycycline 100 mg orally twice a day for fourteen (14) days WITH or WITHOUT
- o Metronidazole 500 mg orally twice a day for fourteen (14) days

OR

Other parenteral third-generation cephalosporin (e.g., ceftizoxime or cefotaxime)

PLUS

- o Doxycycline 100 mg orally twice a day for fourteen (14) days WITH
- o Metronidazole 500 mg orally twice a day for fourteen (14) days

The recommended third generation cephalosporins are limited in the coverage of anaerobes. Therefore, until it is known that extended anaerobic coverage is not important for treatment of acute PID, the addition of metronidazole to treatment regimens with third generation cephalosporins should be considered (Source: Walker CK, Wiesenfeld HC. Antibiotic therapy for acute pelvic inflammatory disease: the 2021 CDC Sexually Transmitted Diseases Treatment

Guidelines. Clin Infect Dis 2021;28[Supp 1]: S29–36).

Management of sex partners:

- Persons who have had sexual contact with a woman with PID during the sixty (60) days preceding the onset of symptoms should be evaluated, tested, and presumptively treated for chlamydia and gonorrhea.
- If the woman's last sexual intercourse was > 60 days before the onset of symptoms or diagnosis, the most recent sex partner should be treated.
- EPT should be used if a partner is likely to delay or not seek care for chlamydia and/or gonorrhea.
- Partners should abstain from sexual intercourse until they and their partners have been adequately treated.

Special Considerations

Allergies:

• If patient has a doxycycline allergy, an alternative regimen is ceftriaxone 250 mg IM in a single dose PLUS azithromycin 1 gram orally once a week for two (2) weeks WITH or WITHOUT metronidazole 500 mg orally twice a day for fourteen (14) days.

Pregnancy:

- Pregnant women with suspected PID should be emergently referred to the prenatal provider and sent to the hospital for parenteral treatment.
- There is a high risk of maternal morbidity and preterm delivery with PID in pregnancy.

HIV infection:

• Manage a patient with HIV the same as a person without HIV.

Intrauterine Contraceptive Devices:

- There is a slight risk of PID associated with IUDs in the first three weeks after insertion.
- If a patient has an IUD and PID, the IUD does not need to be removed. However, if there is no improvement in PID symptoms after forty-eight to seventy-two (48-72) hours of therapy, then providers should consider removing the IUD.

Patient Education/Counseling

- Abstain from sexual intercourse until therapy is completed, symptoms have resolved, and sex partners have been adequately treated.
- Information regarding reducing risk factors for PID and STDs, such as limiting the number of sex partners, avoiding unsafe sex practices, and routinely using appropriate barrier protection.
- Adolescents are at an increased risk for PID and should be advised to delay the onset of sexual activity until age sixteen (16) or older.
- PID can be caused by infections that are not sexually transmitted, such as BV.

- Possible long-term effects of PID are infertility, ectopic pregnancy, and chronic pelvic pain.
- Implement behavioral counseling interventions to reduce the likelihood of acquiring additional STDs.

Follow-up

Follow-up appointment in three (3) days.

If no clinical improvement within seventy-two (72) hours of therapy, then hospitalization, assessment of the antimicrobial regimen, and additional diagnostics are recommended.

Women with a diagnosis of chlamydial or gonococcal PID should be retested in three (3) months, regardless of whether their sex partners were treated. If retesting at three (3) months is not possible, these women should be retested whenever they next present for medical care in the twelve (12) months following treatment.

Consultation/Referral

- Hospitalization is necessary for any of the following criteria:
 - o Surgical emergencies (e.g., appendicitis) cannot be excluded.
 - Tubo-ovarian abscess
 - Pregnancy
 - o Severe illness, nausea and vomiting, or high fever
 - o Unable to follow or tolerate an outpatient oral regimen.
 - o No clinical response to oral antimicrobial therapy within seventy-two (72) hours

Screening

• Screening for lower genital tract chlamydial and gonorrhea infections in younger and high-risk populations is recommended to reduce the incidence of PID. Asymptomatic disease should be treated.

Reporting

- No state mandated reporting is required for PID.
- Gonorrhea and chlamydia infections must be reported.

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What is Genital Herpes Simplex Virus (HSV)?

Genital herpes is a chronic, life-long viral infection. Genital herpes is usually caused by HSV-2, but it can also be caused by HSV-1. HSV is transmitted through direct contact (e.g., kissing, oral sex, sexual contact) from a person who is actively shedding the virus. Most cases of recurrent genital herpes are caused by HSV-2; however, an increasing proportion of anogenital herpetic infections have been attributed to HSV-1 infection, which is especially prominent amount young women and MSM. Lesion location is not necessarily indicative of viral type.

Up to eighty percent (80%) of HSV infections are asymptomatic. Most persons infected with HSV-2 have not had the condition diagnosed. Persons with mild or unrecognized infections spread the infection unknowingly during intermittent periods of viral shedding. HSV management should address the chronic nature of the disease and not only the acute episode.

Subjective Data/Symptoms

History may include:

- Prior HSV infection
- Partner with past or present HSV symptoms or STDs
- Recent change in sex partners
- Multiple partners or partner with multiple partners
- Lack of condom use (STD protection)

Symptoms may include:

- Fever, headache, malaise, and myalgia
- Local symptoms include pain, itching, dysuria, vaginal and urethral discharge, and tender lymphadenopathy.
- Prodrome of tenderness, pain, and burning at the site of eruption

Objective Data

Physical Findings:

Primary genital herpes infection

- Herpetic vesicles may appear on external genitalia, labia majora, labia minora, vaginal vestibule, and introitus of women or glans penis, the prepuce, the shaft of the penis, and sometimes on the scrotum, thighs, and buttocks of men.
- Ulcers or pustules or encrusted pustules
- Vaginal mucosa that is inflamed and edematous.
- Cervix with ulcerative or necrotic cervical mucosa
- Mucoid discharge in male urethra

Recurrent genital herpes infection

- In women, the vesicles are found on the labia majora, labia minora, or perineum.
- In men, one or more patches of grouped vesicles on the shaft of the penis, prepuce, or glans.

Assessment

Lab testing:

- Cell culture or polymerase chain reaction (PCR) testing
 - o Cultures and PCR tests should be typed to determine which type of HSV is causing the infection.
 - o Failure to detect HSV, especially in the absence of active lesions, does not indicate an absence of HSV because viral shedding is intermittent.
- Accurate type-specific HSV serologic assays are based on the HSV-specific glycoprotein G2 (HSV-2) and glycoprotein G1 (HSV-1).
 - o Providers should only request type-specific glycoprotein G (gG) based serologic assays when serology is performed for their patients.
 - o Examples: HerpeSelect ELISA, HerpeSelect immunoblot, POCkit- HSV-2
- Additional STD testing

Plan / Pharmacologic Treatment

Medication:

First clinical episode of genital herpes

- Recommended Regimens*
 - Acyclovir 400 mg orally three (3) times a day for seven to ten (7–10) days
 OR
 - Acyclovir 200 mg orally five (5) times a day for seven to ten (7–10) days
 OR
 - Valacyclovir 1 g orally twice a day for seven to ten (7–10) days OR
 - o Famciclovir 250 mg orally three times a day for seven to ten (7–10) days
 - o Treatment can be extended if healing is incomplete after ten (10) days of therapy.

Established HSV-2 infections – Suppressive therapy for recurrent genital herpes.

- Recommended Regimens
 - Acyclovir 400 mg orally twice a day
 OR
 - Valacyclovir 500 mg orally once a day*

OR

Valacyclovir 1 g orally once a day
 OR

o Famiciclovir 250 mg orally twice a day

Valacyclovir 500 mg once a day might be less effective than other valacyclovir or acyclovir dosing regimens in persons who have very frequent recurrences (i.e., ≥ 10 episodes per year).

Established HSV-2 infections – Episodic therapy for recurrent genital herpes.

