IOWA™ | Health and Human Services

Title X Family Planning Manual

Clinical Policies

FY2024-2025

IOWA | Health and Human Services

Title X Family Planning - Clinical Policies Manual

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C1.1 – VOLUNTARY PARTICIPATION

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including the SR and service sites) with the expectation that projects provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning (42 CFR § 59.5(a)(2)); ensure that acceptance of services is solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the recipient (Sections 1001 and 1007, PHS Act; 42 CFR § 59.5(a)(2)).

Policy

- Family planning services are provided without subjecting individuals to any coercion to accept services or to employ, or not to employ, any particular methods of family planning.
- General consent forms or other documentation provided to client's state that receipt of family planning services is not a prerequisite to receipt of any other services offered by the service site.
- Services are not made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the recipient.
- Staff are informed that any officer or employee of the United States, officer or employee of any state, political subdivision of a state, or any other entity, which administers or supervises the administration of any program receiving federal financial assistance, or person who receives, under any program receiving federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both. (42 U.S.C. § 300a-8, as set out in 42 CFR § 59.5(a)(2)).

Procedure

As part of the Iowa HHS Title X Program, each SR will have a:

- Process for ensuring family planning services, including contraception, are provided on a voluntary basis.
- Process for ensuring that staff are informed during their initial orientation and again, at a minimum of once per project period, that:
    - may not be coerced to use contraception, or to use any particular method(s) of contraception or services,
    - family planning services must not be a prerequisite to eligibility for, or receipt of, any other services, assistance from, or participation in any other program, and
    - they may be subject to prosecution if they coerce, or try to coerce, any person to undergo a pregnancy termination or sterilization procedure.
        - Iowa HHS will monitor through the Title X federal rules and regulations acknowledgment form provided by the Agency as well as the annual attestation form as part of the RFP/RFA application.
- Process for documenting that clients are informed that services are provided on a voluntary basis (such as the use of general consent forms or other documentation maintained in an electronic health record).

- Administrative policies used by all service sites that include a written statement that FP services are provided on a voluntary basis.
- All Title X staff and contracted SR's/staff are required to review the *Title X Requirements Acknowledgement Form.*
    - *This will be reviewed on an annual basis through auditing and/or site visits, as requested.*

Date Revised	**September 2023**
References	Title X Program Handbook, Section 3, Program Administration #1, #2, and #3 (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf#page=16) Sections 1001 and 1007, Public Health Service (PHS) Act (https://opa.hhs.gov/sites/default/files/2020-07/title-x-statute-attachment-a_0.pdf) 2021 Title X Final Rule (42 CFR § 59.5(a)(2)) (https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59#59.5)
Additional Resources	

C1.2 – REPRODUCTIVE LIFE PLAN

Policy

Reproductive life planning (RLP) is a set of goals about having or not having children. Part of the RLP includes goals to improve personal health. Individuals should be reminded of the fact that whenever one is sexually active, the possibility of pregnancy must be considered.

Procedure

The Reproductive Life Plan

A comprehensive overview should include a discussion of whether a client is planning to parent, what time frame they wish for parenthood to occur, what actions can be taken to prevent that from happening before they are ready, and what steps can be taken to protect their fertility. Clients might be encouraged to think about things like:

- Do you plan to have a child in the next year?
- Where do you see yourself in five years?
- Do you want to be a parent one day?
    - If no, what would you like to do to prevent pregnancy?
    - If yes, when would you like to have your first child? How many children do you want? How far apart would you like them to be?
- Have you discussed this with your partner?
- Have you discussed this with your parents (if client is an adolescent)?
- How do you plan to financially prepare to be a parent? What kinds of things do you need to think about?
- If you experience a pregnancy before you are ready, what do you think you would do?
- What can you do to keep from getting pregnant before you are ready?
- What would you do to keep from getting pregnant before you are ready?
- Do you think there are things you can do now to help improve your health prior to pregnancy/parenting? I.e., diet, exercise, emotional wellbeing, avoid STIs, substance use, alcohol and smoking, update vaccinations, and learn family history. These are opportunities for improving the overall health of a client.
- Provide information about the impact social, environmental, medical, behavioral, genetic and occupational factors may have on pregnancy outcome.

Date Revised	**September 2023**
References	
Additional Resources	http://www.cdc.gov/ncbddd/preconception/QandA.htm http://www.marchofdimes.com/ click “Before pregnancy” http://www.health.state.ut.us/rhp/pdf/RLP_Adult.pdf http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5506a1.htm http://beforeandbeyond.org/toolkit/

C1.3 – ONE KEY QUESTION

Policy

Preconception assessment and counseling are useful tools not only for clients planning to become pregnant, but also for men and women in promoting their own health. Preconception assessment and counseling should be a part of health care for every person of reproductive age.

One Key Question® (OKQ), a program of Power to Decide, provides a framework to start a conversation with clients about if, when, and under what circumstances they and/or their partners want to get pregnant and have a child. Clinical Service Providers (CSP)are strongly encouraged to utilize the OKQ framework receive training to ensure:

- They provide person-centered counseling.
- They are responsive to clients' cultural, religious, and personal values and preferences.
- They are aware of and continue to address personal biases that may impact client care.
- They are respectful of a range of pregnancy intentions.
- Clients are aware of all reproductive health services.
- All client choices are free of coercion.

Procedure

Each SR will ensure clients are asked the question, "Do you want to become pregnant and/or a parent within the next year?" and given the following options for a response: "Yes", "No", "Unsure" or "Ok either way". Based on the client's response, the CSP will use the OKQ Clinical Algorithm© tool to provide preconception/interconception or contraception counseling and care or a combination of both.

All clients will be asked OKQ at all client visits, with the following exceptions outlined below:

Situation	When to Ask OKQ
Clients who have had a hysterectomy, bilateral oophorectomy, are naturally or prematurely menopausal, or sterilization.	Never.
Clients who are abstinent and accessing services for reasons other than preventing pregnancy. Clients seeking follow-up care for contraception that they are using appropriately and consistently.	Revisit annually or if the client reports a change.
Frequent access clients – those accessing STI screenings or other services weekly or bi-weekly.	Every 3 months at a minimum.

Counseling, Education and Care

Based on the client's response, provide the following counseling, education and care. This is based on the OKQ Clinical Algorithm©.

Client Responds "Yes"

- Counseling/Education:
  - When would you like to become pregnant? (If client is not trying to get pregnant immediately, assess for birth control use and consider contraceptive counseling.)
  - Educate on simple ways to prepare for a healthy pregnancy (i.e. start prenatal vitamins)

- Preconception/Interconception Care:
  - Prescribe or dispense a prenatal or multivitamin with folic acid at least 400mcg.
    - Note that it is important to begin taking folic acid 1-3 months before getting pregnant
  - Discuss significant risk of pregnancy intervals of less than 6 months. Encourage at least 18 months between a birth and the next conception.
    - Review medications and assess for tetratogenicity
  - Screen for and manage chronic conditions.
  - Evaluate drug/alcohol/smoking risks.
  - Identify support system.
  - Assess for safety/violence.
  - Recommend healthy diet, daily exercise, plenty of sleep, stress reduction.
  - Screen for STIs, toxins and other exposures in the home or at work, and dental status.

Client Responds "No"

- Counseling/Education:
  - Are you currently using a birth control method?
  - How is this method working for you?
  - How important is it to you to prevent a pregnancy?
  - What is most important to you in a birth control method?
- Contraceptive Care:
  - If the patient is satisfied with their method, no other care is needed.
  - Recommend birth control methods based on patient's response to questions.
  - Evaluate for correct and consistent use.
  - Provide full range of contraceptive methods onsite or through referral.
  - Offer and educate about emergency contraception (EC).

Client Responds "Unsure" or "OK Either Way"

Note that it is not the responsibility of the CSP to resolve the client's ambivalence or change their pregnancy desires.

- Counseling/Education:
  - Do you want to have (more) children in the future? If yes, when might that be?
  - How would you feel if you found out you were pregnant today?
  - How important is it to you to prevent a pregnancy now?
  - Are you currently using a birth control method? How is this method working for you?
  - Can we talk about some simple ways to prepare for a healthy pregnancy?
- Preconception/Interconception/Contraceptive Care – based on client responses:
  - Prescribe or dispense a prenatal or multivitamin with folic acid at least 400mcg
    - Note that it is important to begin taking folic acid 1-3 months before getting pregnant.
  - Recommend at least 18 months between a birth and the next pregnancy.
  - Review medications and assess for teratogenicity
  - Screen for and manage chronic conditions.
  - Evaluate drug/alcohol/smoking risks.
  - Identify support system.
  - Assess for safety/violence.
  - Recommend healthy diet, daily exercise, plenty of sleep and stress reduction.

- Screen for STIs, toxins and other exposures in the home or at work, and dental status.

Refer to Policy, Preconception Assessment and Counseling for preconception care.

- Contraceptive Care:
  - If the patient is satisfied with their method, no other care is needed.
    - Recommend birth control methods based on patient's response to questions.
    - Evaluate for correct and consistent use.
    - Provide full range of contraceptive methods onsite or through referral.
    - Offer EC.

Documentation

Document specific client responses and details on counseling provided in participants' medical health record and required data elements in the FP database.

Date Revised	**September 2023**
References	
Additional Resources	http://www.cdc.gov/ncbddd/preconception/QandA.htm http://www.marchofdimes.com/ click "Before pregnancy" http://www.health.state.ut.us/rhp/pdf/RLP_Adult.pdf http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5506a1.htm http://beforeandbeyond.org/toolkit/ http://beforeandbeyond.org/toolkit/

C1.4 – ADOLESCENT SERVICES

Policy

Services for adolescent-friendly health services should follow the standard of care as outlined for initial and periodic visits. Family planning (FP) services are accessible, acceptable, equitable, appropriate, and effective for adolescents. (42 CFR § 59.2).

Procedure

Counseling

- Regarding their decision to be sexually active.
    - All clients under the age of 18 will be encouraged to talk with their parents/guardians or a trusted adult about their decision to seek FP services, to the extent practical. Resources should be provided to parents and guardians as applicable to assist them in these discussions. (Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 466 (2022)).
- Regarding resisting coercive sexual activity, sexual violence and human trafficking.
    - Every minor who presents for services (or care) is provided counseling on how to resist attempts to coerce them into engaging in sexual activities (Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 466 (2022)). Clinical Service Providers will conduct a preliminary screening of any teen who presents with a STI, pregnancy or any suspicion of abuse, to rule out victimization of a minor.
    - Such screening is required with respect to any individual who is under the age of consent in Iowa. Compliance with screening is maintained in records to demonstrate compliance with each of the requirements including the age of minor clients and documentation of each notification or report made pursuant to state notification laws. Iowa law does not require documentation of the age of the minor client's sexual partners but Clinical Services Providers shall ask if suspicion arises.
- Abstinence as an acceptable birth control method, including alternative methods of sexual expression.
- Contraceptive options offering a broad range of medically approved services which include all Food and Drug Administration approved contraceptive products and methods.
- Comprehensive information about how to prevent pregnancy and STIs.
- Note: The age of consent in Iowa is 16. See Iowa Code 709.4. Individuals who are age 13 or younger cannot consent to sexual activity in Iowa. Individuals who are age 14 or 15, who have a sexual partner who is less than four years older than them, may consent to sexual activity.

Referrals

Each SR must provide appropriate referrals to adolescents, including but not limited to, referrals of pregnant and parenting youth to social service programs in their area.

Consent for Services and Confidentiality Statement

Adolescents must be assured that counseling and services are confidential and if follow-up is necessary, every attempt will be made to assure privacy. Parents or guardians cannot be notified before or after a minor has requested or received Title X services without written consent. Parental consent for services (or care) will not be required for adolescent services (Section 1001, PHS Act; 42 CFR § 59.10(b)). A provision for the notification of a parent in the event that a life-threatening condition is identified must be included in the consent for services. This provision is exercised only if the minor is unwilling or unable to follow-up on referrals.

Unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources, provided that the Title X Clinical Services Provider has documented in the minor's medical records the specific actions taken by the Clinical Services Provider to encourage the minor to involve the individual's family (including parents or guardians) in their decision to seek FP services. That documentation of such encouragement is not to be required if the Title X Clinical Services Provider has documented in the medical record that they suspects the minor to be the victim of child abuse or incest; and if permitted or required by, applicable state or local law, reported the situation to the relevant authorities.

Child Abuse Reporting *- Refer to the Child Abuse Reporting Policy*

Human Trafficking *- Refer to the Human Trafficking Policy*

Date Revised	**March 14, 2024**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	(Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 466 (2022)

C1.5 – CARE OF INDIVIDUALS IDENTIFYING AS LGBTQ

Policy

People who are lesbian, gay, bisexual, transgender, queer or questioning (LGBTQ+) are members of every community. Sexual identity, gender identity, gender expression and gender transition should all be considered during the course of a FP visit.

The perspectives and needs of people who identify as LGBTQ+ should be routinely considered in efforts to improve the overall health of every person and help to eliminate health disparities. There is also a need for culturally competent medical care and prevention services that are specific to this population. Social inequality is often associated with poorer health outcomes.

Members of the LGBTQ+ community are at increased risk for a number of health threats when compared to their heterosexual peers. Differences in sexual behavior account for some of these disparities, but others are associated with social and structural inequities, such as the stigma and discrimination that LGBTQ+ populations experience.

Procedure

Refer to the Minimum Standards of Care Policy for further guidance.

The following "additional resources" will supplement additional information for this populations' specific needs regarding sexual and reproductive health care, vaccines, specific health concerns and preventive health recommendations for individuals who are LGBTQ+.

Date Revised	**September 2023**
References	
Additional Resources	http://www.cdc.gov/lgbthealth http://www.cdc.gov/msmhealth/for-your-health.htm http://www.cdc.gov/lgbthealth/women.htm http://www.cdc.gov/lgbthealth/transgender.htm http://www.cdc.gov/lgbthealth/youth.htm http://gima.org http://www.lgbthealtheducation.org

C2.1 – MINIMUM STANDARDS OF SERVICE

Policy

The purpose of this policy is to describe Iowa HHS process for ensuring SRs provide high quality care to clients seeking FP services. Health care quality has the following attributes: safe, effective, client-centered, efficient, timely, culturally and linguistically appropriate, inclusive, trauma-informed, accessible and equitable and cost-effective (value) and are aligned with nationally recognized standards of care. FP services include, at a minimum, a broad range of contraceptive services, pregnancy testing, pregnancy options counseling, education about achieving pregnancy, basic infertility services, preconception health and STI services. Related preventive services include things that may impact reproductive health, such as breast and cervical cancer screening and screening for hypertension. Iowa HHS will ensure all medical services related to FP will be consistent with the Center for Disease Control and Prevention Morbidity and Mortality Weekly Report - Providing Quality Family Planning (QFP) Services and the Title X Program Handbook.