• Recommended Regimens

- Acyclovir 400 mg orally three (3) times a day for five (5) days¹
 OR
- Acyclovir 800 mg orally twice a day for five (5) days
 OR
- Acyclovir 800 mg orally three (3) times a day for two (2) days
 OR
- OR Valacyclovir 500 mg orally twice a day for three (3) days
- Valacyclovir 1 g orally once a day for five (5) days
 OR
- Famciclovir 125 mg orally twice daily for five (5) days
 OR
- o Famciclovir 1 gram orally twice daily for one (1) day OR
- o Famciclovir 500 mg once, followed by 250 mg twice daily for two (2) days.

Management of sex partners:

- Symptomatic sex partners should be evaluated and treated in the same manner as patients who have genital herpes.
- Asymptomatic sex partners of patients who have genital herpes should be questioned concerning histories of genital lesions and offered type-specific serologic testing for HSV infection.

Special Considerations

Allergies:

• Allergic and other adverse reactions to oral acyclovir, valacyclovir, and famciclovir are

¹ Per the CDC, this regimen is effective but not recommended due to frequency of dosing

rare.

• Can be desensitized to acyclovir.

Pregnancy:

- Pregnant women without HSV should abstain from having sex with a partner who is known to have or suspected to have HSV during the third trimester.
- The risk of spreading HSV to the neonate is high if HSV is acquired late in the pregnancy but low if she has recurrent HSV or acquired HSV in the first half of pregnancy.
- All pregnant women should be asked if they have a history of genital herpes.
- Suppressive therapy is recommended starting at thirty-six (36) weeks gestation for pregnant women with known HSV.

HIV infection:

- Immunocompromised patients can have prolonged or severe episodes of genital, perianal, or oral herpes.
- Lesions caused by HSV are common among persons with HIV infection and might be severe, painful, and atypical.
- HSV shedding is increased in persons with HIV infection. Although antiretroviral therapy reduces the severity and frequency of symptomatic genital herpes, frequent subclinical shedding still occurs.

Recommended Regimens for Daily Suppressive Therapy in Persons with HIV

- Acyclovir 400–800 mg orally twice to three (3) times a day
 OR
- Valacyclovir 500 mg orally twice a day OR
- Famciclovir 500 mg orally twice a day

Recommended Regimens for Episodic Infection in Persons with HIV

- Acyclovir 400 mg orally three (3) times a day for seven to ten (7–10) days
 OR
- Valacyclovir 1 g orally twice a day for five to ten (5–10) days
 OR
- Famciclovir 250 mg orally twice a day for five to ten (5-10) days

Patient Education/Counseling

The following topics should be discussed when counseling persons with genital HSV infection:

• the natural history of the disease, with emphasis on the potential for recurrent episodes, asymptomatic viral shedding, and the attendant risks of sexual transmission

- the effectiveness of suppressive therapy for persons experiencing a first episode of genital herpes in preventing symptomatic recurrent episodes
- use of episodic therapy to shorten the duration of recurrent episodes.
- importance of informing current sex partners about genital herpes and informing future partners before initiating a sexual relationship
- potential for sexual transmission of HSV to occur during asymptomatic periods.
- importance of abstaining from sexual activity with uninfected partners when lesions or prodromal symptoms are present.
- effectiveness of daily use of valacyclovir in reducing risk for transmission of HSV-2, and the lack of effectiveness of episodic or suppressive therapy in persons with HIV.
- and HSV infection in reducing risk for transmission to partners who might be at risk for HSV-2 acquisition.
- effectiveness of male latex condoms, which when used consistently and correctly can reduce (but not eliminate) the risk for genital herpes transmission.
- HSV infection in the absence of symptoms
- risk for neonatal HSV infection.
- increased risk for HIV acquisition among HSV-2 seropositive persons who are exposed to HIV.
- HSV does not cause cancer.
- Implement behavioral counseling interventions to reduce the likelihood of acquiring additional STDs.

Follow-up

• As needed.

Consultation/Referral

- Pregnant patients with HSV should be referred to a prenatal care provider.
 - Pregnant women who acquire HSV infection during late pregnancy should be referred to maternal-fetal medicine and infectious disease providers.
- May refer outpatients that are immunocompromised.
- Patients with antiviral resistant HSV need an infection disease specialist.
- Severe cases may need IV medication and hospitalization.

Screening

- Screening for HSV-1 and HSV-2 in the general population is not indicated.
- HSV serologic testing should be considered for persons presenting for an STD evaluation (especially for those persons with multiple sex partners), persons with HIV infection, and MSM at increased risk for HIV acquisition.

Reporting

• Mandated state reporting is not required.

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What is syphilis?

Acquired syphilis is typically a sexually transmitted disease caused by Treponema pallidum. Syphilis is systemic and has an incubation time of ten to ninety (10-90) days. It is classified into four (4) stages: primary, secondary, tertiary, and latent. If syphilis is treated during the primary or secondary stages, the prognosis is good.

Subjective Data/Symptoms

History may include:

- History of syphilis
- Lack of STD protection
- Recent change in sex partner
- Partner that has syphilis or related symptoms
- Multiple partners or partners with multiple partners
- Illicit drug use
- Commercial sex work or coerced sex
- MSM
- HIV⁺
- Being pregnant

Symptoms may include:

- Painless lesion (chancre)
- Rash on palms of hands, soles of feet, and in mouth
- Malaise
- Fever
- Myalgias and/or arthralgias

• Lymphadenopathy

Objective Data

Physical Findings:

- Primary syphilis
 - o Ulcer or chancre at the infection site
 - O The lesion has a punched-out base and rolled edges.
- Secondary syphilis
 - Skin rash
 - Mucocutaneous lesions
 - o Lymphadenopathy
 - o Condylomata lata (gray-white lesions in warm, moist sites)
 - Alopecia
- Tertiary syphilis
 - Cardiac lesions which can cause aortitis and aortic aneurysms, aortic valvular insufficiency, and narrowing of the coronary ostia which could potentially cause heart failure and myocardial infarction.
 - Gummatous lesions
 - Tabes dorsalis
 - o General paresis
- Latent syphilis
 - o No clinical manifestations but can be detected with serologic testing.
- Neurologic manifestations of syphilis
 - Early (first few months or years) cranial nerve dysfunction, meningitis, stroke,
 acute altered mental status, and auditory or ophthalmic abnormalities
 - Late (ten to thirty (10-30) years after infection) tabes dorsalis (loss of pain sensation, loss of peripheral reflexes, impairment of vibration and position senses, progressive ataxia, bladder incontinence, loss of sexual function, lancinating pain, charcot joints, trophic ulcers, paralysis) and general paresis (dementia related psychiatric symptoms often manifesting in depression, confusion, and severe impairment of memory and judgement).

Assessment

Lab testing:

- A presumptive diagnosis of syphilis requires two (2) tests:
 - o Non-treponemal tests: venereal disease research laboratory (VDRL) or rapid plasma regain (RPR)

- A person with a positive non-treponemal test needs to have the treponemal test to confirm the syphilis diagnosis.
- Treponemal tests: fluorescent treponemal antibody absorption (FTA-ABS) tests, treponema pallidum particle agglutination (TP-PA) assay, various enzyme immunoassay (EIA), or chemiluminescence immunoassay
- A definitive method to diagnosis syphilis is via darkfield examination of lesion exudate or tissue.
- Additional STD and HIV testing is recommended.

Plan / Pharmacologic Treatment

Family Planning Clinics are recommended to consult with the medical director and/or communicable disease director to collaboratively diagnose, treat, and care for clients with syphilis.

Medication:

- Recommended Regimen for Adults with Primary or Secondary syphilis
 - o Benzathine penicillin G 2.4 million units IM in a single dose
- Recommended Regimen for Adults with Latent syphilis
 - Early Latent Syphilis = Benzathine penicillin G 2.4 million units IM in a single dose
 - Late Latent Syphilis or Latent Syphilis of Unknown Duration = Benzathine penicillin G 7.2 million units total, administered as three (3) doses of 2.4 million units IM each at one (1) week intervals
- Recommended Regimen for Adults with Tertiary syphilis
 - Tertiary Syphilis with Normal cerebrospinal fluid (CSF) examination =
 Benzathine penicillin G 7.2 million units total, administered as three (3) doses of
 2.4 million units IM each at one (1) week intervals

Management of sex partners:

- Sexual transmission of T. pallidum is thought to occur only when mucocutaneous syphilitic lesions are present. Such manifestations are uncommon after the first year of infection. Persons exposed sexually to a person who has primary, secondary, or early latent syphilis should be evaluated clinically and serologically and treated according to the following recommendations:
 - Persons who have had sexual contact with a person who receives a diagnosis of primary, secondary, or early latent syphilis within ninety (90) days preceding the diagnosis should be treated presumptively for early syphilis, even if serologic test results are negative.
 - Persons who have had sexual contact with a person who receives a diagnosis of primary, secondary, or early latent syphilis > 90 days before the diagnosis should be treated presumptively for early syphilis if serologic test results are not immediately available and the opportunity for follow-up is uncertain. If serologic

- tests are negative, no treatment is needed. If serologic tests are positive, treatment should be based on clinical and serologic evaluation and stage of syphilis.
- In some areas or populations with high rates of syphilis, health departments recommend notification and presumptive treatment of sex partners of persons with late latent syphilis who have high nontreponemal serologic test titers (i.e., >1:32), because high titers might be indicative of early syphilis. These partners should be managed as if the index case had early syphilis.
- Long-term sex partners of persons who have late latent syphilis should be evaluated clinically and serologically for syphilis and treated based on the evaluation's findings.
- The following sex partners of persons with syphilis are considered at risk for infection and should be confidentially notified of the exposure and need for evaluation: partners who have had sexual contact within.
 - Three (3) months plus the duration of symptoms for persons who receive a diagnosis of primary syphilis,
 - Six (6) months plus duration of symptoms for those with secondary syphilis, and
 - One (1) year for persons with early latent syphilis.

Special Considerations

Allergies:

- If the patient has a penicillin allergy, please see pages 49-51 of the <u>CDC STD Treatment</u> <u>Guidelines 2021.</u>
- The Jarisch-Herxheimer reaction is an acute febrile reaction frequently accompanied by headache, myalgia, fever, and other symptoms that can occur within the first twenty-four (24) hours after the initiation of any therapy for syphilis.
 - o Patients should be informed about this possible adverse reaction and how to manage it if it occurs.
 - The Jarisch-Herxheimer reaction occurs most frequently among persons who have early syphilis, presumably because bacterial burdens are higher during these stages.
 - Antipyretics can be used to manage symptoms, but they have not been proven to prevent this reaction.
 - The Jarisch-Herxheimer reaction might induce early labor or cause fetal distress in pregnant women, but this should not prevent or delay therapy.

Pregnancy:

- Parenteral penicillin G is the only therapy with documents efficacy for syphilis during pregnancy.
- o Pregnant women with syphilis in any stage who report penicillin allergy should be desensitized and treated with penicillin.

HIV infection:

• Persons with HIV infection who have syphilis should be treated as those without HIV infection.

Patient Education/Counseling

- Stress the importance of compliance with the entire antibiotic course of treatment and follow-up appointments.
- Discuss use of clean needles and avoiding sharing needles to those who use IV drugs.
- Stress the importance of safer sex practices and the need for evaluation and treatment of chancres and STD symptoms.
- All MSM who test positive for syphilis should be considered at risk for HIV, and if not infected with HIV, should start taking PrEP.
- Counsel patients to notify their partners of infection and to inform them of the need to be treated.
- Conditions such as autoimmune diseases, older age, pregnancy, immunizations, and IV drug use may cause false positives in the non-treponemal test.
- Implement behavioral counseling interventions to reduce the likelihood of acquiring additional STDs.

Follow-up

- For primary and secondary syphilis, clinical and serologic evaluation should be performed at six (6) and twelve (12) months after treatment.
- Clients who have symptoms that persist or recur after treatment should be evaluated and retested.
- HIV status should be evaluated.

Consultation/Referral

- Refer pregnant clients to primary or prenatal care.
- Referral to another provider must be made if syphilis treatment and management is not provided in your clinic.

Screening

- Pregnant women should be screened at first prenatal visit.
- If at high risk, pregnant women should be retested early in third trimester and at delivery.
- MSM who are sexually active should be tested at least annually.
- MSM who are at an increased risk should be tested every three to six (3-6) months.
- For sexually active individuals with HIV, screen at first HIV evaluation and at least annually thereafter.

Reporting

• Syphilis is a state mandated reportable disease.

References

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US Preventive Services Task Force. (2020). Behavioral counseling interventions to prevent sexually transmitted infections. JAMA, 324(7). doi:10.1001/jama.2020.13095

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What is human immunodeficiency virus (HIV)?

HIV is a blood-borne virus that is commonly transmitted through sexual contact, sharing IV drug needles, and mother-to-child transmission. An HIV infection may first present with a brief, acute retroviral syndrome. Without treatment, HIV will advance into chronic illness and end with symptomatic, life-threatening acquired immunodeficiency syndrome (AIDS). Persons who receive early effective treatment may have a near normal lifespan. In addition to medications that slow the progression of HIV, there are medications designed to lower the risk of getting HIV for high-risk individuals. There are PrEP and post-exposure prophylaxis (PEP) medications.

Subjective Data/Symptoms

History may include:

- Unprotected sexual intercourse, especially receptive anal intercourse
- Previous or current STDs
- Partner history of HIV or STDs
- Sharing IV drug needles or syringes
- Multiple sex partners, high-risk partners, MSM
- Report of engaging in commercial sex work or human trafficking
- Needle-stick injuries or mucosal contact with infected blood.
- Receipt of blood products before 1985 in the U.S.

Symptoms may include:

- Within two to four (2-4) weeks of exposure, flu-like symptoms that may last a few days to several weeks.
 - o fever, chills, rash, night sweats, muscle aches, sore throat, fatigue, swollen lymph nodes, or mouth ulcers.
- No symptoms
- HIV wasting syndrome (chronic diarrhea and weight loss with no identifiable cause)

Objective Data

Physical Findings:

- Acute retroviral syndrome
 - Generalized rash
 - o Generalized lymphadenopathy
- Advanced HIV infection
 - Weight loss
 - Oral candidiasis
 - o Cough

Assessment

Lab testing:

- The recommended diagnostic algorithm for HIV infection consists of a laboratory-based enzyme linked immunoassay (ELISA), which if positive is followed by a supplemental test (e.g., an HIV-1/HIV-2 antibody differentiation assay, Western blot, or indirect immunofluorescence assay).
- 4th generation testing is highly recommended.
- If a patient recently had a high-risk exposure or possible exposure and has early symptoms of HIV infection, may use a nucleic acid test (NAT) because it detects HIV sooner than other tests. However, it is very expensive and not routinely used for screening.

Plan / Pharmacologic Treatment

Management and treatment of HIV is not within the scope of Title X services, but Ryan White Programs (RWP) clinics must perform.

- HIV risk assessments,
- counsel on HIV-risk reduction, and
- provide a list of referrals for HIV testing sites if the testing is not done on site.

Partner notification:

- In Nevada, notification of partners (including sexual and persons with whom syringes or other injection equipment is shared) of possible HIV exposure is required.
- Partners should be tested.
- Many health departments have partner notification programs to help contact partners.
- If a partner has been reached and is not known to have HIV infection, he or she should be offered postexposure prophylaxis (PEP) with combination antiretrovirals if he or she was exposed to genital secretions or blood of a partner with HIV infection though sex or injection-drug use within the preceding seventy-two (72) hours.

Special Considerations

Pregnancy:

- If pregnant, get HIV testing. Starting early treatment reduces the risk of transmission to the baby to one percent (1%) or less.
- All pregnant women should be screened.