Procedure

Initial Health Screening Visit

- Demographics
- Medical history including purpose of visit/chief complaint, physical exam, laboratory test orders, results, PCP and follow-up;
- Reproductive Life Plan (RLP)/ One Key Question (OKQ)
- Complete menstrual, obstetric and gynecologic history, including complications and unexpected pregnancy outcomes for females.
- Sexual health assessment and contraceptive history.
- Partner medical/risk history, if available.
- Family and social history.
- Immunizations, including Human papillomavirus (HPV).

Assessing Reasonable Certainty that a Client is Not Pregnant

One or more must be present:

- Absence of pregnancy signs and symptoms.
- ≤7 days after the start of normal menses.
- Has not had sexual intercourse since the start of last normal menses.
- Using a reliable method of contraception correctly and consistently.
- >14 days since the last unprotected sexual encounter and a negative urine pregnancy test
- ≤7 days after spontaneous or induced abortion.
- Within 4 weeks postpartum.
- Fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrhea, and <6 months postpartum.

Physical Exam – As required by contraceptive method chosen, national standards of practice and clinical protocol

Must include but is not limited to:

- Height, weight and BMI.
- BP.
- Pelvic and/or genital exam as indicated for method and as required by clinic protocol according to national standards of practice.

Patient Consent

Each SR must obtain a written, informed consent from the patient to indicate voluntary acceptance of FP services. The consent must be obtained prior to providing services. All consents must appear in the client's record. If clients choose to delay or defer a service, counseling must be provided about the risks associated with such a delay and documented in the record.

Each SR must document that the client received education about contraceptive alternatives, safety, effectiveness, advantages, disadvantages, potential side effects and complications of the method. Documentation of teach back or a checkbox in the health record is acceptable as long as a policy indicates what teaching is done for each method.

Confidentiality

There must be a confidentiality statement signed by the client in the record that they were informed about confidentiality and any limitations.

Laboratory Services

If laboratory services are provided, services must be in accordance with Clinical Laboratory Improvement Amendments (CLIA) to ensure quality testing.

Periodic Health Screening Visits

An updated history including demographic data, significant illnesses, surgeries or hospitalizations and medical care incurred since most recent visit at which a medical history was obtained as well as:

- RLP as appropriate (review and update).
- Immunization history.
- Review of contraceptive method use, problems, barriers, satisfaction with method.
- Sexual assessment and social histories (review and update).
- Physical exam as indicated.
- Plan for follow-up.

Education should include:

- Information about a broad range of methods using a client centered approach.
- Importance of FP to client's health.
- Emergency Contraception.
- Clinic procedures.
- Referrals as medically necessary or requested by client.
- All counseling and education must be documented in the client record.
- Contraceptive counseling is neutral, factual and nondirective on each option. Counseling is non-coercive and

informative, while prioritizing the holistic health needs and optimal wellbeing of the client, regardless of parenting intent, including participation of trusted adult.
- Client-centered counseling is provided that is culturally sensitive, includes client priorities about pregnancy prevention, acceptability of methods, considers the relationship, partner comfort and function, and CDC Medical Eligibility Criteria and US Selected Practice Recommendations.

Client Education

- Universal education about relationship safety.
- For clients interested in a method of contraception including abstinence and natural FP, client should receive information about mechanism of action, effectiveness and failure rates, advantages and disadvantages, non-contraceptive benefits, STI protection, including HIV, side effects and potential complications, managing side effects, correct method use and discontinuation, and resumption of menses when method discontinued for any method(s) for which interest is expressed. Discuss potential barriers to correct and consistent use with the client.
- Male clients should also be given information about female controlled methods as well as EC when interest is expressed.
- Reduction of risk of STI and HIV.
- *Refer to the Client Education Policy for further guidance.*

Referral and Follow-up

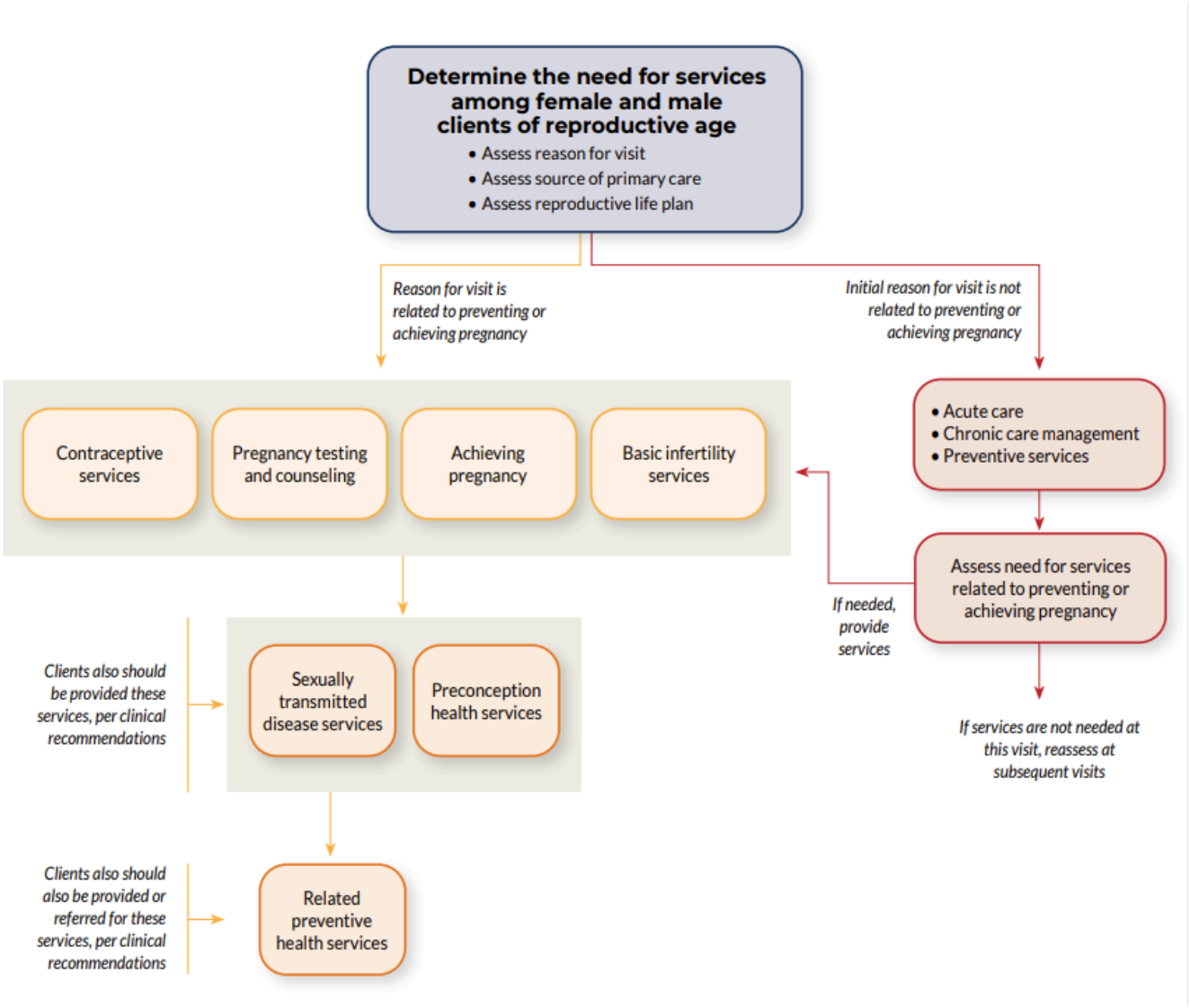
- Must have a planned mechanism for client follow-up.
- Referral for services beyond the scope of the agency is expected.
    - Each SR is expected to have, by prior arrangement, clinical services providers or agencies to which the client may be referred. These may include local health and welfare departments, hospitals, voluntary organizations and health services provided by other federal programs.
- If SRs do not offer comprehensive primary health services onsite, they must have a robust referral linkage with Clinical Services Providers who are in close physical proximity to the Title X site in order to promote holistic health and provide seamless care.
- Provision of medications and/or supplies as needed. If SRs do not provide a contraceptive method on site, they will have a written policy for referring clients for that method, or providing a prescription
    - Grantee must arrange and pay for referral of required services.

Iowa HHS will ensure each SR is in compliance by having each SR complete an annual chart review (internally or externally), monitoring policies and procedures along with the annual site visit observation.

Date Revised	**September 2023**
References	Title X Program Handbook - https://hhs.iowa.gov/sites/default/files/p

	ortals/1/userfiles/88/title%20x%20program%20handbook_final.pdf Center for Disease Control and Prevention Morbidity and Mortality Weekly Report - Providing Quality Family Planning (QFP) Services - https://opa.hhs.gov/sites/default/files/2020-10/providing-quality-family-planning-services-2014_1.pdf
Additional Resources	

C2.2 – CLINICAL PATHWAY FOR FAMILY PLANNING SERVICES



Date Revised	September 2023
References	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
Additional Resources	

C2.3 – NONDIRECTIVE COUNSELING AND REFERRAL

Purpose

The purpose of this policy is to describe Iowa HHS process for ensuring SRs are providing nondirective counseling and referral services. Iowa HHS will ensure contracted SRs are in compliance with requirements that the project: 1) will not provide abortion as a method of family planning and 2) will offer pregnant clients the opportunity to be provided neutral, factual information regarding:

1. Prenatal care, pregnancy, and delivery
2. Parenting, or adoption; and
3. Pregnancy termination

Policy

Title X projects must not provide abortion as a method of family planning (42 CFR 59.5 (a)(5)).

Title X projects must offer pregnant clients the opportunity to be provided information and counseling regarding each of the following options: (42 CFR 59.5 (a)(5)(i))"

- Prenatal care, pregnancy and delivery;
- Parenting, Infant care, foster care, or adoption; and
- Pregnancy termination.

If requested to provide such information and counseling, each SR must provide neutral, factual information and nondirective counseling on each of the options, and, referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling (42 CFR 59.5 (a)(5)(ii)).

Procedure

Iowa HHS will ensure each SR complies with the following:

- Pregnant clients will be offered the opportunity to be provided **information and counseling** regarding each of the following options:
    a. Prenatal care, pregnancy and delivery;
    b. Parenting or adoption; and
    c. Pregnancy termination (42 CFR § 59.5(a)(5))
- If requested to provide such information and counseling, staff at the service site will provide neutral, factual information and nondirective 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).
    a. **Referral** for additional services (e.g. for prenatal care, pregnancy, delivery, parenting, adoption, or pregnancy termination) will be made **upon request** (42 CFR § 59.5(a)(5)).
    b. When a client requests referral for pregnancy termination/abortion, they will be given a name, address, and telephone number. Staff will not take further affirmative action (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)).
    c. Where a referral to another provider who might perform a pregnancy termination/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 a referral by a Title X project is not prohibited by section 1008 and is required by 42 CFR § 59.5(b)(1). The limitations on referrals do not apply in cases in which a referral is made for medical indications (65 Fed. Reg. 41281 (July 3, 2000)).

Each SRs protocol for nondirective counseling should have the following identified:

- Description of which staff will provide non-directive options counseling at the service site (e.g. clinical services providers (MD/NP/CNM/PA), nurses, or service site staff)
- Description of referral workflow for different types of referral
    a. Note: Referrals for abortion services must comply with Title X regulations as summarized in the above sample policy
- Where staff will be able to locate clinics up-to-date referral clinic's names and contact information and schedule for updating referral information.
- Description of the legal status of abortion in your state
    a. Contact the Iowa HHS staff for specific details on the legal status in Iowa as changes may occur frequently.
- Procedure for vetting referral resources
    a. Efforts should be made to ensure resources are neutral, factual, and nondirective.
    b. There are no geographic limits for Title X recipients making referrals for their clients in order to provide a seamless continuum of care (42 CFR § 59.5(b)(8))
- Process for updating referral information
- Process on how staff will be trained and updated on changes to this policy

Date Revised	**September 2023**
References	Title X Program Handbook, Section 3, Provision of High Quality Family Planning Services #9 (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf#page=20) 2021 Title X Final Rule 42 CFR § 59.5 (a)(5) (https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A/section-59.5) 65 Fed. Reg. 41281 (July 3, 2000) (https://www.govinfo.gov/content/pkg/FR-2000-07-03/pdf/00-16758.pdf) Section 1008, PHS Act (https://opa.hhs.gov/sites/default/files/2020-07/title-x-statute-attachment-a_0.pdf) Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 444 (2022)

	(https://www.congress.gov/117/plaws/publ103/PLAW-117publ103.pdf)
Additional Resources	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) (pages 4-20) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)

C2.4 – CLIENT EDUCATION

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including the SRs and service sites) for client education regarding diagnosis, lab results and plan of care or discharge/home instructions are stored and how they are maintained to ensure best practices are the standard.

Policy

Client education must be documented in the client record by referencing material name. The education provided should be appropriate to the client's age, level of knowledge, language, and socio-cultural background, be presented in an unbiased manner and from a reputable source (e.g. RHNTC, AWHONN, CDC, etc). A mechanism to determine that the information provided has been understood should be established. Documentation that the client appears to understand the information must be made.

Procedure

Client-centered counseling about contraceptive methods should be employed. Information must be medically accurate, balanced, and provided in a non-judgmental manner. Clinical Services providers should work with their client interactively to establish a plan, identify barriers, use of contraceptives and establish a follow-up plan.

- Contraceptive counseling is neutral, factual, and nondirective on each option. Counseling is non-coercive and informative, while prioritizing the holistic health needs and optimal wellbeing of the client, regardless of parenting intent, including participation of trusted adult.
- Client-centered counseling is culturally sensitive, includes client priorities about pregnancy prevention, acceptability of methods, and consider the relationship and CDC Chart of U.S. Medical Eligibility Criteria for Contraceptive Use and CDC U.S. Selected Practice Recommendations for Contraceptive Use
- Non-clinical counseling (nondirective options counseling, reproductive life planning etc) can be provided by an adequately trained staff member who is involved in providing family planning services to Title X clients. An adequately trained staff member may be a non-clinical service provider (e.g. health educator, doula, community health worker) who has attended and participated in required orientation, courses, curriculums, maintains appropriate competencies and is knowledgeable in providing non-clinical counseling services (2021 Final Rule FAQs)

Education Services Must Provide Clients with the Information Needed To:

- Make informed decisions about FP and their RLP.
- Use their choice of methods of contraception and identify adverse effects.
- Reduce risk of transmission of STIs and HIV.
- Understand the range of services available to them, their purpose in maintaining overall health and sequence of clinic procedures.
- Understand the importance of recommended screening tests and other procedures involved in the Title X FP visits.

Additional education should include information on reproductive health and health promotion/disease prevention, including nutrition, exercise, smoking cessation, alcohol and drug abuse, domestic violence and sexual abuse.

Informed Consent

Written informed consent must be signed before services are provided. The consent forms must be written in a language understood by the client or translated and witnessed by an interpreter. To provide informed consent for contraception, the client must receive information on the benefits and risks, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the contraceptive method chosen. Clients must be informed that services are voluntary and can be stopped at any time.

The signed informed consent form must be a part of the client's record.

Date Revised	**September 2023**
References	CDC Chart of U.S. Medical Eligibility Criteria for Contraceptive Use (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf) CDC U.S. Selected Practice Recommendations for Contraceptive Use (https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/summary.html) Title X Program Handbook, Section 3, Provision of High Quality Family Planning Services (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf#page=20)
Additional Resources	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] https://opa.hhs.gov/sites/default/files/2020-10/providing-quality-family-planning-services-2014_1.pdf

C2.5 – PRECONCEPTION HEALTH SCREENING AND COUNSELING

Policy

The purpose of this policy is to describe the process for ensuring compliance with the requirement to offer preconception and interconception health services to clients as a part of the core family planning service.

Procedure

Preconception Health Screening and Counseling

Preconception screens, counseling, education, and general health care are provided to identify and modify behavioral & social risks as well as biomedical conditions in order to improve maternal and infant outcomes. These services improve the health of individuals of reproductive age and capability before pregnancy (preconception) as well as in between (interconception) births. and the health of women, men and adolescents who seek family planning services, and the prevention, diagnosis and treatment of infections and diseases which may threaten childbearing capability or the health of the individual, sexual partner and potential future children.

At all visits, clients (regardless of sex, gender, and age) will be counseled about developing a reproductive life plan (RLP) *Refer to policy C1.2 Reproductive Life Plan.* Part of the RLP includes setting goals around how and when to achieve or avoid pregnancy and to improve personal health by addressing modifiable risk factors. Individuals should be reminded of the fact that whenever one is sexually active, the possibility of pregnancy must be considered.

The following should be assessed:

Pregnancy Intention	Utilizing *One Key Question* assess if the client would like to become pregnant within the next year

Medication Review	• Ideally 400mcg of folic acid should be taken for at least one month before pregnancy, taken daily during pregnancy
	• Immunization status
	  ○ Annual influenza
	  ○ Tdap
	  ○ MMR
	  ○ Hep B
	  ○ Varicella
	  ○ COVID-19
	  ○ HPV
	• Use of teratogenic medications (there are others not included on this list)
	  ○ herbal & supplemental products
	  ○ ACE Inhibitors
	  ○ ARB (angiotensin-2 receptor blockers)
	  ○ androgens
	  ○ carbamazepine
	  ○ lithium
	  ○ methimazole
	  ○ methotrexate

	○ minoxidil ○ misoprostol ○ mycophenolate mofetil ○ phenytoin ○ trimethadione ○ paramethadione ○ retinoids ○ tetracycline ○ thalidomide ○ valproic acid ○ vitamin A ○ warfarin
Health History	• History of Medical Conditions ○ Diabetes Mellitus ○ Chronic hypertension ○ Hypothyroidism ○ Bariatric surgery ○ Mood disorders • Family History ○ Genetic disorders ○ birth defects ○ cystic fibrosis ○ Fragile X ○ hemoglobinopathies ○ Tay-Sachs
Need for screening	• STIs • HIV • Tuberculosis • Hepatitis C • Intimate partner violence
Risk of exposure to toxins	• Alcohol, nicotine and illegal drugs • Plastics with bisphenol-A (BPA) • Lead paint • Asbestos • Pesticides • Organic solvents • Heavy metals • Radiation
Assess nutrition and physical activity	• BMI <18 or >25 • Diet rich with: ○ protein ○ vegetables ○ fruits ○ whole grains • Minimum of 30 minutes of moderate physical activity most

	days of the week • Screening for food insecurity

Date Revised	**September 2023**
References	RHNTC - Preconception Health Toolkit, 2022 (https://rhntc.org/resources/preconception-health-toolkit)
Additional Resources	CDC - Before Pregnancy, 2023 (https://www.cdc.gov/preconception/index.html) March of Dimes - Getting ready for pregnancy: Preconception health, 2023 (https://www.marchofdimes.org/find-support/topics/planning-baby/getting-ready-pregnancy-preconception-health) Before, Between & Beyond Pregnancy, 2023 (https://beforeandbeyond.org/resources/toolkits-reports/)

C2.6 – INITIAL VISIT

Policy

To ensure each SR and service site has the reason for the visit documented. Each SR and service site will obtain and record the purpose of the visit, chief complaint, and/or additional health concerns prompting the desire for health care.

Procedure

Refer to Minimum Standards of Service for a complete overview.

History

Past Medical History (Illnesses, hospitalizations, exposure to blood products, chronic or acute medical conditions, injectable drug use)	• Anemia.
	• Dyscrasia.
	• Breast neoplasm.
	• Cancer.
	• Diabetes mellitus.
	• DES or intrauterine estrogen exposure (if born in USA before 1971), if positive, counsel and screen Epilepsy/seizures.
	• Gall bladder disease.
	• Hemoglobinopathy.
	• Hyperlipidemia.
	• Liver disease/jaundice/mononucleosis.
	• Lung disease.
	• Migraine (with or without aura).
	• Psychosocial history:
	  o Depression screening (utilizing PHQ-9 or GAD-7) and counseling.
	  o Family dynamics.
	  o Trauma/violence.
	  o Educational level.
	• Renal/UTI.
	• Substance use, including tobacco, alcohol, injectable drugs, prescription drugs, illegal substances. Screen and counsel.
	• Surgery.
	• Thromboembolism.
	• Thyroid disease.
	• Transfusions.

History of Allergies	• Medicine. • Environmental/Other.
Current Use of Prescription and Over-the-counter Medication	• Current medications including prescription and over-the-counter, herbs and supplements. • Medication taken in past 60 days. • Other concerns not specifically mentioned by interviewer.
Extent of Use of Tobacco, Alcohol and Other Drugs	*Reference smoking cessation, alcohol and substance abuse prevention policies.* • Desire/readiness for use changes.

Immunization Status: Required to Check Rubella, HPV and HBV	• Discuss TDAP vaccine and influenza vaccine, especially if around newborns.
Review of Systems	• Include nutrition and weight changes, and include folic acid discussion.
Family History (First Degree Relatives: mother, father, brother, sister)	• Cancer: 2019 USPSTF recommends using an assessment tool (Ontario Family History Assessment Tool) for women with a personal or family history of breast, ovarian, peritoneal, or tubal cancer or those with ancestry associated with BRAC 1/2 (like Ashkenazi Jewish descent). Routine genetic assessment and testing is not indicated in women who don't meet the above criteria. • Diabetes. • Hypertension/heart disease. • Stroke. • Other (i.e. Sickle Cell Anemia, Phenylketonuria (PKU)). • Blood clots or bleeding disorders.
Partner History	• Injectable drug use. • Multiple partners. • Risk history for STI and HIV. • Bisexuality. • Recent international travel.
Contraceptive History	• What methods of birth control has the client used by name? • What was the method last used regularly? When was it discontinued and why? • Name the current method. • If not presently on a method, how long did the client use the last method? • History of a significant contraceptive complication (i.e., specific type, symptomatology and outcome).
Menstrual History	• Onset. • Interval (last menstrual period). • Duration. • Quantity of bleeding (number of sanitary products per day). • Dysmenorrhea. • Premenstrual symptoms. • Last Menstrual Period (LMP): o Normal. o Abnormal. o Withdrawal bleeding.

Sexual History/IPV (Sexual history combined with contraceptive history and partner history completes the sexual health assessment.)	• Are you sexually active and at what age did you become sexually active? • Are you in a monogamous relationship or multiple partners? • Have you changed partners in the last six (6) months? • Engage in anal sex or oral sex? • Are you experiencing any pain, discomfort or bleeding related to sexual activity? • Do you have any questions about human sexuality? (i.e., orgasm, sexual response, lubrication) • Have you ever experienced sexual trauma or been forced into having sexual activity against your will? • Have you ever had a partner of the same sex? • Does a partner or anyone at home hit, punch, slap, push, kick, hurt or threaten you or your children? • Does a partner or anyone at the home put you down or humiliate you? • Has anyone ever approached you asking you to get involved with prostitution? • Do you feel safe at home?
Obstetrical History	• Gravidity and parity with dates. Number of cesarean deliveries versus vaginal deliveries. • Number of living children. • Number of abortions (spontaneous or induced, medical or procedural). • Neonatal deaths, stillbirths. • Past obstetrical complications.
Gynecologic History	• Abnormal bleeding. • Dyspareunia. • Genital neoplasm. • Endometriosis. • Gynecological surgery. • Vaginitis. • STI or pelvic inflammatory disease. • HIV. • Cervical cancer screening history (includes HPV Vaccine administration).

Overview of Family Planning Methods, Needs and Importance

- A patient-centered overview of all contraceptive methods must be offered, especially for new or undecided clients.
- Offer guidance to facilitate choice of method, if unable to provide client with method of choice AGENCY NAME will provide a prescription to client for their method of choice or referral to another provided (42 CFR § 59.5(a)(1))
- Assess ability to comply with chosen method.

- Provide instructions concerning effectiveness, proper use, indications/precautions, risks, benefits, possible minor side effects and potential life threatening complications of their chosen method must be provided.
- Initiate method of choice.
- Discuss future plans for pregnancy, desired family size, spacing of children.
- Provide interim contraception for sexually active clients if a visit with the Clinical Services Provider cannot be accommodated on the day
- of the visit. Clinic policies must address same day starts. Encourage consistent and correct use of condoms for all at-risk for STI/HIV.
- Discuss the value of FP.
- Instruct the client on clinic routines and exam procedures.
- Document elements of informed consent.

Physical Assessment

During the process of evaluation, the following systems are assessed and the findings documented on the chart by the examining Clinical Services Provider:

- Height, weight and BP.
- Hgb. and/or Hct., if indicated.
- Serology for syphilis, rubella, HIV and Hepatitis B, Hepatitis C, if indicated.
- UA (Dipstick assessment for glucose, protein, ph) if indicated.
- Cervical cancer screening. Though many clients will not need to have a cervical cancer screening every year, they may need to have STI testing.
- Reference policy - Cervical Cancer Screening and Pelvic Exam.
- Thyroid.
- Heart.
- Lungs.
- Breast and axillary nodes (Instruct breast self-examination), as age appropriate.
- Abdomen/extremities.
- Rectovaginal, as indicated.
- Inspection of rectum and rectal exam for clients 50 years and over, as indicated.
- Other lab tests as indicated and available (sickle cell, pregnancy, blood glucose, cholesterol, lipid screen, diabetes testing).
- Gonorrhea/Chlamydia (GC) screening and testing and Wet Mount, as indicated

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Counseling and Education

Counseling and Education Efforts includes an Exploration of the following

- Education.
- Employment.
- Health promotion.
- Affiliations.
- Tobacco.
- Substance and alcohol use.
- Living situation.
- Mental health, suicide, depression, anger management and rage.
- RLP.
- Condom use.
- STI/HIV risk reduction and HPV vaccine.
- Emergency Contraception (use and access
- Mammography, as indicated.
- Colon cancer screening, as indicated.

Counseling for Adolescents must also include:

- Abstinence.
- Safer sex practice options.

- Resisting sexual coercion.
- Confidentiality of services.
- Family involvement/participation.

Date Revised	**September 2023**
References	ASCCP Consensus Guidelines 2006; ACOG Practice Bulletin 109; USPSTF Recommendations 2012; QFP, 2014; Recommendations for Well Woman Care, A Well Woman Chart, HRSA, 2019
Additional Resources	ACOG Practice Bulletin #122 "Breast Cancer Screening", 2011; ACOG Practice Bulletin #131 “Screening for Cervical Cancer”, 2012; U.S. Preventive Services Task Force Recommendation Statement, August 2018, JAMA 2018:320(7)674-686; Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer, accessed 8/26/19 at https://jamanetwork.com/journals/jama/fullarticle/2748515; Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)

C2.7 – PERIODIC HEALTH ASSESSMENT

Policy

To ensure each SR and service site have the reason for the visit documented. Each SR and service site will obtain and record the purpose of the visit, chief complaint, and/or additional health concerns prompting the desire for health care.

Procedure

Refer to the Initial Visit and Minimum Standards of Care Policies for further guidance.

History

Review and update the initial history

- Obstetrical history (if applicable)
- LMP (if applicable)
- Medical history
- Immunizations
- Gynecologic history (if applicable)
- Family medical history
- Allergy history
- Contraceptive history
- Nutrition and weight changes
- Sexual history, including STIs
- IPV and sexual violence
- Psychosocial history
- Social history
- Miscellaneous information:
  - Review current medication intake
  - Review smoking/alcohol/drug abuse

Assess Contraceptive Need

- Review knowledge, correct use and compliance of current method of birth control.
- Review client's acceptance of method. If a method change is indicated, review any contraceptive methods the client expresses interest in and any appropriate alternatives due to client contraindications
- Review side effects and warning signs related to current method of choice.
- Discuss Emergency Contraception.

Perform Thorough Chart Review

- Include assessment of past/current lab (including routine and exam procedures).
- Review Clinic Routine and Exam Procedure of Initiation of Mammography Examinations, if indicated, 2019 USPSTF recommends using an assessment tool (i.e. Ontario Family History Assessment Tool) for women with a personal or family history of breast, ovarian, peritoneal or tubal cancer, or those with ancestry associated with BRAC 1/2 (i.e. Ashkenazi Jewish descent). Routine genetic assessment and testing is not indicated in women who don't meet the above criteria. Women with a family history of breast cancer diagnosed in a first degree relative before the age of 50 should be managed according to the American Cancer Society (ACS) Guidelines or referred to their Clinical Services Provider for appropriate screening.

Breast Cancer Screening Recommendations for AVERAGE Risk

POPULATION	RECOMMENDATIONS

Age under 40	No routine breast screening.
Age 40-49	Shared decision making with patient about screening. If screening is planned, screening interval recommendations differ between annually or every other year.
Age >50	Screening should be done. Recommendations for interval of screening vary between annually or every other year.
Age 75 and up	Screen if life expectancy is more than 10 years or based on a shared decision-making process with patient.

*If mammography identified "extremely dense" breast tissue, consider addition of screening breast ultrasound. Breast cancer risk assessment and screening in average-risk women. Practice Bulletin No. 179. American College of Obstetricians and Gynecologists.
Obstet Gynecol 2017; 130:e1–16. Reaffirmed 2021.

Review STI/HIV Risks and Prevention

Refer to the Sexually Transmitted Infections and HIV Policy.

Referrals

Initiate appropriate referrals if abnormalities are noted. Order appropriate testing and/or refer to appropriate CSP.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Obstetrics & Gynecology, 2017 Practice Bulletin #170 "Breast Cancer Risk Assessment in Average Risk Women." Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer, accessed 8/26/19 at https://jamanetwork.com/journals/jama/fullarticle/2748515

C2.8 – REPRODUCTIVE HEALTH SCREENING

Policy

At the initial and annual visit, the health professional needs to review with the individual the importance of routine health screenings. These screens are not only for reproductive health but also for health in general. The purpose of periodic health screening include:

- Screen for diseases or infections, including sexually transmitted infections.
- Assess risk of future medical problems.
- Encourage a healthy lifestyle including a discussion of exercise, nutrition, smoking cessation and substance use avoidance, avoiding risky behaviors and disease prevention.
- Update vaccinations.
- Initiate discussion of a healthy lifestyle relative to reproductive outcomes, including pregnancy intention and reproductive life plan.