Patient Education/Counseling

- Post-test counseling in cases of positive HIV results is required.
 - o Importance of prompt medical care for own health and reducing transmission rates
 - o Effectiveness of HIV treatments
 - What to expect as the enter medical care for HIV
- SBIRT for HIV
 - Treatment as prevention
 - o Barrier protection (condoms, dental dams)
 - o Clean needles (needle exchange programs/ not sharing needles, etc.)
 - Post-exposure prophylaxis (PEP)
 - o Pre-exposure prophylaxis (PrEP)
 - o Routine STI screening and treatment
- Advice on safe sex practices
- If positive, avoid donating blood or blood products.
- If positive, start taking medication to reduce the viral load. If the viral load is undetectable, the risk of transmitting HIV to another person is basically gone.
- A window period is the time between when a person may have been exposed to HIV and when a test can tell for sure if a person has HIV.
 - o A NAT test can tell if a person has HIV within days after exposure.
 - An antigen/antibody test with venipuncture detects HIV in eighteen to forty-five (18-45) days and with a finger prick eighteen to ninety (18-90) days after exposure.
 - An antibody test takes twenty-three to ninety (23-90) days after exposure to detect HIV.
- You can only be sure you are HIV-negative if:
 - O Your most recent test is after the window period, and
 - You have not had potential HIV exposure during the window period.
 - o If you get an HIV test after a potential HIV exposure and the result is negative, get tested again after the window period.
- Implement behavioral counseling interventions to reduce the likelihood of acquiring additional STDs.

Follow-up

- Ensure that patients with positive HIV screens are receiving HIV services and have established on-going medical care.
- Refer to SNCHC-Ryan White Program.

Consultation/Referral

- Newly diagnosed patients may need immediate medical care and support for case management, substance abuse, mental health, reproductive counseling, emotional distress, risk-reduction counseling, etc.
- Patients experiencing psychological distress should be referred accordingly.
- Refer to SNCHC-Ryan White Program

Screening

- Persons aged thirteen to sixty-four (13-64) years should be screened annually for HIV in healthcare settings.
 - Screening should be routine.
 - People should be notified that testing will be performed but have the option to optout.
 - o Do not use a separate consent form for HIV testing.
 - If a person is considered high-risk, and has early syphilis, gonorrhea, or chlamydia, they should be screened for HIV at the time of STD diagnosis, even if a recent HIV test was performed.
- Persons seeking STD evaluation and/or treatment should also be screened for HIV.
- All pregnant women should be screened.

Reporting

• Mandated state reporting is required in Nevada.

References

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What is Human Papillomavirus (HPV)?

Human Papillomavirus (HPV) infections are typically self-limited, asymptomatic, and very

common as most sexually active persons will have at least one HPV infection in their lifetime. Low-risk HPV infection (e.g., HPV types 6 and 11) cause genital warts and recurrent respiratory papillomatosis. High-risk, oncogenic HPV infections (e.g., HPV types 16 and 18) cause most cervical, penile, vulvar, vaginal, anal, and oropharyngeal cancers and precancers. Having a persistent oncogenic HPV infection is the strongest risk factor of developing HPV associated precancers and cancers.

The American Cancer Society and Centers for Disease Control recommend that all girls and boys aged eleven to twelve (11-12) years receive the HPV vaccine. To increase effectiveness, the two (2) dose series should be complete by age thirteen (13) years. If the series is not completed by age fifteen (15) years, the three (3) dose series may be given to persons aged fifteen to twenty-six (15-26) years. Please see https://www.cdc.gov/hpv/hcp/schedules-recommendations.html for vaccination schedules, dosing, and common questions and answers about the HPV vaccine schedule.

Subjective Data/Symptoms

History may include:

- Cervical disease (low or high-grade squamous intraepithelial lesion [LSIL or HLIS, respectively]) or previous abnormal PAP results
- Personal or partner history of STDs
- Partner Symptoms
- Multiple Sex Partners
- Dyspareunia

Symptoms may include:

- Genital warts -- smooth and papular or keratotic, generally not painful but may itch or bleed.
- Genital or anal pruritis
- Bumps, growths, or lesions on genital area (vulva, perineum, vagina, urethra penis, and/or rectum) or oral cavity (mouth, throat)
- Asymptomatic

Objective Data

Physical Findings:

- No findings or subclinical infection
- Anogenital warts
 - Condylomata acuminate (cauliflower like appearance and may be skin colored, pink, or hyperpigmented and often on multiple moist surfaces),
 - o smooth papules (usually dome-shaped and skin colored),
 - o flat papules (macular to slightly raised skin-colored, and have a smooth surface),

OR

- keratotic warts (with a thick keratinized layer that can resemble common warts or seborrheic keratosis, often on dry surfaces)
- Dysplasia and cancers
 - Cervical dysplasia may be apparent on physical exam with visual inspection of cervix.
 - o May find gross erosion, bleeding, ulcer, or mass (internal or external)

Assessment

- Visual inspection
- Most cases of anogenital warts are diagnosed clinically, but confirmation by biopsy may be needed when:
 - o The patient is immunocompromised.
 - o Warts are pigmented, indurated, or fixed.
 - o Lesions do not respond to or worsen with standard treatment.
 - o There is persistent ulceration or bleeding.
 - o The diagnosis us uncertain
 - o Postmenopausal women
 - Women with a history of vulvar dysplasia
- External genital warts are not an indication for cervical colposcopy or type specific HPV DNA testing.
- Screen persons with newly diagnoses anogenital warts for additional STIs (e.g., chlamydia, gonorrhea, HIV, syphilis)
- Application of three to five percent (3-5%) acetic acid is not routinely recommended because it does not influence clinical management and there are many false positives.

Lab testing that may be considered:

- Cervical cytologic testing with the (PAP) test to screen for cervical neoplasia.
 - Please refer to the ASCCP 2019 Updated Consensus Guidelines for Managing Abnormal Cervical Cancer Screening Tests and Cancer Precursors at http://www.asccp.org/guidelines
- HPV DNA testing (e.g., with Hybrid Capture II or polymerase chain reaction [PCR] assay) for detection of HPV and posttreatment follow-up of cervical intraepithelial neoplasia.
- The acetic acid test: This test can be used in conjunction with colposcopy to examine cervical lesions; however, it is reserved for suspicious lesions and should not be used for routine screening.

Plan / Pharmacologic Treatment

• Recommended Regimens for External Anogenital Warts (i.e., penis, groin, scrotum, vulva,

perineum, external anus, and perianal*)

- o Patient-Applied:
 - Imiquimod 3.75% or 5% cream†

OR

■ Podofilox 0.5% solution or gel

OR

- Sinecatechins 15% ointment†
- o Provider-Administered:
 - Cryotherapy with liquid nitrogen or cryoprobe

OR

 Surgical removal either by tangential scissor excision, tangential shave excision, curettage, laser, or electrosurgery

OR

Trichloroacetic acid (TCA) or bichloroacetic acid (BCA) 80%–90% solution

Many people with external anal warts also have intra-anal warts. Thus, people with external anal warts might benefit from an inspection of the anal canal by digital examination, standard anoscope, or high-resolution anoscope.

- † Might weaken condoms and vaginal diaphragms.
 - Recommended Regimens for Vaginal Warts
 - o Cryotherapy with liquid nitrogen. The use of a cryoprobe in the vagina is not recommended because of the risk for vaginal perforation and fistula formation.

OR

Surgical removal

OR

- o TCA or BCA 80%–90% solution
- Recommended Regimens for Urethral Meatus Warts
 - o Cryotherapy with liquid nitrogen

OR

Surgical removal

Management of sex partners:

- Clients with genital warts should inform current sex partner(s) because the HPV infection can be passed on to others.
- Partners may have HPV infection, even if they have no signs of genital warts.

- Partners may want to consider genital wart exam and STD screening.
- Patients should have no sexual activity with new partners until warts are gone or removed.
- Patients can still potentially transmit HPV to sexual partners after visible warts are gone since HPV can remain persistent in the tissues.

Special Considerations

Pregnancy:

- HPV vaccines are not recommended during pregnancy.
- Genital warts may proliferate rapidly and become friable during pregnancy.
- Watchful waiting is acceptable with smaller lesions.
- Cytotoxic agents (e.g., podophyllin, podofilox, imiquimod) should not be used during pregnancy.
- A Cesarean section should not be performed solely to prevent HPV transmission to the neonate.