Procedure

Health Screens

The health screens to be addressed include the following:

1. Breast Cancer Screening Procedure for women including:
   a. Breast Self-Exam (BSE) – Clinical Services Providers may counsel women that desire BSE how to perform it, the appropriate procedure may be demonstrated. Beginning in their early 20s, women should be told about the benefits and limitations of BSE. Regardless of whether an individual ever performs BSE, the importance of prompt reporting of any new breast symptoms to a health professional should be emphasized. Individuals who choose to do BSE should receive instruction and have their technique reviewed on the occasion of a periodic health examination.
   b. Annual breast examination by a health care professional for cancer screening in women over 40 and at least every 3 years in women between the ages of 21 and 40.
      - Routine mammography screening should be discussed with each client even when the client is not yet of the age for the screening. Mammography using the USPSTF[1] criteria for "average risk" women should be encouraged:
      - Baseline Mammogram - Women who wish to begin screening earlier may choose to begin biennial screening between the ages of 40 and 49 years. Women with a parent, sibling or child with breast cancer may benefit from beginning screening in their 40s.
      - Mammogram Every One to Two Years - For women who are at average risk for breast cancer, most of the benefit of mammography results from biennial screening during ages 50 to 74 years.
2. Annual pelvic examination is not a routine part of the annual assessment in women unless medically indicated. The decision to perform a pelvic examination should be a shared decision between the patient and their gynecologic Clinical Services provider.
   a. The pelvic exam typically includes the bimanual portion of the exam, assessing the vagina, cervix, uterus, bladder and adnexa. The pelvic exam may also include a speculum exam of the vagina and cervix and a rectovaginal exam, as appropriate.
3. Cervical Cytology as indicated.

[1] The U.S. Preventative Task Force (USPTF) updated its guidelines in 2018, advising women of average cancer risk to get screened every other year

   a. *Reference policies Pap Smear and Pelvic Exam and Abnormal Cervical Cytology Results.*
4. Men should have yearly prostate exams after the age of 50.
5. Clinicians should provide information about recommendations for periodic screening tests such as diabetes, thyroid and cholesterol.
6. Emphasize the importance of folic acid supplementation in all women who may/can get pregnant.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	The U.S. Preventative Task Force (USPTF) updated its guidelines in 2018, advising women of average cancer risk to get screened every other year between ages 50-74 while high-risk women should begin at 40.

C2.9 – PAP SMEAR AND PELVIC EXAM

Policy

Title X CSPs must use a nationally recognized standard of practice for cervical cancer screening. Acceptable standards include the ACOG, USPSTF, ASCCP or the ACS. The Title X CSPs who choose to implement guidelines that vary from national standards must have a policy in place referencing evidence-based literature supporting their decision.

Patients at any age should NOT be screened annually by any screening method; rather, recommended screening intervals for patients are based on age and clinical history. Screening should begin at age 21 years, regardless of the age of initiation of sexual activity with the exception of patients who are HIV positive or who are otherwise immunocompromised.

Procedure

The USPSTF recommends cervical cytology screening based on the table below.

ASCCP Pap Smear (Cervical Cytology) Screening Recommendations (2018)

POPULATION	RECOMMENDED SCREENING
Under 21	Should NOT be screened regardless of the age of sexual initiation or other risk factors
Age 21-29	Every 3 years with cervical cytology only regardless of their sexual history or HPV vaccination
Age 30-65	Every 3 years with cervical cytology OR every 5 years with cervical cytology and high risk HPV co-testing (preferred)
Age >65	No screening following adequate negative prior screenings.*
History of Hysterectomy	No screening if done for benign indications and no history of ≥CIN 2.*
History of HPV Vaccine	Follow age specific guidelines.

* Those with a history of CIN2 or more severe lesion should be screened for at least 20 years, regardless of age

For abnormal cytology management recommendations, please see ASCCP guidelines (2020).

Detailed Screening Recommendations and Special Considerations

Cervical cytology screening should be avoided before the age of 21 regardless of their sexual history or HPV vaccination, because it may lead to unnecessary and harmful evaluation and treatment procedures in women at very low risk of cancer. If cervical cytology screening was done for any reason, HPV testing should not be used for screening or management of ASC-US in this group. HPV vaccination status does not change these cervical cytology screening recommendations.

Patients at average risk (without immune-compromise or history of CIN grade 2 or higher) should start screening at age 21 with repeat cytology every 3 years between ages 21-65. Screening should end at age 65 for patients with three consecutive negative cytology results or two negative results with negative high-risk HPV tests within 10 years of screening cessation. The most recent test should have been performed within the last 5 years.

High-risk patients (immune-compromised, prior CIN2 results or higher) should start screening when sexually active or by 21 years if HIV positive. Otherwise, start at age 21. Thereafter, screen

annually and extend to every three years if three tests are negative. From age 30 onward, perform cytology every year until three normal tests, then every three years or cytology plus high risk HPV testing every three years. Continue lifelong screening.

For patients with DES exposure in utero, screen annually with cervical cytology.

Patients who have had removal of the cervix but have a history of CIN2 or higher (or for whom no record is available) should be screened every three years until they have a 20-year history of no abnormal Pap smear results.

Once screening is discontinued, it should be not resumed for any reason, even if a woman reports having a new sexual partner. Following spontaneous regression or appropriate management of CIN2, CIN3 or adenocarcinoma in situ (AIS), routine screening should continue for at least 20 years (even if this extends screening past age 65).

HPV Testing

The ASCCP has issued these recommendations:

- As HPV DNA testing becomes more widespread, we need to remember that there are situations where high-risk HPV DNA testing and genotyping are NOT recommended. These include:
- Adolescents, defined as patients 24 years and younger (regardless of their cytology results, if performed).
- In patients considering vaccination against HPV.
- For routine STI screening.
- As part of a sexual assault workup.
- HPV genotyping is not recommended for patients with atypical glandular cells (AGC), previously referred to as AGUS.
- HPV genotyping is not recommended as the initial screening test for patients 30 years and older.
- It should also be recognized that there are situations where the 2006 Consensus Guidelines recommend limits on the frequency of HPV DNA testing to avoid over-testing and unnecessary treatment. When managing patients with ASC-US it is recommended that HPV DNA testing not be performed at intervals of less than 12 months. In addition, patients 30 years of age and older who are negative by both cytology and high-risk HPV DNA testing should not be rescreened (using either cervical cytology or HPV DNA testing) before 3 years.

Pelvic Exam

The pelvic examination serves multiple purposes, including the assessment of the vulva, vagina, cervix, uterus, and adnexa. Based on the current limited data on potential benefits and harms and expert opinion, the decision to perform a pelvic examination should be a shared decision between the patient and her obstetrician–gynecologist or other gynecologic care provider.

A limited number of studies have evaluated the benefits and harms of a screening pelvic examination for detection of ovarian cancer, bacterial vaginosis, trichomoniasis, and genital herpes. Data from these studies are inadequate to support a recommendation for or against performing a routine screening pelvic examination among asymptomatic, non-pregnant patients who are not at

increased risk of any specific gynecologic condition. Data on its effectiveness for screening for other gynecologic conditions are lacking.

Regardless of whether a pelvic examination is performed, a client should see a provider at least once a year for preventative care.

A pelvic examination is not necessary before initiating or prescribing contraception other than for an intrauterine device or to screen for STIs.

The QFP Guidelines discuss the physical and laboratory assessment recommendations prior to initiating a birth control method.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	ASCCP Consensus Guidelines 2019; 2014 ACOG Committee Opinion on the Utility and Indications for Routine Pelvic Exam, 754, 2018; US Preventive Services Task Force; EVIDENCE REPORT August 2018.

C2.10 – PROBLEM VISIT

Policy

To ensure each SR and service site has the reason for the visit documented. Obtain the purpose of the visit, chief complaint, and/or additional health concerns prompting the desire for health care.

Procedure

Review and Update the Initial History

- Obstetrical history (if applicable)
- LMP (if applicable).
- Medical history
- Immunizations.
- Gynecologic history (if applicable).
- Family medical history.
- Allergy history.
- Contraceptive history.
- Nutrition and weight changes
- Sexual history, including STIs
- IPV and sexual violence.
- Psychosocial history.
- Social history
- Miscellaneous information:
  - Review current medication intake.
  - Review smoking/alcohol/drug abuse.

Analyze Symptoms

Onset	• Date • Manner • Precipitation and predisposing factors related to onset.
Characteristics of Pain: Quality, Quantity, Consistency	• Location and radiation. • Intensity or severity. • Timing. • Aggravation and/or relief factors. • Associated symptoms.
Course since Onset	• Incidence. • Progress. • Effect of therapy.
Unusual Discharge/Bleeding	• Amount. • Timing. • Character (quality, quantity, consistency). • Aggravation and/or relief factors. • Associated symptoms.

Review

Clinic routine and exam procedures and stress importance of follow-up care, if indicated.

Elicit Client Opinion

Elicit client's opinion about the cause and continuation of problem.

Reassess Contraceptive Status

Reproductive Life Plan and One Key Question

Physical Assessment

If indicated - order appropriate testing

Treatment

Treat as indicated using the clinical protocols

Referrals

Initiate appropriate referrals and follow-up as needed

Date Revised	September 2023
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Women's Preventive Services Initiative "Recommendations for Well-Woman Care, A Well Woman Chart" HRSA, 2019

C2.11 – ORAL CONTRACEPTIVE REFILL VISIT

Policy

Clients prescribed a new method should be re-evaluated after three months if the CSP determines it is indicated. A new client who chooses to continue a method already in use may choose not to return for this early revisit unless an indication for re-evaluation is found by the CSP at the initial visit.

Procedure

Oral contraceptive (OCP) refill counseling is using the following but is not necessarily limited to:	• An update of the LMP, obstetrical, gynecological and medical histories,
	• Current use or changes in medications or changes
	• Smoking habits
	• An assessment of the client's correct utilization and satisfaction with the method
	• Review knowledge of how to make up missed OCPs
	• A review of minor side effects and provisions of counseling appropriate to resolution/relief if a problem is identified
	• Screening for symptoms of serious, possibly life threatening complications, and appropriate referral of the identified problem, including:
	  ○ Shortness of breath.
	  ○ Severe chest pain.
	  ○ Severe, persistent headaches.
	  ○ Visual disturbances (double vision-blurring)
	  ○ Severe pain, redness or numbness in extremity.
	  ○ Hypertension.
	  ○ Acute abdominal pain

Refill Counseling	Sessions vary with the individual client and method of choice, usually numbering one to four visits per year. Established clients may receive a one-year supply of OCPs (from the date of the annual visit) in the absence of contraindication or a CSP identified need for increased surveillance.
Vitals	• BP • Weight • Other laboratory tests, as indicated • Review results of last laboratory tests (if applicable).
Referrals	Update information on previous referrals

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs

	(QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Contraceptive Technology, 19th Edition,

C2.12 – INTRAUTERINE DEVICE (IUD) CHECK VISIT

Policy

An intrauterine device check (IUD) is routinely performed 4-8 weeks following insertion, but clients are encouraged to call for a follow-up appointment at any time if they suspect the IUD has been expelled, partially expelled, or if the client identifies any other IUD related problem.

Procedure

Type of IUD

- Identify the type of IUD
- Remind the client of the anticipated replacement date

Review History

- LMP (amount and length of flow) or other bleeding history since insertion.
- Sexual concerns and satisfaction with IUD.
- Ability to feel strings.
- History of STIs.

Assess the Utilization of the IUD

- Review client's technique for checking IUD string following menses and reinforce the importance of periodic self-checks.
- Assess the client's (and partner, if appropriate) acceptance of the IUD as their contraceptive method.
- Reinforce instructions regarding the need for follow-up care in the following circumstances:
  - Strings not felt.
  - IUD expelled/partially expelled.
  - Partner complaining of feeling strings during coitus.

Review Possible Side Effects

- Dysmenorrhea.
- Menorrhagia.
- Dyspareunia.
- Vaginal discharge.
- Intermenstrual bleeding (after 1st 3 months of use).
- Amenorrhea, metrorrhagia.

Review Warning Signals

Reinforce the need to call clinic or report to Clinical Services Provider if any of the following should occur:

- Fever/chills.
- Severe cramps/abdominal pain.
- Foul smelling vaginal discharge.
- Amenorrhea (if not progesterone containing).
- Intermenstrual bleeding/spotting.
- Unusually heavy bleeding (more than 7 days) or cramping with menses.
- Absence of strings.
- Positive pregnancy test.
- Subjective signs or concerns about pregnancy.

Reminders

Reinforce the need for continued screening and pelvic exams, as indicated, even though she may have an effective birth control method for many years.

Vital Signs

- BP
- Weight (as indicated).
- Other lab procedures may be done according to need, i.e., pregnancy test for amenorrhea, Hgb and/or Hct for menorrhagia, STI screen.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Contraceptive Technology, 19th Edition,

C2.13 – INTRAUTERINE DEVICE (IUD) REMOVAL VISIT

Policy

Intrauterine Device (IUD) is removed at the client's request or when there is a medical indication to do so.

Procedure

If Client Requests Removal of the IUD Device

- Obtain and document the reason for the request (seeking pregnancy, pain/discomfort, increased menses or dysmenorrhea, etc.).
- If client requests removal for reason other than seeking pregnancy, offer counseling regarding:
  - Available methods of contraception.
  - How to initiate the chosen method.
- Counsel client regarding exam technique utilized to remove IUD.
- Notify client before removing the device.
- Counsel client regarding possibility of dysmenorrhea and increased bleeding for hormonal IUD and decreased bleeding for copper-IUD, for the first 1-3 cycles after removal of device, depending on the type of the IUD. Discuss resumption of normal menses. Discuss the risk of pregnancy and immediate return of fertility after removal.
- Suggest measures to alleviate any discomfort.
- Assess the need for other methods of contraception and/or STI prevention.

Education

- Cramping and spotting is common in the first couple hours to several days post removal
- Refer client to see their provider if cramping becomes severe, spotting increases, foul smelling discharge, pain during intercourse or a fever >101F
- It can take up to 3 months after removal for normal menstrual cycles to return
- Remind client return to fertility is immediate and offer an alternative form of birth control if pregnancy is not desired

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Vital Signs

BP is obtained routinely on all clients for IUD removal. Height, weight and BMI are also recommended. Other labs may be performed as indicated, i.e. pregnancy test, Hgb and/or Hct, or urinalysis.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	

C2.14 – PREGNANCY TEST VISIT

Policy

A pregnancy test may be performed at the client's request or if the Clinical Service Provider deems it necessary.

Procedure

Determine Client's Reason

Determine client's reason for suspecting pregnancy as well as onset of potential signs/symptoms of pregnancy.

Obtain the following information and/or update regardless of the results:

- Obstetrical history.
- Medical history.
- Menstrual history (with emphasis on LMP).
- Contraceptive history and current status.
- Date of last unprotected intercourse.
- Sexual history, sexual violence and reproductive coercion.
- Current medication, prescription, over-the-counter drug use.
- Alcohol, tobacco and illicit or prescription drug use, as indicated.

Education and Referral

Based the results of the pregnancy test:

1. Interpret the test results and exam findings.
2. Consider possible reasons for false negative results.
3. If a possibility exists that it is too early to confirm or rule out a pregnancy:
   a. The client should be advised to return to the clinic in two (2) weeks for a repeat pregnancy test.
   b. Discontinue hormone contraceptive methods if early gestation is probable, as indicated. Provide an alternative contraceptive, such as foam, condoms, sponge or diaphragm if the client does not desire pregnancy at this time. A Clinical Services Provider may choose to use reasonable certainty that the client is not pregnant and allow the client to continue hormone contraception if the client meets any of the following criteria and has been educated about the risks:
      i. Less than 7 days from start of normal menses;
      ii. Consistently and correctly using a reliable method of contraception;
      iii. Less than 7 days after spontaneous or induced abortion;
      iv. Within 4 weeks postpartum;
      v. Is fully or nearly fully exclusively breastfeeding and amenorrhea and less than 6 months postpartum; or has not had intercourse since the last normal menses.
4. Those clients who have a positive pregnancy test may have a pelvic exam to corroborate the test results. If the pregnancy test and/or the exam findings are positive for pregnancy, the following pregnancy options counseling and information should be rendered and documented:
   - Prenatal care and delivery with infant care/parenting or, foster care/adoption; and
   - Pregnancy termination.
     - If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with the respect to any option(s) about which the

pregnant client indicates they do not wish to receive such information and counseling.
    - Assessed for any risk factors which might adversely influence the pregnancy and provide appropriate education.

5. Clients with negative pregnancy test results who wish to become pregnant:
    - Instruct regarding timing of intercourse. Intercourse prior to ovulation is important to conception. While sperm can survive over 72 hours in the female genital tract, the ovum has a life expectancy of only 12 hours if it is not fertilized. The availability of sperm in the genital tract at or shortly after ovulation is essential. Clients should receive instruction to determine their most fertile time of the month. Natural FP techniques may be useful.
    - Women who have been trying to achieve pregnancy for more than 12 months or if the client is 35 or older with unprotected intercourse with the same partner, referral for infertility workup should be made. Clinics should maintain a resource list where services are available.
6. Clients with negative pregnancy test results who do not wish to become pregnant should be assessed for:
    - Continued appropriateness of current contraceptive method (if applicable)
    - A contraceptive method should be provided with detailed instructions on use
    - RLP counseling should be done during this session.
7. If ectopic pregnancy is suspected, immediately refer client for immediate medical care
8. All clients, regardless of pregnancy test results, should be offered STI screening at the time of the pregnancy test visit.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	

C2.15 – POSTPARTUM VISIT

Policy

Ideally, clients will have their postpartum exam done by the CSP who provided prenatal care and delivery. Attempts to obtain records of prenatal care and delivery should be made.

- New- postpartum client, initiate initial visit protocol and counseling.
- Revisit- postpartum client, initiate annual visit protocol and counseling.

Procedure

Review OB Discharge Summary (if available)

- Date and method of delivery (vaginal or cesarean) and any associated complications.
- Infant's sex, weight, health status.
- Complication of pregnancy and/or labor and delivery:
  - Hemorrhage.
  - Infection.
  - Pregnancy-induced hypertension (e.g. gestational hypertension, preeclampsia).
- Length of hospital stay.
- Gestational diabetes.
- Premature rupture of membranes
- Premature delivery.
- Other.

Other Concerns

- History of coitus since delivery and birth control method used.
- Review when client may resume coitus and discuss associated fears.
- Knowledge of breast care/presence of breast engorgement.
- Infant feeding (breast, formula or combination) and any concerns
- Screen for postpartum depression using EPDS tool
- Bladder and bowel function.
- Support and help at home.
- Sleep patterns and rest.
- Resolution of lochia, onset of menses.
- Current medication.
- Status of episiotomy, or abdominal incision
- Contraceptive plans and RLP.
- Intimate violence screening and education.
- Tobacco screening and counseling.
- Folic acid supplementation.
- Infant care (with a focus on sleep safety and shaken baby prevention)

Contraceptive

Initiate contraceptive method according to protocols.

Referrals

- Initiate referrals as appropriate. If abnormalities are noted, order appropriate testing and/or refer to appropriate CSP.
- *Refer to Title V Healthy Pregnancy program in your community when available.*

Date Revised	September 2023
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Contraceptive Technology, 19th edition: www.who.int/reproductive-health/publications/msm_98_3/msm_98_3_14.html; Women's Preventive Services Initiative "Recommendations for Well-Woman Care, A Well Woman Chart" HRSA, 2019.

C2.16 – POST-TERMINATION VISIT

Policy

Abortion/termination services are not provided as a part of the Title X Program. Ideally, the post-abortion examination should be provided by the facility that performed the procedure and should include a negative pregnancy test. If the client seeks care at the Title X clinic for a post-termination visit, the procedure is outlined below.

Procedure

Up to Six Weeks Post Termination Visit

NEW post-abortion client. Reference policy - Initial Visit.

- **REVISIT** post-abortion client. *Refer to the Periodic Health Assessment Policy for further guidance.*
- If current with annual exam, the client only needs a pelvic exam.

Additional History Components Obtained

1. Type of Abortion:
    a. Induced (i.e. termination) or spontaneous (i.e. miscarriage)
    b. Management type: Medication (i.e. misoprostol with or without mifepristone) or procedural (i.e. uterine aspiration or dilation and evacuation)
2. Gestational age at time of abortion.
3. Presence of pregnancy symptoms before and after the abortion.
4. Results of pregnancy test performed this visit (pregnancy test may be positive if less than 4 weeks post-abortion, especially in a medication abortion).
5. History of Post-abortion Complications:
    a. Excessive vaginal bleeding.
    b. Nausea.
    c. Abdominal tenderness.
    d. Fever>38 degrees C (100.4 degrees F).
    e. Emergency room visit.
6. Current medication status.
7. Sexual History: History of intercourse since abortion (protected or unprotected).
8. Feelings about abortion.
9. Future pregnancy plans/reproductive life plan (refer to C1.2 Reproductive Life Plan)

Reassess Current Contraceptive Needs

- Past method/user satisfaction/method failure.
- RLP counseling.
- Education about all method options.

Referrals

Initiate appropriate referrals if abnormalities are discovered, order appropriate testing and/or refer to appropriate CSP.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and

	the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	

C2.17 – LEVEL 1 INFERTILITY SERVICES

Policy

Infertility is commonly defined as the failure to achieve pregnancy after 12 months or longer of regular unprotected intercourse with the same partner. Earlier assessment is appropriate for women over age 35, women with a history of infrequent menstruation, with a known or suspected uterine or tubal disease or abnormality. Earlier assessment may also be appropriate in the presence of male risk factors for infertility or questions about the male partner's fertility potential. The Title X Clinical Services Provider's role is to determine potential causes of infertility and referrals for further evaluation and management.

Basic infertility care for women should include a thorough medical history, obstetric history, sexual health assessment and complete physical examination. The RLP and a reproductive history about the client's efforts to conceive should be taken. Clients should be referred for further diagnosis and treatment as appropriate.

Basic infertility care for males should include a thorough medical history, sexual health assessment and physical examination focusing on examination of the genitals for abnormalities. The RLP and a reproductive history about the client's efforts to conceive should be taken. Refer for further diagnosis and management as appropriate.

Partners may also be counseled about ways to maximize fertility and offered resources to deal with the emotional and psychological issues of dealing with infertility.

Procedure

Each SR shall make basic infertility services available to clients desiring such services. Infertility services are categorized as follows:

Level I: Includes initial infertility interview, education, physical examination, counseling and appropriate referral.

Level II: Includes testing such as semen analysis, assessment of ovulatory function and postcoital testing.

Level III: More sophisticated and complex than Level I and Level II services.

Level II services may be offered with CSPs who have special training in infertility. Level III services are considered beyond the scope of Title X Program.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	

C2.18 – LONG ACTING REVERSIBLE CONTRACEPTIVE REMOVAL

Policy

Client-centered counseling is a critical part of initiating contraceptive care and the same must be true for discontinuing a method as well. Clients must always be free to discontinue use of LARCs, even without a medical reason for doing so. The purpose of this policy is to ensure reproductive autonomy for clients seeking removal of long acting reversible contraceptive (LARC) methods.

Procedure

If a client requests LARC removal, even if the agency did not provide the LARC initially, the client's request will be honored. If the clinic schedule does not allow same day removal, the client will be given the next available appointment for removal.

Removal of the LARC should only be performed under aseptic conditions by a CSP who is familiar with, and trained on the removal technique. CSPs should receive training in insertion and removal techniques prior to attempting removal and follow current manufacturer's instructions.

Clients willing to attempt management of side effects in order to resolve problems and continue using the LARC will be provided appropriate treatment. The clinic will assure that clients are provided LARC removal without any required mitigation efforts that the client does not agree to. However, if the client is willing to attempt management of side effects in order to resolve problems and continue using the LARC, the CSP will provide appropriate counseling and treatment.

Except as restricted by third party payers, no time restrictions may be placed on the client's choice of receiving another LARC if no medical contraindications exist.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	

C2.19 – EMERGENCY CONTRACEPTIVE PILLS

Policy

Emergency contraception pills (ECP) can be used in the following situations: unprotected intercourse, concerns about possible contraceptive failure, incorrect use of contraceptives, and sexual assault.

There are three types of emergency contraceptive pills (ECPs):

1. Progestin (levonogestrel) only pills
2. Ulipristal Acetate (ella® or ellaOne®), progesterone agonist/antagonist who's likely main effect is to inhibit or delay ovulation. ella® is available by prescription only and not stocked by all pharmacies.
3. Estrogen (ethinyl estradiol) and Progestin

Mode of Action

- Primary mechanism of action is to delay or inhibit ovulation.
- Interferes with sperm migration and function.
- May interfere with fertilization.
- Affects necessary hormone levels, by the corpus luteum.
- May interfere with tubal transport.

Procedure

Contraindications

Pregnancy and lactation

If a client is already pregnant, treatment with progestin-only ECPs is ineffective (ECP will not disrupt an established pregnancy). There is no evidence on post-fertilization effects. Women who are breastfeeding should not use ella® or should pump/dump for 24 hours after taking. Progestin as well as progestin/estrogen EC is not an abortifacient and progestin-only EC does not have a negative effect on an already developing pregnancy. Data on the impact of ella® on a pregnancy is lacking due to the fact that it is so effective at preventing ovulation and thus preventing pregnancy. Access to progestin-only ECP can be provided without a pregnancy test or visit.

Women with BMI >30% of Ideal Body Weight

These women will likely have decreased effectiveness of progestin and estrogen/progestin EC. Women with a BMI >30% who desire oral EC should be encouraged to consider ella® if possible and available. However, there may be some decreased efficacy of ella® in persons with BMI >30 as well. All clients, but specifically for clients with a BMI >30, discussion of intrauterine device as the most effective EC should be completed (IUD does not protect against STIs).

Precautions

Risks During Pregnancy Usually Outweighs Risks for ECPs

There are no medical contraindications to the use of ECP except pregnancy. The advantages of ECP usually outweigh the theoretical risk even for women with contraindications to the ongoing use of combined oral contraceptive pills (such as vascular disease).

Client Education and Counseling

All FP clients should be provided information about ECPs and when to use them. Clients must be provided with any one of the following:

1. ECP to have on hand
2. A phone number to call in case of need.
3. Where to purchase ECP over the counter or get a prescription for ella®.

Indications for Use

- No more than 5 days since an act of intercourse where no contraceptive was used.
- Male condom slipped, broke or leaked.
- Female condom, diaphragm or cervical cap inserted incorrectly.
- More than 2 days late starting vaginal ring or patch.
- Error in coitus interruptus.
- Missed contraceptive pills.
- More than 14 days late for Depo-Provera injection.
- Error in periodic abstinence.
- IUD partially or totally expelled.
- Exposure to a teratogen when not protected by effective contraception.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Current CDC U.S. Medical Eligibility Criteria; ACOG Practice Bulletin No. 112, Emergency Contraception, May 2010; Current US Selected Medical Practice Recommendations for contraceptive use Emergency Contraception. Practice Bulletin 152. American College of Obstetricians and Gynecologists. Obstet Gynecol 2015; 126e: 1-11

C2.20 – INTRAUTERINE (AS EMERGENCY CONTRACEPTION)

Policy

CSPs should exclude the possibility that a client may already be pregnant by assessing the date of the last menstrual period, the first episode of unprotected intercourse and the last episode of unprotected intercourse. A pregnancy test may be helpful if there is some doubt about whether the client is already pregnant from intercourse in the past. EC should not be withheld because the unprotected coital act may not have occurred on a fertile day of the menstrual cycle.

Procedure

When should Emergency Contraception Be Initiated

Treatment should be initiated as soon as possible after unprotected or inadequately protected intercourse to maximize efficacy, which decreases with time. The copper T-380 or 52mg levonogestrel IUD can be inserted up to 5 days of the first act of unprotected intercourse as an EC. *Refer to the Emergency Contraception policy for additional options.*

STI Testing

If a client has not been screened for STIs according to STI screening guidelines, screening must be performed at the time of insertion.

When is an IUD Appropriate for Emergency Contraception

Both the Copper T-380A and 52mg Levonogestrel (LNG) IUDs prevent pregnancy more than 99% of the time when placed within 5 days of unprotected intercourse. One advantage of using an IUD for EC is that it can be retained for continued long-term contraception. Insertion of an IUD is not cost saving when used solely for EC. However, it becomes cost-effective when used for as little as 4 months as an ongoing contraceptive method following insertion as an EC.

The copper or 52mg levonogestrel IUD is appropriate for EC in women who meet standard criteria for IUD insertion and is most effective if inserted within 5 days after unprotected intercourse. This method is particularly useful for women who desire long-term contraception and who are otherwise appropriate candidates for IUD use.

What Clinical Follow-Up Is Necessary After Use of Emergency Contraception

Side effects after emergency insertion of an IUD are similar to those experienced after routine IUD insertion and include abdominal discomfort, cramping and vaginal bleeding or spotting.

Follow-up should be scheduled according to IUD insertion guidelines. The individual should be advised that if their menstrual period is delayed by a week or more, they should consider the possibility that they may be pregnant and seek clinical evaluation. The individual should also seek follow-up care for persistent irregular bleeding or lower abdominal pain because these symptoms could indicate a spontaneous abortion or an ectopic pregnancy.

Date Revised	September 2023

References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Current CDC U.S. Medical Eligibility Criteria; ACOG Practice Bulletin No. 112, Emergency Contraception, May 2010; Current US Selected Medical Practice Recommendations for contraceptive use. Turok DK, Gero A, Simmons RG, Kaiser JE, Stoddard GJ, Sexsmith CD, Gawron LM, Sanders JN, Levonorgestrel vs. Copper Intrauterine Devices for Emergency Contraception. N Engl J Med. 2021 Jan 28:384(4):335-344.