HIV infection:

- The general approach is the same.
- Persons with advanced immunosuppression may have larger or more numerous warts that do not respond as well to therapy.
- HSIL and invasive cancers arising with the region of a genital wart are more common, so hyperpigmented and persistent lesions should be evaluated with biopsy.
- Women with HIV infection have an increased risk of cervical precancers and cancers and require more frequent PAP screening.

Patient Education/Counseling

- Abstaining from sexual activity is the most reliable method to prevent genital HPV infections.
- Correct and consistent condom use and limiting the number of sex partners can reduce the chances of getting an HPV infection.
- Anogenital HPV infections are very common. Most sexually active people get HPV, although many people do not know they have it.
- Most persons who acquire HPV clear the infection spontaneously and have no associated health problems. When the HPV infection does not clear, genital warts, precancers, and cancers of the cervix, anus, penis, vulva, vagina, head, and neck might develop.
- The types of HPV that cause genital warts are different from the types that can cause cancer.
- HPV may be transmitted by oral, vaginal, and/or anal sex, along with genital-to-genital contact without penetration.

- HPV vaccines are FDA approved and recommended for persons aged nine to twenty-six (9-26) years. The vaccine is also FDA approved for ages twenty-seven to forty-five (27-45) and may be considered based on risk.
- Implement behavioral counseling interventions to reduce the likelihood of acquiring STDs.

Follow-up

- Most anogenital warts respond within three (3) months of therapy.
- Although genital warts can be treated, the treatment does not cure the virus. Thus, it is common for genital warts to return.
- Women with genital warts do not need PAP tests more often than other women.
- If HPV is found on cervical cytology/PAP test, follow ASCCP guidelines http://www.asccp.org/guidelines

Consultation/Referral

- Patients with cervical or intra-anal warts should see a specialist.
- If a biopsy of an atypical wart reveals HSIL or cancer of the anogenital tract, referral to a specialist is needed.
- If results of a PAP test are abnormal and the clinic cannot manage (see http://www.asccp.org/guidelines), then refer for proper follow-up care.

Screening

- Women aged thirty to sixty-five (30-65) may have HPV test with their PAP test (cotesting) every five (5) years to test for cervical cancer.
- Women aged twenty-one to twenty-nine (21-29) should have a PAP test every three (3) years but do not need co-testing because HPV is extremely common in women those ages and the virus tends to clear on its own.
- There is no FDA-approved HPV test for men or for the mouth or throat, only the cervix.

Reporting

• HPV infection is not reportable.

References

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What is Bacterial Vaginosis (BV)?

BV is a gynecologic condition related to changes in the normal vaginal flora, and it is the most prevalent cause of vaginitis and malodorous vaginal discharge among women of reproductive age. It is caused by normal vaginal lactobacilli being replaced by anaerobic bacteria which leads to polymicrobial clinical syndrome.

BV is related to having multiple partners, a new sex partner, douching, lack of condom use, and lack of vaginal lactobacilli; women who have never been sexually active are rarely affected.

Subjective Data/Symptoms

History may include:

- Multiple sexual partners
- Recent changes in sexual partner
- Lack of condom use
- Non-best practice vaginal hygiene practices ex douching, improper wiping techniques, using unclean sex toys, using soap on vagina.

Symptoms may include:

- Up to half of women with BV are asymptomatic.
- "Fishy odor" with discharge
- Increased amount of discharge
- Odor and amount of discharge increase after sex or end of menses.
- Burning with urination
- Itching on outside of vagina or vaginal irritation

Objective Data

Physical Findings:

- Homogeneous, thin, milky-white, or dull gray discharge that coats vaginal walls.
- Amine odor

Assessment

Lab testing:

The presence of three (3) of the four (4) Amsel's criteria will diagnose BV.

• pH of vaginal fluid > 4.5

- "Clue cells" on wet mount exam
- Homogeneous, non-viscous silky-white discharge that coats the vaginal walls.
- Positive amine or "whiff" test (ability to smell amines with or without addition of ten percent (10%) KOH)

Other diagnostic approaches:

- Gram's stain with Nugent scoring
- BD MAX[™] Vaginal Panel
- BD Affirm[™] VPIII hybridization probe.
- OSOM® BVBlue® Test
- PAP testing and cultures are not recommended.

All women with BV should be tested for HIV and other STDs.

Plan / Pharmacologic Treatment

Treatment is recommended for women with symptoms.

Medication:

- Recommended Regimens
 - Metronidazole 500 mg orally twice a day for seven (7) days*
 OR
 - Metronidazole gel, 0.75%, one (1) full applicator (5 g) intravaginally, once a day for five (5) days*

OR

 Clindamycin cream, 2%, one (1) full applicator (5 g) intravaginally at bedtime for seven (7) days+

• <u>Alternative Regimens</u>

Tinidazole 2 g orally once daily for two (2) days*

OR

Tinidazole 1 g orally once daily for five (5) days*

OR

O Clindamycin 300 mg orally twice daily for seven (7) days

OR

Clindamycin ovules 100 mg intravaginally once at bedtime for three (3) days.
 OR

o Secnidazole 2g oral granules in a single dose

^{*}Consuming alcohol should be avoided during treatment and for twenty-four (24) hours thereafter

when using Metronidazole. When using Tinidazole alcohol needs to be avoided for seventy-two (72) hours thereafter.

+Clindamycin ovules are oil-based and might weaken latex condoms and diaphragms for seventy-two (72) hours following treatment (refer to clindamycin product labeling for additional information).

• Regimens for Recurrent BV

- o May repeat initial treatment regimen after first occurrence.
- o If there are multiple recurrences after completion of a recommended regimen, try.
- 0.75% metronidazole gel twice weekly for four to six (4-6) months
 OR
- o oral nitroimidazole (metronidazole or tinidazole 500 mg twice daily for seven (7) days) followed by intravaginal boric acid 600 mg daily for thirty (30) days and then suppressive 0.75% metronidazole gel twice weekly for four to six (4-6) months.

Partner notification:

• Is not state mandated.

Management of sex partners:

- Treatment of male sex partners has not been beneficial in preventing recurrence.
- The option of screening and treatment of female sex partners may be considered due to frequent concurrent infections.

Special Considerations

Allergies:

- Intravaginal clindamycin cream is preferred in case of allergy or intolerance to metronidazole or tinidazole.
- Intravaginal metronidazole gel can be considered for women who are not allergic to metronidazole but do not tolerate oral metronidazole.
- Intravaginal metronidazole should not be administered to women allergic to metronidazole.

Pregnancy:

- BV has been associated with late miscarriage, premature delivery and rupture of membranes, and low birth weight.
- Treatment is recommended for all symptomatic pregnant women.
- Tinidazole should be avoided in pregnant women.

HIV infection:

• Having BV may increase your risk of contracting HIV, HSV-2, chlamydia, and gonorrhea.

• Patients with HIV should follow the same treatment regimen as patients without HIV.

Patient Education/Counseling

- BV is common and is caused by a shift in normal vaginal flora.
- Condoms and oral contraceptive pills are protective against BV.
- BV is not a STI, but having sex more often, with multiple partners, at younger ages, orally or anally, or without condoms increases the risk of getting BV.
- Consuming alcohol should be avoided during treatment and for twenty-four (24) hours thereafter when using Metronidazole. When using Tinidazole alcohol needs to be avoided for seventy-two (72) hours thereafter.
- Clindamycin ovules are oil-based and might weaken latex condoms and diaphragms for seventy-two (72) hours following treatment.
- Refrain from sexual activity or use condoms consistently and correctly during the treatment regimen.
- Do not douche.
- Sexual partner treatment is not recommended.
- Use best-practice vaginal hygiene practices.
 - Wipe front to back (vagina to anus)
 - o Do not use soap to wash the inside or outside of your vagina.

Follow-up

- Unnecessary if symptoms resolve.
- Encourage patients to return if symptoms return or do not resolve.

Consultation/Referral

- Refer pregnant patients to primary or prenatal care.
- Refer clients with persistent or recurrent BV.

Screening

- Screening for BV in asymptomatic women is not recommended.
- Screening for BV before a vaginal related surgery may be considered to reduce rates of post-surgical infections.
- Due to high concordance in female same-sex relationships, if one partner has BV, the provider may want to screen the other female partner(s)

Reporting

• Mandated state reporting is not required.

References

Kinney, R., Spach, D., & Marrazzo, J. (2019). National STD curriculum: Vaginitis.

https://www.std.uw.edu/go/syndrome-based/vaginal-discharge/core-concept/all

Office on Women's Health in the Department of Health and Human Services. (2015). Bacterial vaginosis. https://www.womenshealth.gov/files/documents/fact-sheet-bacterial-vaginosis.pdf

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What is trichomoniasis?

Trichomoniasis, commonly called Trich, is the most prevalent nonviral STD. It is caused by a motile parasitic protozoan Trichomonas vaginalis. The prevalence of trichomoniasis is low among MSM, but it affects men and women and is easily passed via penile vaginal sex. T. vaginalis infection is associated with an increased risk of infection with several STDs, including gonorrhea, HPV, HSV, and, most importantly, HIV. Trichomoniasis is also associated with adverse pregnancy outcomes, infertility, postoperative infections, and cervical neoplasia.

Subjective Data/Symptoms

History may include:

- New or multiple sex partners
- Exchanging sex for money or drugs
- Sexual contact with an infected partner
- Not using barrier protection
- History or current STD
- History of or present use of injection drugs

Symptoms may include:

- Vaginal discharge that is diffuse, malodorous, and/or yellow green
- Vulvar irritation -- itching, burning, or soreness.
- Postcoital bleeding
- Lower abdominal pain
- Dyspareunia
- Dysuria (from urethritis or prostatitis)
- Scrotal pain and swelling (from epididymitis)
- Penile discharge

Objective Data

Physical Findings:

• Abnormal vaginal discharge - purulent, frothy, or bloody

- Abnormal vaginal odor "musty"
- Cervicitis -- easily induced endocervical bleeding and purulent discharge in endocervical canal.
- Petechiae on ectocervix ("strawberry cervix")
- Purulent to mucoid urethral discharge

Assessment

Lab testing options:

- NAAT
- APTIMA[®] assay
- BD Probe Tec TV Q Amplified DNA Assay
- OSOM® Trichomonas Rapid Test
- Affirm VP III
- Culture
- Wet prep
 - The wet prep is very common because it is convenient and low cost, but it has low sensitivity.
 - When highly sensitive (e.g., NAAT) testing on specimens is not feasible, a testing algorithm (e.g., wet mount first, followed by NAAT if negative) can improve diagnostic sensitivity in persons with an initial negative result by wet mount.

Plan / Pharmacologic Treatment

Medication:

- Recommended Regimen
 - o Women
 - Metronidazole 500 mg orally twice a day for seven (7) days*
 - o Men
 - Metronidazole 2 g orally in a single dose*
- Alternative Regimen
 - o Tinidazole 2 g orally in a single dose*
- *Avoid consuming alcohol while taking metronidazole or tinidazole and for an additional twenty-four (24) hours after completion for metronidazole and seventy-two (72) hours for tinidazole.

Management of sex partners:

- The sexual partner(s) of the infected patient should be treated.
- Both the patient and the partner(s) should abstain from sexual activity until the pharmacological treatment has been completed and they have no symptoms.

• In Nevada, EPT is allowed for treatment of trichomoniasis.

Special Considerations

Allergies:

• Desensitization to nitroimidazoles can be managed in consultation with a specialist.

Pregnancy:

- Pregnant patients should be referred to primary or prenatal care.
- If treatment is considered, the recommended regimen in pregnant women is metronidazole 2 g orally in a single dose. Tinidazole should be avoided.
- Symptomatic pregnant women, regardless of pregnancy stage, should be tested and considered for treatment.

Breastfeeding

- Consider deferring breastfeeding for twelve to twenty-four (12-24) hours following maternal treatment with a single 2g dose of metronidazole.
- Breastfeeding should be deferred for seventy-two (72) hours following a single 2g dose of tinidazole.

HIV infection:

- Among women with HIV infection, T. vaginalis infection is associated with increased risk for PID and increased viral load and viral shedding.
- Likelihood of adverse outcomes in women with HIV is reduced with T. vaginalis therapy.
- Recommended treatment for patients with HIV and trichomoniasis infection is metronidazole 500mg twice daily for seven (7) days.
- Rescreen in three (3) months, and at least annually thereafter.

Patient Education/Counseling

- Among sexually active people, the best method to prevent trichomoniasis is through consistent and correct use of condoms during all penile-vaginal sexual encounters.
- Douching is not recommended because it might increase the risk for vaginal infections.
- Stress the importance of additional STD testing and treatment.
- Encourage patients to inform their sexual partner(s) of diagnosis and to receive testing or EPT.
- Implement behavioral counseling interventions to reduce the likelihood of acquiring STDs.

Follow-up

- Rescreening at three (3) months posttreatment is recommended for women.
- Data are insufficient to support retesting men.

- If treatment failure occurs, retreat with metronidazole 500mg twice a day for seven (7) days or tinidazole 2g single dose.
- If treatment failure occurs repeatedly, treat with a single 2g dose of metronidazole or tinidazole orally once a day for five (5) days.

Consultation/Referral

• Refer pregnant patients to primary or prenatal care.

Screening

- Testing for T. vaginalis infection is recommended in all women seeking care for vaginal discharge.
- Consider screening women receiving care in high-prevalence settings (e.g., STD clinics and prisons) and for women at high risk for infection (e.g., women with multiple sex partners, exchanging sex for payment, illicit drug use, and a history of STD)
- Recommended for sexually active women with HIV at entry to care and at least annually thereafter.
- Rectal and oral screenings are not recommended.

Reporting

Mandated state reporting is not required.

References

Smith, MD, et al., (2022). Trichomoniasis. https://emedicine.medscape.com/article/230617-overview#a7

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What is vulvovaginal candidiasis?

Vulvovaginal candidiasis (VVC), commonly referred to as a yeast infection, is usually caused by Candida albicans, and is not generally considered to be a sexually transmitted infection. Approximately seventy-five percent (75%) of women will have a least one VVC infection. A VVC infection can be classified as uncomplicated or complicated and acute, chronic, recurrent, or persistent.

Subjective Data/Symptoms

History may include:

- Being pregnant
- Using birth control with high levels of estrogen

- Compromised immune system i.e., diabetes, HIV.
- Recent use of antibiotics, chemotherapy, or corticosteroids

Symptoms may include:

- Vulvar puritus and burning.
- Thick, white, curdy vaginal discharge
- Vulvar pain, swelling, and redness.
- External dysuria
- Dyspareunia

Objective Data

Physical Findings:

Edema and erythema of the vestibule, labia majora, and labia minora

Thrush patches may be found loosely attached to the vulva.

May have rash extending to perineum and thighs.

Fissures or excoriation

Thick, white, curdy vaginal discharge

Assessment

Lab testing:

- Vaginal pH of 4.0-4.5
- Wet preparation (ten percent (10%) potassium hydroxide (KOH) or saline) or Gram stain of discharge showing budding yeasts, pseudohypahe, or hyphae.
- A fungal culture may be used if the diagnosis is uncertain.