C3.1 – RELATED PREVENTIVE HEALTH SERVICES

Policy

For many individuals, the Title X FP clinics are their only source of health care. Therefore, visits should include the provision of or referral for other preventive health services. For agencies without an infrastructure to provide comprehensive primary care services, a strong link to other community CSPs should be developed to ensure clients have access to services.

Procedure

Medical History

USPSTF recommends that women be asked about family history that would be suggestive of an *increased risk for deleterious mutations in BRCA1 or BRCA2 genes* (e.g., receiving a breast cancer diagnosis at an early age, bilateral breast cancer, history of both breast and ovarian cancer, presence of breast cancer in one or more female family members, multiple cases of breast cancer in the family, both breast and ovarian cancer in the family, one or more family members with two primary cases of cancer, and Ashkenazi background). Women with identified risk(s) should be referred for genetic counseling and evaluation for BRCA testing (Grade B). The USPSTF also recommends that women at increased risk for breast cancer should be counseled about risk-reducing medications (Grade B).

Cervical Cytology

Individuals seeking services at Title X clinics may expect/prefer to obtain cervical cancer screening services at that location, CSPs should provide cervical cancer screening to clients receiving related preventive health services. If CSP follow USPSTF (2018) recommendations, women should be screened with cervical cytology screening alone every three (3) years for women between the ages of 21 and 29 years, regardless of their sexual history or HPV vaccination. HPV testing should not be used for screening in this age group.

For women aged 30 to 65 years, the USPSTF recommends screening every 3 years with cervical cytology alone, every 5 years with high risk HPV (hrHPV) testing alone, or every 5 years with hrHPV testing in combination with cytology (cotesting), regardless of their sexual history or HPV vaccination.

Title X programs may choose to follow ACOG standards as well, which includes cervical cytology screening with reflex hrHPV testing for clients 21-29 years of age. Cervical cytology no longer is recommended on an annual basis. Further, it is not recommended (Grade D) for women aged <21 years. Women with abnormal test results should be treated in accordance with professional standards of care, which may include colposcopy. The need for cervical cytology should not delay initiation or hinder continuation of a contraceptive method. CSPs should also follow ACOG and AAP recommendations that a genital exam should accompany a cervical cancer screening to inspect for any suspicious lesions or other signs that might indicate undiagnosed STIs.

Clinical Breast Exam

Despite a lack of definitive data for or against, clinical breast examination has the potential to detect palpable breast cancer and can be recommended. Clients should be informed there is not enough evidence to balance the benefits and risks of screening. If a client requests a clinical breast exam, it should be performed.

ACOG recommends annual examination for all women aged >19 years. ACS recommends screening every 3 years for women aged 20–39 years, and annually for women aged ≥40 years. However, the USPSTF recommendation for clinical breast exam is insufficient evidence and patients should be informed that there is insufficient evidence to assess the balance of benefits and harms of the service.

Mammography

CSPs should follow USPSTF recommendations to screen low-risk women aged 50–74 years on a biennial basis; they should screen women aged <50 years if other conditions support providing the service to an individual patient.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	

C3.2 – REFERRALS AND FOLLOW-UP

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including SRs and service sites) for providing all Title X services identified as core FP services in the QFP either on-site, by prescription, or by referral. When required services are to be provided by referral, the SR and service site must establish formal arrangements with a referral agency for the provision of services and reimbursement of costs, as appropriate.

Policy

All SRs will have processes for effective referrals to relevant social and medical services not available on-site such as childcare agencies, transportation providers, and Women, Infant and Children (WIC) programs. (Optimally signed written collaborative agreements.) The relevant agencies may also include emergency care, HIV/AIDS care and treatment, infertility, other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services supported by other federal programs. If SRs and/or service sites do not offer comprehensive primary health services on-site, it must have a robust referral linkage with primary health providers in order to promote holistic health and provide seamless care.

Procedure

SRs must have written policies/procedures for documentation of and follow-up on referrals that are made as a result of client history, abnormal physical examination or laboratory test findings. These policies must be sensitive to clients' concerns for confidentiality and privacy.

For services determined to be necessary but which are beyond the scope of Title X, clients must be referred to other Clinical Services Providers for care. When a client is referred for non-FP or emergency clinical care, the agency must:

1. Make arrangements for the provision of pertinent client information to the referral Clinical Services Provider. The agency will obtain client's consent to such arrangements, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality.
2. Advise the client on their responsibility in complying with the referral.
3. Counsel the client on the importance of such referral and the agreed upon method of follow-up.

Efforts may be made to aid the client in identifying potential resources for reimbursement of the referral clinical services provider, but Title X is not responsible for the cost of this care. The SR will maintain a current list of providers, local health and human services departments, hospitals, voluntary agencies, and health services to be used for referral purposes. Whenever possible, clients should be given a choice of clinical services providers from which to select.

Date Revised	September 2023
References	Title X Program Handbook, Section 3, Provision of High Quality Family Planning Services (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf)
Additional Resources	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)

C3.3 – NUTRITION PROMOTION

Policy

All clients seen for an initial Title X appointment shall be assessed for nutrition risk.

Procedure

Assessment for nutritional risk includes height, weight, and ideally, BMI. Nutritional risk factors include being overweight, underweight, eating fewer than 2 meals per day, few fruits and vegetables, dental problems, poverty and unintentional weight gain or loss. Tools for completing a self-nutritional assessment can be found at the following link: https://www.sampleforms.com/nutrition-assessment.html

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Warning signs of Disordered Eating Behavior

- Binge eating or eating large amounts of food, more than what most people would eat under similar circumstances.
- Loss of control during these eating episodes.
- Self-induced vomiting.
- Misuse of laxatives, diuretics, enemas or other medications.
- Fasting.
- Excessive exercise.
- Severe self-scrutiny of one's weight or shape.

Referral or Follow-Up

Clients identified as being at nutritional risk and requiring a level of expertise which the CSP does not have should be scheduled to return when a nutritionist is available or referred for nutrition services. Written procedures and defined criteria for referrals are recommended along with a list of outside professional nutrition services which will accept referrals.

All clients should be instructed on adequate calcium intake and folic acid supplementation if desiring pregnancy within one year.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	

C3.4 – SMOKING CESSATION

Policy

As part of the health history, clients will be assessed on tobacco use. All clients who smoke or vape should be urged to discontinue smoking at each visit.

Procedure

Any client who smokes and is known to have children living with them should be told of the dangers of environmental smoke to the children.

All clients who smoke and are using estrogen contraceptives should be informed of their increased risk for vascular diseases and the recommendation to discontinue smoking or the estrogen contraceptive at age 35.

All clients who smoke or vape and may become pregnant should be informed about the potential negative health effects of smoking/vaping on their health and the health of their pregnancy.

Clients should be told that lung injury has been reported with the use of e-cigarettes and vaping.

Defective e-cigarette batteries have caused some fires and explosions, a few of which have resulted in serious injuries.

Children and adults have been poisoned by swallowing, breathing or absorbing e-cigarette liquid through their skin or eyes.

The protocol service is to utilize: Ask Advise and Refer (AAR) system.

Anytime a client has a condition which is caused by, exacerbated by or adversely affected by smoking or nicotine, smoking cessation should be discussed.

All clients should be given written materials about smoking cessation programs available in their area. Free resources include:

- http://www.smokefree.gov/
- http://www.quitlineiowa.org/

Date Revised	September 2023
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)

Additional Resources	Ask Advise and Refer: https://idph.iowa.gov/tupc/quitting-tobacco/healthcare-provider-resources Centers for Disease Control and Prevention: https://www.cdc.gov/tobacco/index.htm

C3.5 – ALCOHOL AND SUBSTANCE ABUSE PREVENTION

Policy

As part of the intake process, clients will be assessed about alcohol and substance use.

Procedure

All clients who give a history of substance use should be counseled about the impact that substance may have on their ability to use some methods of contraception effectively. Based on the CSPs judgment, they may be given a referral phone number or an appointment for the local substance abuse treatment facility.

All clients who give a history of substance use should be advised about the potential negative health impacts of various substances on a developing pregnancy and their health. If the client is planning a pregnancy in the future, counseling should be offered about the need to discontinue substance use before pregnancy begins. A motivational interview-based brief intervention is recommended when discussing client goals for their substance use and alcohol consumption.

Clients requesting help with a substance abuse problem should be referred immediately to a local substance abuse treatment facility: http://idph.iowa.gov/substance-abuse

When the client seems to be impaired at the time of the Title X visit, the CSP should:

1. Tell the client of concern about their ability to give informed consent for a method and about their ability to understand and remember instructions for use of the method.
2. Arrange for the client to return to the clinic as soon as possible at a time when they are more likely to be sober (perhaps first appointment in the AM).
3. Provide a non-prescription method to last until the next appointment.
4. Arrange alternate means of transportation if the client drove to the clinic.
5. Contact the police if the client insists on driving while impaired.
6. Screening tools for CSPs to incorporate into their practice can be found at: https://www.sbirtoregon.org/screening-forms/

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	United States Department of Health and Human Services. Substance Abuse and Mental Health Services Administration. *White Paper on Screening, Brief Intervention and Referral to Treatment*

	(SBIRT) in Behavioral Healthcare [Internet] Substance Abuse and Mental Health Services Adminstration; Rockville, MD: 2011. [cited 2013 Feb 17]. Available from: http://www.samhsa.gov/prevention/sbirt/SBIRTwhitepaper.pdf. [Google Scholar]

C3.6 – HUMAN TRAFFICKING

Purpose

The purpose of this policy is to ensure Iowa HHS along with contracted SRs (including grantee and subrecipient and service sites) have a policy in place that describes the process for ensuring that staff are trained to identify survivors of human trafficking, to make reports to authorities as needed and to refer survivors to the appropriate resources..

Policy

- All Title X staff will be trained at least annually on:
  - Human trafficking identification and response
  - Mandatory reporting requirements
  - Confidentiality
  - Trauma-informed care
- SRs will establish knowledge of and/or maintain relationships with:
  - The National Human Trafficking Hotline;
  - State child protective services;
  - Local organizations that serve human trafficking victims; social service agencies; and human trafficking prevention coalitions; and/or
  - Law enforcement agencies, including relevant FBI task forces, police and/or sheriffs' offices.
- Family planning and requested services will be provided as requested and needed, regardless of a client's willingness to report human trafficking or other violence
- SRs will incorporate the expertise and experience of survivors when altering or developing protocols
- Procedures for responding to survivors of human trafficking should:
  - Use gender- and age-neutral language;
  - Use non-judgmental, non-blaming language to describe trafficking;
  - Refer to site protocols regarding other forms of violence and response; and
  - Use existing anti-trafficking resources from the National Human Trafficking Hotline or the National Human Trafficking Training and Technical Assistance Center (NHTTAC).
- SRs will distribute and post violence education and prevention materials in languages accessible to the client population. These materials can include human trafficking education and information on resources available to a client who may not be ready or able to disclose victimization or accept assistance. All client materials must be reviewed by the Information and Education (I&E) Committee per I&E policies.
- SRs will identify key personnel to be involved if human trafficking is suspected, based on site capacity.
  - Some sites may have specialized staff who can conduct more intensive interviews or assessments related to sexual assault, human trafficking, or other forms of violence. Sites with more limited expertise in this area can focus on referrals.
- SRs will consider safety concerns (for client and staff) that may be a part of assisting a victim of trafficking and will consider other organizational policies related to when to call security or law enforcement.

Definition and Overview

Human Trafficking

Human Trafficking is a crime that involves exploiting a person for labor, services or commercial sex. The Trafficking Victims Protection Act of 2000 and its subsequent reauthorizations outline two types of human trafficking:

- Labor Trafficking - Individuals are compelled to work or provide services through the use of force, fraud or coercion.
- Sex Trafficking - Individuals are compelled to engage in commercial sex through the use of force, fraud or coercion. When a person under 18 years old performs a commercial sex act, it is a crime regardless of whether there is any force, fraud or coercion.

SRs must assure that all staff members are familiar with federal and state human trafficking laws. SRs must develop written internal procedures for staff on how to address human trafficking incidents.

Procedure

Iowa HHS will monitor all contracted SRs to ensure that they adhere to the following protocols:

- SR clinicians and staff will work together to craft a statement of shared commitment to compassionate human trafficking response. SRs will post this agreement for public view. For example:

  > "***(Insert Agency Name)*** is committed to responding to the unique needs of human trafficking victims and survivors. It is our policy to support those who have been trafficked with a victim-centered and trauma-informed approach."

- SRs will integrate human trafficking identification and response into existing staff workflows
  - At intake, SRs will:
    - Apply a client-centered approach;
    - Consider signs and indicators of human trafficking (refer to Identifying and Referring Human Trafficking Victims and Survivors: Red Flags for Title X Clinicians or National Human Trafficking Hotline materials); and
    - Maintain and enforce clinic policy that patients spend time alone with their clinician during the assessment
  - If signs of human trafficking are present during intake or clinical assessment, providers will take three steps:
    1. Notice red flags
    2. Establish trust and safety
    3. Take action

    Step 1: Notice red flags

    - Refer to "Identifying and Referring Human Trafficking Victims and Survivors: Red Flags for Title X Clinicians"

    Step 2: Establish trust and safety

    - Build trust by demonstrating warmth, care, and non-judgemental interest and concern
    - Ensure client has time alone with providers and access to language interpretation
    - Leverage your expertise to carry out patient-centered screening for violence, including intimate partner violence, trafficking, and sexual or physical violence

- Refer to existing institutional protocols for victims of violence
    - Remember: while human trafficking is a distinct federal crime, victims may experience trafficking as intimate partner violence, sexual assault, or child sexual abuse
- Be aware of incremental disclosure issues in human trafficking, similar to those in intimate partner violence or other abuse experiences
- *It is important to obtain client permission and consent before disclosing any personal information to others, including Clinical Service Providers.*

Step 3: Take action (Strongly encourage SRs to identify action steps listed below in their policies)**:**

- SRs will follow institutional policies for reporting to law enforcement in situations of immediate danger
- SRs will consult protocols for human trafficking and mandatory reporting
- Call the National Human Trafficking Hotline at 1-888-373-7888 or text BEFREE (233733) for additional support and referrals
    - The National Human Trafficking Hotline can support clinicians and staff through patient assessment and shared decision-making with the patient about best next steps
    - Call local anti-trafficking organizations **(*insert names and contact info here*)**
    - If it becomes necessary to file a mandatory report, follow best practices for involving and empowering clients
- Follow up on the client's case. A potential victim may require fulfillment of some basic needs—such as food, clothing, or temporary shelter—in order to take next steps, and may not be ready to accept help right away.

Note About The National Human Trafficking Hotline

The National Human Trafficking Hotline offers confidential, round-the-clock access to a safe space to report tips, seek services, and ask for help. The Hotline is operated 24/7 and has access to more than 200 languages through a tele-interpreting service.

All communications with the National Human Trafficking Hotline are strictly confidential to the extent permitted by law, and callers need not disclose personal information to access services. The Hotline can also be used by health care institutions to help identify and connect clients with existing resources in their area or to guide providers through human trafficking assessments.