Plan / Pharmacologic Treatment

Medication:

- Recommended Regimens
 - o Over-the-Counter Intravaginal Agents:
 - Clotrimazole 1% cream 5g intravaginally for seven to fourteen (7–14) days
 OR
 - Clotrimazole 2% cream 5g intravaginally for three (3) days
 OR
 - Miconazole 2% cream 5g intravaginally for seven (7) days
 OR
 - Miconazole 4% cream 5g intravaginally for three (3) days

OR

- Miconazole 100mg vaginal suppository, one suppository for seven (7) days
 OR
- Miconazole 200mg vaginal suppository, one suppository for three (3) days
 OR
- Miconazole 1,200mg vaginal suppository, one suppository for one (1) day OR
- Tioconazole 6.5% ointment 5g intravaginally in a single application

Prescription Intravaginal Agents:

Butoconazole 2% cream (single dose bio adhesive product), 5g intravaginally for one (1) day

OR

- Terconazole 0.4% cream 5g intravaginally for seven (7) days
 OR
- Terconazole 0.8% cream 5g intravaginally for three (3) days
 OR
- Terconazole 80mg vaginal suppository, one suppository for three (3) days

Oral Agent:

- Fluconazole 150mg oral tablet, one tablet in single dose (avoid in pregnancy)
- For recurrent VVC (defined as three (3) or more episodes of symptomatic VVC in less than one (1) year), an optimal regimen has not been established, but maintenance/suppressive therapies include the following options:
 - The first line maintenance regimen
 - Oral fluconazole (100mg, 150mg, or 200mg) weekly every third day for a total of three (3) doses (days 1,4,7)
 OR
 - Seven to fourteen (7-14) days of topical azole, followed by maintenance regimen: Fluconazole 100mg, 150mg or 20 mg oral dose, weekly for six (6) months.
- o For Severe VVC, treating with either seven to fourteen (7–14) days of topical azole or 150 mg of fluconazole in two sequential oral doses (second dose seventy-two (72) hours after initial dose) is recommended.
- o For nonalbicans Candida, the optimal treatment is unknown, but treatment options include the following:

- longer duration of therapy (seven to fourteen (7–14) days) with a non-fluconazole azole regimen (oral or topical) as first-line therapy.
- If recurrence occurs, 600mg of boric acid in a gelatin capsule is recommended, administered vaginally once daily for three (3) weeks.
- Consider vaginal culture or PCR to confirm diagnosis and identify nonalbicans Candida.

Management of sex partners:

- VVC is not usually sexually acquired, so treatment of sex partners is not warranted.
- Male sex partners may have balanitis.
 - o Glans of penis may be erythematous and have pruritus or irritation.
 - o May treat with topical antifungal agents to relieve symptoms.

Special Considerations

Allergies:

- The topical agents usually cause no systemic effects, but they may result in local burning or irritation.
- Oral azoles may cause headache, abdominal pain, and nausea.

Pregnancy:

- VVC infections are common in pregnancy.
- Only use seven (7) day topical azole therapies for treatment

HIV infection:

- Patients with HIV may not respond well to short-term therapies, so a longer, seven to fourteen (7–14) day, treatment may be necessary.
- Rates of VVC are higher in women with HIV infections as compared to seronegative women.

Patient Education/Counseling

- VVC is not a sexually transmitted infection.
- Limiting dietary intake of (sucrose and lactose) sugars may reduce the number of VVC infections.
- Wear loose fitting, nonocclusive clothing.
- Wear cotton underwear
- The creams and suppositories in the recommended regimens are oil-based and may weaken latex condoms and diaphragms.
- If symptoms persist or there is a recurrence of symptoms within two (2) months of treatment, a patient should be clinically evaluated and treated.
- If diabetic, maintaining good glycemic control may help prevent VVC.

Follow-up

- Follow-up is not usually required unless symptoms persist or return.
- If symptoms return within two (2) months of treatment, the patient should schedule a follow-up visit.

Consultation/Referral

- Patients with persistent or chronic infections
- Patients who are pregnant should be referred to primary or prenatal care.

Screening

• Screening for VVC in asymptomatic women is not recommended.

Reporting

• Mandated reporting is not required.

References

Centers for Disease Control. (2021). Vulvovaginal candidiasis. 2021 STD Treatment Guidelines. https://www.cdc.gov/std/treatment-guidelines/candidiasis.htm

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What is Nongonococcal Urethritis (NGU)?

NGU is an inflammation of the urethra that is not caused by a gonorrheal infection. It can be transmitted sexually or during birth. It can also be caused by a urinary tract infection, bacterial prostatitis, urethral stricture, phimosis, or catheterization. It is more common in males than females.

Signs or Symptoms

In men, urethral infection, symptoms may include the following:

- Discharge from the penis
- Burning or pain when urinating
- Itching, irritation, or tenderness
- Underwear stain

Symptoms of NGU in women can include:

- Discharge from the vagina
- Burning or pain when urinating

• Abdominal pain or abnormal vaginal bleeding may be an indication that the infection has progressed to PID.

Anal or oral infections may occur in both men and women. Anal infections may result in rectal itching, discharge, or pain during a bowel movement. Oral infections may occur but most, ninety percent (90%) of these infections are asymptomatic. Some people might have a sore throat.

Diagnosis

Urethritis, including NGU, can be documented based on any of the following signs or laboratory tests:

- Mucopurulent or purulent discharge on examination; or
- Gram stain of urethral secretions demonstrating \geq 5 WBC per oil immersion field.
 - The Gram stain is the preferred rapid diagnostic test for evaluating urethritis and is highly sensitive and specific for documenting both urethritis and the presence or absence of gonococcal infection.

All clients who have confirmed or suspected urethritis will be tested for gonorrhea and chlamydia.

Treatment

Clinicians will attempt to obtain objective evidence of urethral inflammation. However, if clinic-based diagnostic tools (e.g., Gram-stain microscopy) are not available, clients will be treated with drug regimens effective against both gonorrhea and chlamydia.

To minimize transmission and reinfection, men treated for NGU will be instructed to abstain from sexual intercourse until they and their partner(s) have been adequately treated (i.e., for seven (7) days after single-dose therapy or until completion of a seven (7) day regimen and symptoms resolved).

Men who receive a diagnosis of NGU will be tested for HIV and syphilis.

- RECOMMENDED REGIMENS
 - o Doxycycline 100mg orally twice a day for seven (7) days
- ALTERNATIVE REGIMENS
 - o Azithromycin 1g orally in a single dose

OR

o Azithromycin 500mg orally in a single dose; then 250mg orally daily for four (4) days

Administration of the first dose of any treatment regimen will be directly observed in clinic.

Follow-Up

Men will be provided results of the testing obtained as part of the NGU evaluation, and those with a specific diagnosis of chlamydia, gonorrhea, or trichomonas will be offered partner services and instructed to return three (3) months after treatment for repeat testing because of high rates of reinfection, regardless of whether their sex partners were treated.

Clients will also be instructed to return for evaluation if symptoms persist or recur after

completion of therapy.

Symptoms alone, without documentation of signs or laboratory evidence of urethral inflammation, are not a sufficient basis for retreatment.

Providers should be alert to the possibility of chronic prostatitis/chronic pelvic pain syndrome in male clients experiencing:

- Persistent pain (perineal, penile, or pelvic)
- Discomfort
- Irritative voiding symptoms.
- Pain during or after ejaculation
- New-onset premature ejaculation lasting for > 3 months.

Men with persistent pain will be referred to a urologist.

Special Considerations

HIV Infection:

- Gonococcal urethritis, chlamydial urethritis, and nongonococcal, non-chlamydial urethritis might facilitate HIV transmission.
- Clients co-infected with HIV will receive the same treatment regimen as those who are HIV negative.

Client Education

How to reduce the risk of getting NGU:

- Practice abstinence. Not having sex is the best protection against acquiring NGU and other STIs.
- Use latex condoms, consistently and correctly, from start to finish every time you have sexual intercourse.
- Have sex with only one uninfected partner who only has sex with you (mutual monogamy).
- Have regular checkups if you are sexually active.
- If you have an STI, don't have sex (oral, vaginal, anal) until all partners have been treated.
- Seek prompt, qualified and appropriate medical intervention, treatment, and follow-up to break the disease cycle.
- Know your partner(s). Careful consideration and open communication between partners may protect all partners involved from infection.

If left untreated, NGU and its causes can lead to serious complications:

- For men, complications may include:
 - o Epididymitis (inflammation of the epididymis, the elongated, cordlike structure along the posterior border of the testes) which can lead to infertility if left

untreated.

- o Reiter's syndrome (arthritis)
- Conjunctivitis
- Skin lesions
- Discharge
- For women, complications may include:
 - o PID which can result in ectopic (tubal) pregnancy.
 - o Recurrent PID which may lead to infertility.
 - o Chronic pelvic pain
 - Urethritis
 - Vaginitis
 - Mucopurulent cervicitis
 - Spontaneous abortion (miscarriage)
- For men or women, infections caused by anal sex may lead to severe proctitis.
- Infants exposed to the bacteria causing NGU during passage through the birth canal may develop conjunctivitis (eye infection) and/or pneumonia.

Encourage clients to inform sexual partner(s) and have them seek evaluation and treatment. Sexual activity should not resume until all partners have been treated.

References

Centers for Disease Control and Prevention. (2021). Sexually transmitted diseases treatment guidelines. https://www.cdc.gov/std/treatment-guidelines/default.htm

ATTACHMENTS

Attachment A – Abbreviations and Acronyms

DIRECT RELATED INQUIRIES TO

FQHC Title X Program Director

Abbreviations and Acronyms

- AA Alcoholics Anonymous
- AAC Ask Advice Connect
- ACHES Abdominal Pains, Chest Pains, Headaches, Eye Problems, Several Leg Pain
- ACOG American College of Obstetricians and Gynecologists
- ACS American Cancer Society
- AED Automated External Defibrillator
- AGC Atypical Glandular Cells
- AHA American Heart Association
- AIDS Acquired Immunodeficiency Syndrome
- ALT Alanine Transaminase
- AP Anteroposterior
- APRN Advanced Practice Registered Nurse
- ARV Antiretroviral Therapy
- ASAP As Soon As Possible
- ASCCP American Society for Colposcopy and Cervical Pathology
- ASC-H Atypical Squamous Cell Cannot Exclude High Grade Squamous Intraepithelial Lesion
- ASCUS Atypical Squamous Cell of Undetermined Significance
- BCA Bichloroacetic Acid
- BLS Basic Life Support
- BMD Bone Mineral Density
- BMI Body Mass Index
- BP Blood Pressure
- BSE Breast Self-Exam
- BV Bacterial Vaginosis
- CAGE Cut, Annoyed, Guilty, Eye Opener
- CBE Clinical Breast Examination
- CDC Centers for Disease Control

- CIN Cervical Intraepithelial Neoplasia
- CLIA Clinical Laboratory Improvement Amendments
- CMS Centers for Medicare and Medicaid Services
- CMV Cytomegalovirus
- COC Combined Oral Contraceptives
- COCP Combined Oral Contraceptive Pill
- CPR Cardio-Pulmonary Resuscitation
- CRAFFT Car, Relax, Alone, Forget, Friends, Trouble
- CSF Cerebrospinal Fluid
- CSP Clinical Service Providers
- CT Chlamydia
- Cu-IUD Copper Intrauterine Device
- DBP Diastolic Blood Pressure
- DMPA Depo Medroxyprogesterone Acetate
- DNA Deoxyribonucleic Acid
- DO Doctor of Osteopathic Medicine
- DVT/PE Deep Venous Thrombosis/Pulmonary Embolism
- EC Emergency Contraception
- ECP Emergency Contraceptive Pill
- ED Emergency Department
- EIA Enzyme Immunoassay
- ELISA Enzyme Linked Immunoassay
- EMR Electronic Medical Record
- EMS Emergency Medical Services
- ENG Etonogestrel
- EOB Explanation of Benefits
- EPA Environmental Protection Agency
- EPT Estrogen and Progestin Therapy
- EPT Expediated Partner Therapy
- ET Estrogen Treatment

- ETOH Ethyl Alcohol
- FABM Fertility Awareness-Based Methods
- FBS Fasting Blood Sugar
- FDA Food and Drug Administration
- FP Family Planning
- FQHC Federally Qualified Health Center
- FRAX Fracture Risk Assessment Tool
- FSH Follicle Stimulating Hormone
- FTA-ABS Fluorescent Treponemal Antibody Absorption
- GC Gonorrhea
- gG glycoprotein G
- HBV Hepatitis B Virus
- Hct Hematocrit
- HCV Hepatitis C Virus
- HDL High-Density Lipoprotein
- Hgb Hemoglobin
- HHS Department of Health and Human Services
- HIPAA Health Insurance Portability and Accountability Act
- HITECH Health Information for Economic and Clinical Health
- HITS Hurt, Insult, Threaten and Scream
- HIV Human Immunodeficiency Virus
- HPV Human Papilloma Virus
- HR High Risk
- HRT Hormone Replacement Therapy
- HSIL High Grade Squamous Intraepithelial Lesion
- HSV Herpes Simplex Virus
- HTN Hypertension
- I & E Informational and Educational
- IM Intramuscular
- IPV Intimate Partner Violence

- IUD Intrauterine Device
- IUS Intrauterine System
- IV Intravenous
- KOH Potassium Hydroxide
- LARC Long-Acting Reversible Contraceptive
- LDL Low-Density Lipoprotein
- LGBTQ Lesbian, Gay, Bi-Sexual, Transgender, And Queer
- LH Luteinizing Hormone
- LMP Last Menstrual Period
- LSIL Low Grade Squamous Intraepithelial Lesion
- MA Medical Assistant
- MD Medical Doctor
- MEC Medical Eligibility Criteria
- MHT Menopausal Hormone Therapy
- MSM- Males Who Have Sex with Males
- NA Narcotics Anonymous
- NAAT Nucleic Acid Amplification Tests
- NAT Nucleic Acid Test
- NCTCFP National Clinical Training Center for Family Planning
- NGU Nongonococcal Urethritis
- NNRTI Non-Nucleoside Reverse Transcriptase Inhibitors
- NNRTI Ritonavir Boosted Protease Inhibitors
- NP Nurse Practitioner
- NRT Nicotine Replacement Therapy
- NRTI Nucleoside-Reverse Transcriptase Inhibitors
- NSAID Nonsteroidal Anti-Inflammatory Drugs
- NTC National Training Center
- NVPCA REACCHH Nevada Primary Care Association Reproduction Education and Care in Community Health Homes
- OASH Office of Assistant Secretary of Health

- ODH Ohio Department of Health
- OPA- Office of Population Affairs
- OSHA Occupational Safety and Health Administration
- OTC Over the Counter
- PA Physician Assistant
- PAP Papanicolaou Test
- PCP Primary Care Physician
- PCR Polymerase Chain Reaction
- PEP Post Exposure Prophylaxis
- PHS Public Health Service
- PID Pelvic Inflammatory Disease
- PPE Personal Protective Equipment
- PPMP Provider Performed Microscopy Procedures
- PPN Program Policy Notice
- PrEP Pre-Exposure Prophylaxis
- POP Progestin Only Pills
- QA Quality Assurance
- QC Quality Control
- QFP Quality Family Planning Services
- QI Quality Improvement
- RDA Recommended Daily Allowance
- RHNTC Reproduction Health National Training Center
- RHWP Reproductive Health and Wellness Program
- RLP Reproduction Life Plan
- RN Registered Nurse
- ROI Release of Information
- RPR Rapid Plasma Reagin
- RWP Ryan White Program
- RW Ryan White
- SAB Spontaneous Abortion

- SAMHAS Substance Abuse and Mental Health Services Administration
- SBE Sub-Bacterial Endocarditis
- SBIRT Screening, brief intervention and referral to treatment
- SBP Systolic Blood Pressure
- SCC Squamous Cell Carcinoma
- SDM Standard Days Methods
- SERM Selective Estrogen Receptor Modulator
- SMAST Short Michigan Alcohol Screening Test
- SNCHC Southern Nevada Community Health Center
- SPR Selected Practice Recommendations
- SSNRI Serotonin and Norepinephrine Reuptake Inhibitors
- SSRI Selective Serotonin Reuptake Inhibitor
- STD Sexually Transmitted Diseased
- STI Sexually Transmitted Infection
- TCA Trichloroacetic Acid
- TP-PA Treponema Pallidum Particle Agglutination
- TSS Toxic Shock Syndrome
- U.S. United States
- UPI Unprotected Intercourse
- USPSTF United States Preventive Services Task Force
- UTI Urinary Tract Infection
- VDRL Venereal Disease Research Laboratory
- VVC Vulvovaginal Candidiasis
- WBC White Blood Cell Count
- WHI Women's Health Initiative
- WIC Women, Infants and Children