The National Human Trafficking Hotline maintains a database of service providers and resources throughout the United States; this database is available here.

Contacting the Hotline will not fulfill mandatory reporting requirements, but it can facilitate a report to specialized law enforcement trained to handle human trafficking cases. When working with adults who have been trafficked, Title X providers must follow state and federal confidentiality and mandatory reporting rules.

Iowa HHS will review training compliance on an annual basis with each SR as part of their contract and monitoring compliance. *Required training is outlined in the required training tool as well as RHNTCs Federal Training Requirements.*

Date Revised	September 2023
References	Title X Legislative Mandates https://opa.hhs.gov/grant-programs/title-x-service-grants/title-x-statutes-regulations-and-legislative-mandates Title X Program Handbook (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf#)
Additional Resources	Adult Human Trafficking Screening Tool and Guide (https://www.acf.hhs.gov/otip/training-technical-assistance/resource/nhhtacadultscreening) A Screening Tool for Identifying Trafficking Victims (https://nij.ojp.gov/topics/articles/screening-tool-identifying-trafficking-victims) Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html) Trafficking Victims Protection Act of 2000 (https://www.govinfo.gov/content/pkg/USCODE-2010-title22/html/USCODE-2010-title22-chap78-sec7104.htm)

C3.7 – DOMESTIC ABUSE

Policy

All clients should have universal education and access to information about domestic abuse, including information about community resources for people experiencing domestic violence .

Procedure

All clients should be evaluated for intimate partner violence in their recent intimate relationships and should be assessed for evidence of physical injury yearly and as indicated.

If domestic abuse is reported, refer to appropriate community resources as determined by the course of action the client would prefer. The client should be given information regarding domestic abuse and encouraged to develop a plan for protection and assistance in case of emergency.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Iowa Coalition Against Domestic Violence, 1-800-942-0333, 24 hour statewide hotline https://idph.iowa.gov/disability-injury-violence-prevention/violence-against-women If in immediate danger, clients can call 911 or the 24-hour Iowa Victim Service Call Center at 1-800-770-1650 or text "iowahelp" to 201211-800-770-1650

C3.8 – CHILD ABUSE REPORTING

Purpose

The purpose of this policy is to describe Iowa HHS process for ensuring that no Title X Clinical Services Provider and Title X staff (including the recipient, subrecipient, and service sites, as appropriate) shall be exempt from any State law requiring a notification or report of child abuse, child molestation, sexual abuse, rape, or incest. (Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 444, 466–67 (2022)).

Policy

Staff must report child abuse, child molestation, sexual abuse, rape, or incest in accordance with state law. See Iowa Code Chapter 232.

A child is defined in Iowa Code section 232.68 as any person under the age of 18 years. A "victim of child abuse" is a person under the age of 18 years who has suffered one or more of the categories of child abuse as defined in Iowa Code section 232.68.

If a mandatory reporter suspects sexual abuse of a child under the age of 12 by a non-caretaker, they are required by law to make a report of that suspected abuse. If the child is age 12 or older, the mandatory reporter may report the suspected sexual abuse by a non-caretaker, but is not required by law to do so.

Iowa law does not require health practitioners to document the age of the minor client's sexual partners. However, if a provider suspects that the minor client has been the victim of abuse, they should ask additional questions and make any reports required by the law.

Mandatory reporters are not required to make a report if a client over the age of 18 discloses childhood abuse. However, if a client who is 17 or younger discloses abuse that happened in weeks, months, or years prior, health practitioners should make a report of suspected abuse based on that disclosure.

Procedure

Iowa HHS will ensure that SRs comply with the following:

- Process (step-by-step instructions) for notification and reporting of child abuse, child molestation, sexual abuse, rape, or incest, including notification of supervisor that a report has been made.
    - SRs will ensure that every minor who presents for services or care is provided counseling on how to resist attempts to coerce them into engaging in sexual activities. Providers will conduct a preliminary screening of any teen who presents with an STI, pregnancy or any suspicion of abuse, in order to rule out victimization of a minor.
- Such screening is required for any individual who is under the age of consent in Iowa.
- SRs must maintain screening records demonstrating:
    1. The age of minor clients, and
    2. Documentation of each notification or report made under the state law.

The HHS secretary may review records maintained by a grantee or SR for the sole purpose of ensuring compliance with the requirements of this section.

Training Requirements

To ensure that all project staff have been educated about state laws which require the report of child abuse, child molestation, sexual abuse, rape, or incest, staff shall complete the following trainings at the listed intervals.

Annually:

- Title X State Reporting Requirements: Mandatory Reporting for Abuse, Rape, Incent, and Human Trafficking (Legislative Mandate)
  - *Refer to the RHNTC Federal Title X Training Requirements Summary for the Title X Training Resources*
- Family Involvement and Coercion (Legislative Mandate)
  - *Refer to the RHNTC Federal Title X Training Requirements Summary for the Title X Training Resources*

Every three years:

- Iowa Mandatory Reporter Training

SRs will provide proof upon request that all project staff have completed the required training.

Date Revised	**September 2023**
References	Title X Program Handbook, (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf#page=9) Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 444 (2022) (https://www.congress.gov/117/plaws/publ103/PLAW-117publ103.pdf) Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Iowa Code Section 232.69 (https://www.legis.iowa.gov/docs/code/232.69.pdf) Iowa Code Section 235B.3(2) (https://www.legis.iowa.gov/docs/code/235B.3.pdf)

C3.9 - IMMUNIZATION

Policy

Title X clinic staff should review immunization status of all clients. This review may include but is not limited to: MMR, HPV, Tdap, Hepatitis B, Varicella, Influenza, COVID-19, Meningococcal Conjugate, and Pneumonia, as appropriate.

Procedure

All clients should be offered information about the HPV vaccine (age 9-45). Vaccination of persons 27 through 45 years of age will be based on "shared clinical decision-making" between the patient and the CSP, based on discussion of the benefits and risks of the HPV vaccination. This means that the decision to vaccinate persons 27 through 45 years of age should be based on a discussion of benefits and risks between the patient and the clinician.

Clients under age 19 and all unvaccinated adults should be informed about the importance of Hepatitis B vaccines.

All patients receiving a vaccination in the FP setting should receive the appropriate CDC Vaccine information statement. *Refer to CDCs Vaccine Information Statements*

Immunizations administered in the Title X clinics must be documented in the client's record and in IRIS. Consents for vaccines should be placed in the client's record. If the client declines immunization, note in the record.

Clients should be provided with referral information about vaccines if they are not available in the Title X clinic.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	The Advisory Committee on Immunization Practices (ACIP), June 2019

C4.1 - AMENORRHEA

Policy

Amenorrhea is the absence or cessation of menstruation. Primary amenorrhea refers to the absence of any menstrual periods by age 16. Clients with primary amenorrhea should be referred to a Clinical Services Provider for evaluation. Secondary amenorrhea occurs when a client was previously menstruating, but then stopped having periods for an equivalent of three previous cycle intervals or for three months. In sexually active women, pregnancy is the most likely cause of missed periods.

Procedure

If amenorrhea is accompanied by a negative pregnancy test, clinicians should consider other causes for the absence of menses. Clinical Services Providers may choose either to refer clients with secondary amenorrhea to another provider or clinic for evaluation or initiate evaluation themselves. The evaluation of amenorrhea is not a Title X service except for pregnancy diagnosis. Clients who are referred must be made aware of the importance of timely follow up care to their long-term health.

If initial evaluation is undertaken in the Title X clinic, a policy agreed upon by the CSP and medical director must be in place, including indications for referral.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	

C4.2 – ABNORMAL CERVICAL CANCER SCREENING TESTS (Excluding Adolescents)

Policy

SRs must implement policies that reflect current national standards of care for the management of abnormal cervical cancer screening tests. The national standards may include USPSTF, ACOG or American Society for Colposcopy and Cervical Pathology (ASCCP).

Procedure

The cervical cancer screening measure for cervical cancer is not diagnostic. **Abnormal results must be further evaluated.** An endometrial tissue biopsy or some other diagnostic procedure would be necessary to identify endometrial cancer.

Risk Factors

Human Papillomavirus (HPV)	HPV is a group of viruses that can infect the cervix. An HPV infection that doesn't go away can cause cervical cancer in some women. HPV is the cause of nearly all cervical cancers.
Lack of Regular Cervical Cancer Screening Tests	Cervical cancer is more common among women who don't have regular cervical cancer screening tests.
Other Factors	These include smoking, immunocompromised, multiple sexual partners or having a male sexual partner who has had multiple sexual partners, personal or family history of cervical dysplasia or cancer, early sexual debut, and certain STIs (such as Chlamydia).
DES (Diethylstilbestrol)	DES may increase the risk of a rare form of cervical cancer in daughters exposed to this drug before birth. DES was given to some pregnant women in the United States between about 1940 and 1971. It is no longer given to pregnant women but is currently used in the treatment of prostate cancer and occasionally, breast cancer.

Terminology

There are multiple categories of epithelial cell abnormalities identified on a cervical cancer screening test, including unsatisfactory, atypical squamous cells (ASC), low-grade or high-grade squamous intraepithelial lesions (LSIL or HSIL), atypical glandular cell abnormalities (AGC), and adenocarcinoma in situ (AIS). The histological diagnosis of cervical cell abnormalities are reported as cervical intraepithelial neoplasia (CIN) categories from 1-3.

Follow-Up on Abnormal Findings

ASCCPs 2019 guidelines (below box) include the following guiding principles for individuals with current or previous abnormal screening results:

1. HPV–based testing is the basis for risk estimation. The term HPV-based testing is used throughout this document and refers to use of either primary HPV testing alone or HPV testing in conjunction with cervical cytology (cotesting).
2. Personalized risk-based management is possible with knowledge of current results and past history
3. Guidelines must allow updates to incorporate new test methods as they are validated, and to adjust for decreasing CIN3+ risks as more patients who received HPV vaccination reach screening age.
4. Colposcopy practice must follow guidance detailed in the ASCCP Colposcopy Standards.
5. The primary goal of screening and management is cancer prevention through detection and treatment of cervical precancer.
6. Guidelines apply to all individuals with a cervix.
7. Discussion regarding balancing benefits and harms essential in shared decision-making.
8. Guidelines apply to asymptomatic patients that require management of abnormal cervical screening test results.
9. Guidelines are intended for use in the United States.

Box 1. Essential Changes From Prior Management Guidelines

1) Recommendations are based on risk, not results.

- Recommendations of colposcopy, treatment, or surveillance will be based on a patient's risk of CIN 3+ determined by a combination of current results and past history (including unknown history). The same current test results may yield different management recommendations depending on the history of recent past test results.

2) Colposcopy can be deferred for certain patients.

- Repeat HPV testing or cotesting at 1 year is recommended for patients with minor screening abnormalities indicating HPV infection with low risk of underlying CIN 3+ (*e.g.,* HPV-positive, low-grade cytologic abnormalities after a documented negative screening HPV test or cotest).

3) Guidance for expedited treatment is expanded (*i.e.,* treatment without colposcopic biopsy).

- Expedited treatment was an option for patients with HSIL cytology in the 2012 guidelines; this guidance is now better defined.
- For non-pregnant patients 25 years or older, expedited treatment, defined as treatment without preceding colposcopic biopsy demonstrating CIN 2+, is preferred when the immediate risk of CIN 3+ is ≥60%, and is acceptable for those with risks between 25% and 60%. Expedited treatment is preferred for nonpregnant patients 25 years or older with high-grade squamous intraepithelial lesion (HSIL) cytology and concurrent positive testing for HPV genotype 16 (HPV 16) (*i.e.,* HPV 16–positive HSIL cytology) and never or rarely screened patients with HPV-positive HSIL cytology regardless of HPV genotype.
- Shared decision-making should be used when considering expedited treatment, especially for patients with concerns about the potential impact of treatment on pregnancy outcomes.

4) Excisional treatment is preferred to ablative treatment for histologic HSIL (CIN 2 or CIN 3) in the United States. Excision is recommended for adenocarcinoma in situ (AIS).

5) Observation is preferred to treatment for CIN 1.

6) Histopathology reports based on Lower Anogenital Squamous Terminology (LAST)/World Health Organization (WHO) recommendations for reporting histologic HSIL should include CIN 2 or CIN 3 qualifiers, *i.e.,* HSIL(CIN 2) and HSIL (CIN 3).

7) 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).

- Additional testing from the same laboratory specimen is recommended because the findings may inform colposcopy practice. For example, those HPV-16 positive HSIL cytology qualify for expedited treatment.
- HPV 16 or 18 infections have the highest risk for CIN 3 and occult cancer, so additional evaluation (*e.g.,* colposcopy with biopsy) is necessary even when cytology results are negative.
- If HPV 16 or 18 testing is positive, and additional laboratory testing of the same sample is not feasible, the patient should proceed directly to colposcopy.

8) Continued surveillance with HPV testing or cotesting at 3-year intervals for at least 25 years is recommended after treatment and initial post-treatment management of histologic HSIL, CIN 2, CIN 3, or AIS. Continued surveillance at 3-year intervals beyond 25 years is acceptable for as long as the patient's life expectancy and ability to be screened are not significantly compromised by serious health issues.

- The 2012 guidelines recommended return to 5-year screening intervals and did not specify when screening should cease. New evidence indicates that risk remains elevated for at least 25 years, with no evidence that treated patients ever return to risk levels compatible with 5-year intervals.

9) Surveillance with cytology alone is acceptable only if testing with HPV or cotesting is not feasible. Cytology is less sensitive than HPV testing for detection of precancer and is therefore recommended more often. Cytology is recommended at 6-month intervals when HPV testing or cotesting is recommended annually. Cytology is recommended annually when 3-year intervals are recommended for HPV or cotesting.

10) Human papillomavirus assays that are Food and Drug Administration (FDA)-approved for screening should be used for management according to their regulatory approval in the United States. (*Note:* all HPV testing in this document refers to testing for high-risk HPV types only).

- For all management indications, HPV mRNA and HPV DNA tests without FDA approval for primary screening alone should only be used as a cotest with cytology, unless sufficient, rigorous data are available to support use of these particular tests in management.

Reference the 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors for further details and full clinical decision-making guidance.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	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. 2019 ASCCP Risk-Based Management Consensus Guidelines Committee. J Low Genit Tract Dis 2020;24:102-31 Update to Cervical Cancer Screening and Management: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/10/updated-guidelines-for-management-of-cervical-cancer-screening-abnormalities

C4.3 – MANAGEMENT OF ABNORMAL CERVICAL CYTOLOGY IN ADOLESCENTS

Policy

Routine cervical cytology screening is not recommended in women under 21 years of age.
Reference policy Management of Abnormal Cervical Cytology Results.

Procedure

If cervical cytology testing was completed for clinical indications, the following policy should apply:

ACOG and the USPSTF recommend that cervical cancer screening should only begin at age 21, unless sexually active and:

1. HIV positive
2. Organ transplant recipient or
3. Immuno-compromised.

In these instances, begin testing yearly after diagnosis and extend to every three years after three tests are negative.

The management of abnormal cervical cytology in adolescents and young women differs from that of the adult population. Cervical cancer is almost nonexistent in adolescents; yet HPV infection is very common in this population. Natural history studies of adolescents with newly acquired HPV infection show that HPV usually becomes undetectable after an average of 8 months. In most adolescent patients with an intact immune system, 90% of HPV infections will resolve within 24 months.

The ASCCP guidelines now advise against routine HPV testing in women under the age of 30 and recommend against treatment of low-grade squamous intraepithelial lesions or cervical intraepithelial neoplasia in those under the age of 25. These new guidelines were established to minimize the potential negative impact that treatment can have on future pregnancy outcomes, while taking advantage of the natural history of HPV in young women.

Each agency must have a policy in place for management and follow-up of abnormal cervical cytology results in adolescents.

ASCCP Pap Smear (Cervical Cytology) Screening Recommendations (2012)

POPULATION	RECOMMENDED SCREENING
Under 21	Should NOT be screened regardless of the age of sexual initiation or other risk factors.+
Age 21-29	Every 3 years with cervical cytology only (reflex HPV for ASCUS results in those 26-29 years old).
Age 30-65	Every 3 years with cervical cytology OR Every 5 years with cervical cytology and high risk HPV co-testing (preferred).
Age >65	No screening following adequate negative prior screenings.*

History of Hysterectomy	No screening if done for benign indications.*
History of HPV Vaccine	Follow age specific guidelines.

[†]Unless sexually active and HIV positive/immune compromised or organ transplant recipient.
*Those with a history of CIN 2 or more severe lesion should be screened for at least 20 years.

For abnormal cytology management recommendations, please see ASCCP guidelines (2020).

Abnormal Cervical Cytology Results

ASC-US: Atypical squamous cells of undetermined significance.
ASC-H: Atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion.
LSIL: Low squamous intraepithelial lesion.
HSIL: High squamous intraepithelial lesion.
AGC: Atypical glandular cells.

Management of Abnormal Findings

If cervical cytology screening is performed during adolescence for any reason indicated above, or screening, follow-up is dictated by the Pap smear result:

- If No Abnormality: No further testing is required until age 21.
- If ASCUS or LSIL:
  - Perform cervical cytology screening yearly for 2 years.
  - If followed by two normal cervical cytology screens, can halt further testing until age 21.
  - If ASC-US/LSIL persists for 2 years, refer for colposcopy.
  - If any single cervical cytology screening shows HSIL, colposcopy is indicated.
- If ASC-H: Follow with a six month repeat screening.
  - If negative x 2, no further testing until age 21.
- If HSIL: Refer for colposcopy with endocervical sampling.

Special Considerations

Pregnancy in adolescents does not alter screening and management of abnormal cytology. Endocervical curettage and excisional procedures should never be performed during pregnancy unless invasive cancer is highly suspected. Screening for pregnancy, therefore, should be performed before evaluation and management of abnormal cervical cytology in adolescents.

Consent

Minors undergoing a colposcopic examination may find it helpful to have parental involvement for the procedure. However, colposcopic examinations are considered evaluation for STIs, and minors are allowed to consent for diagnosis and treatment of STIs. For that reason, parental consent, although preferred, is not required to perform the procedure.

If parental consent is not obtained, consent for the examination should be obtained from the minor and indicated in the medical record. Any Clinical Service Provider who delivers such care should be fully informed of their state laws and established local standards of care. Even if the minor legally can consent, the law may not ensure confidentiality. Some states allow minors to consent for STI care, but give the Clinical Service Provider discretion to disclose information to parents, particularly if it is necessary to protect the minor's health. Colposcopy, biopsy and therapy for cervical dysplasia are likely to generate a bill, which can compromise confidentiality. These issues need to be considered when determining whether parental consent should be obtained, even if it is not legally required.

Screening for STIs

Having a non-HIV STI diagnosis is not an indicator for earlier cervical cytology screening. Because of high rates of STIs in adolescents, screening and treatment for Chlamydia trachomatis and Neisseria Gonorrhea before treatment for abnormal cervical cytology is strongly recommended. *Reference Sexually Transmitted Infections and HIV policy for further guidance.*

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	ACOG Updated Cervical Cancer Screening Guidelines, April 2021 (https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/04/updated-cervical-cancer-screening-guidelines

C4.4 – ABNORMAL BREAST FINDINGS

Policy

Despite a lack of definitive data for or against clinical breast exams, they do have the potential to detect previously undetected breast masses. Patients should be informed there is not enough evidence to balance the benefits and risks of screening. However, if a client presents with concerns, the following should be considered. If a client requests a clinical breast exam, it should be performed. An August, 2019 USPSTF report recommends using an assessment tool (like the Ontario Family History Assessment Tool) for women with a personal or family history of breast, ovarian, peritoneal, or tubal cancer or those with ancestry associated with BRAC 1/2. Routine genetic assessment and testing is not indicated in women who don't meet the above criteria.

Procedure

Abnormal Breast Mass

Subjective	• *"Lump" felt during a self-exam.* • *Enlarging breast mass with no cyclic changes.* • *Maternal history of breast cancer.* • *History of nipple change, discharge or bleeding.* • *Breast pain.* • *History of previous mastitis, papillomas or fibroadenomas.* • *Recent postpartum breast-feeding.*
Objective	• *Uneven nipple line on breast exam.* • *Palpable, fixed, unilateral, hard mass.* • *Orange peel appearance.* • *Unilaterally enlarged or tender axillary and/or supraclavicular lymph nodes.* • *Galactorrhea.* • *Nipple discharge.* • *Reddened and/or warm area on breast.* • *Pain on palpation* • *Fever > 38˚c (100.2˚F)*
Assessment	*Suspicious breast mass or mastitis.*
Plan	*Order appropriate testing or refer to appropriate Clinical Services Provider. If lesion is not suspicious and the client is on oral contraceptives, may continue for 1-2 cycles pending evaluation. If lesion is suspicious, discontinue combined oral contraceptive and offer an alternate birth control method pending evaluation.*
Patient Education	*Stress importance of immediate follow-up evaluation.* *If mastitis is suspected, instructions include:* • *Use heat to area.* • *Continue nursing or use breast pump if breastfeeding.* • *Rest and hydration.* • *Complete course of antibiotics if ordered.* • *Good hygiene and attentive breast care.*

Fibrocystic Breast Disease

Subjective	• Increased "lumpiness" of breasts. • Multiple masses (may or may not be cyclic). • Breast tenderness.
Objective	Multiple, non-fixed masses, usually bilateral.
Plan	Order appropriate testing or refer to appropriate Clinical Services Provider.
Alternative Treatment	Re-check after menses if patient is premenstrual and exam is suspicious.

Patient Education	• Reinforce self-breast exam as desired.
	• Stress importance of follow-up.
	• Advise patient of the following:
	  o Consider limiting or eliminating caffeine if symptoms are associated, although medical studies of caffeine's effect on breast pain and other premenstrual symptoms have been inconclusive.
	  o Heat or cold compresses may decrease pain.
	  o Breasts should be well supported.
	  o Mild analgesics may be helpful.
	  o Wear a firm support bra, fitted by a professional if possible.
	  o Wear a sports bra during exercise and while sleeping, especially when your breasts are extra sensitive.
	  o Decrease the fat in your diet to less than 20 percent of total calories, which may decrease breast pain or discomfort associated with fibrocystic breasts.

Galactorrhea

Subjective	• Nipple discharge, bilateral or unilateral.
	• History of recent pregnancy.
	• History of recent use of:
	  o Marijuana.
	  o Tranquilizers and antipsychotics (e.g., Phenothiazines such as Chlorpromazine, Thioridazine, Trifluoperazine, Thiothixene Hcl, and Haloperidol).
	  o Tricyclic antidepressants (e.g., Amitriptylines, Tofranil).
	  o Narcotics (e.g., Morphine, Codeine, Methadone).
	  o Antihypertensives (e.g., Methyldopa, Reserpine. Verapamil).
	  o Oral contraceptives/Depo-Provera.
	  o Cimetidine, Metoclopramide.
	• History of breast stimulation.
	• Recent change in headache patterns.

	• Recent change in peripheral vision. • Symptoms of Hyperthyroidism, Acromegaly, Cushing's syndrome.

Other Breast Discharge

Subjective	• Bloody, purulent or greenish discharge, bilateral or unilateral. • History of breast stimulation. • History of pain or redness. • History of fever. • History of previous ductal papillomas or other.
Objective	• Bilateral or unilateral bloody or purulent discharge. • Reddened and/or warm area on breast. • Pain on palpation.
Assessment	Other breast discharge.
Plan	Order appropriate testing or refer to appropriate Clinical Services Provider.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html) Title X Program Handbook (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf)
Additional Resources	The United States Medical Eligibility Criteria for Contraceptive Use, 2016 (US MEC) - https://www.cdc.gov/mmwr/volumes/65/rr/rr6503a1.htm?s_cid=rr6503a1_w

C4.5 – EXPEDITED PARTNER THERAPY

Policy

The purpose of this policy is to promote the health of individuals by treating the sex partners of patients diagnosed with STIs (chlamydia and/or gonorrhea). Clinical Services Providers may provide prescriptions or medications to the patient's partner(s) without examining the partner(s). This practice is recommended by the CDC and allowed under Iowa Code section 139A.4.

Procedure

- When a client requires treatment for STIs, Clinical Services Providers should recommend that any sexual partners in the past 60 days be treated.
- Ideally, the partner(s) should attend the clinic to be evaluated, examined, tested, counseled and treated by a Clinical Services Provider.
- If the partner is unable or unwilling to seek medical care, Expedited Partner Therapy (EPT) will be offered.
- If a client reports no partners in the past 60 days, education needs to be provided to the patient on safe sex practices. In addition, medication or a prescription is provided for the most recent partner.
- The client and partner will be instructed to avoid intercourse until 7 days after both have been treated.
- The patient's chart will include information about the number of partners (names excluded) being provided with EPT, the medication, quantity and dosage provided to the partner. Each agency will determine how documentation is completed for EPT.
- Patient's insurance or Medicaid will NOT be billed for EPT for their partner.
- Written medication information will be provided for each partner either in person or given to the client to give to the partner using medication sheets provided by Iowa HHS. Partners are encouraged to be clinically evaluated after receiving their EPT, informed of symptoms that need immediate evaluation, warned not to take medication if they are allergic, and informed of common side effects.

Header 2 based on policy

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)

	Title X Program Handbook (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf)
Additional Resources	The United States Medical Eligibility Criteria for Contraceptive Use, 2016 (US MEC) - https://www.cdc.gov/mmwr/volumes/65/rr/rr6503a1.htm?s_cid=rr6503a1_w Expidited Partner Therapy in Iowa: /https://hhs.iowa.gov/media/7600/download?inline=

C4.6 – SEXUALLY TRANSMITTED INFECTIONS AND HIV

Policy

At the initial visit and annually thereafter, each client must be counseled about STIs and be given information needed to reduce their risk of acquiring or transmitting STIs and HIV. Clients should be made aware that whenever they have unprotected sexual intercourse (no barrier method is used), they are exposed to any STIs their partner either has had or has, and also to any diseases that the partner's former or current partners have had.

Clients need to be made aware of common STIs, their symptoms and complications, and the importance of diagnosis and treatment. Clients will be informed about where to go for testing, treatment and follow-up if services are not provided on-site.

Procedure

Counseling and Education

Requires addressing the following areas:	• Individual dialogue about personal risks and risk reduction. • At-risk behavior, risk reduction and further evaluation. • HIV education, risks and referral.
Counseling should also include the following information:	• Abstinence is the most effective method to avoid STIs and HIV. • Barrier methods can significantly reduce, but not eliminate STIs. • Oral sex can also result in STIs.
STIs that must be discussed include:	• HIV. • Chlamydia. • Gonorrhea
STIs that should be discussed include:	• Genital herpes. • Cytomegalovirus. • Trichomoniasis. • Pediculosis pubis. • Scabies. • Hepatitis B. • Syphilis.

Screening and Testing

SRs have the option and are highly recommended to participate in the state Community Based Screening Services project (CBSS). This program provides testing for chlamydia and gonorrhea. SRs that participate in the CBSS must comply with the following:

1. CBSS Screening Criteria.
2. Iowa STI Reporting Requirements.
3. CDC and Prevention Treatment Guidelines.

Screening and testing for other STIs should be conducted based on the CDC recommendations.

Hepatitis C testing should be recommended based on CDC's Testing Recommendations for Hepatitis C Virus Infection. Persons with HIV infection should be tested at least annually for Hepatitis C.

Rescreening (or retesting) is recommended three (3) months after someone is treated for chlamydia or gonorrhea. The timeline is the same for both infections. This is to check for re-infection (since this is common with these infections, especially from asymptomatic partners). If it can't occur at three (3) months, it should occur as soon as possible after that.

A test of cure is recommended for gonorrhea if someone is treated with a regimen outside of the CDC STI Treatment Guidelines. This is to check to see whether the person is truly cured. The recommended timeframe from CDC on this is 7-14 days after the completion of treatment. We say 14 days with CBSS sites because with 7 days, you may detect dead bacteria with nucleic acid amplification tests (NAATs) -- essentially a false positive result. 14 days gives more space and reduces the likelihood of detecting dead bacteria. Additionally, the test of cure 14 days after treatment applies to anyone with pharyngeal (throat) gonorrhea, even if a recommended treatment is used. This is because pharyngeal gonorrhea is notoriously more difficult to treat than urogenital or rectal gonorrhea.

Treatment

If client tests positive for an STI, treatment and follow-up must follow CDC STD Treatment guidelines.

EPT is legal for treatment of Chlamydia and Gonorrhea in Iowa and should be utilized when appropriate. *Reference Expedited Partner Therapy Policy C4.5 for further guidance.*

The Iowa CBSS gives Title X access to STI treatment drugs purchased by the Iowa HHS STD Prevention Program.

Reporting

SRs are required to comply with all reporting laws. In the State of Iowa, chlamydia, gonorrhea, syphilis, HIV and AIDS are reportable to Iowa HHS. By Iowa Code, both the CSP who ordered the test and the laboratory that processed the specimen are to report names and other patient demographics to Iowa HHS. This information is protected by law and cannot be released to anyone other than individuals (disease prevention specialists and county public health communicable disease investigators) who perform partner notification and partner referral. In Iowa, by law, a minor can be tested and treated for STIs without parental consent.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)

	Title X Program Handbook (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf)
Additional Resources	Current CDC STD Treatment Guidelines; CDC revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings; CDC's Testing Recommendations for Hepatitis C Virus Infection: https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf

C5.1 – PHARMACY LABELING OF MEDICATION AND SUPPLIES

Policy

Title X SR staff is allowed by code to dispense contraceptive methods (Iowa Code, Section 234.22). TItle X funded clinics should not fill prescriptions for contraceptive supplies not written/provided by clinic staff. Title X clinics are not licensed pharmacies, and therefore provide prescriptive supplies to only their own patients.

Procedure

Patient safety is best insured by providing clear, written information about any prescription provided. Therefore, each prescription medication must be labeled with the following:

1. Client name.
2. Clinical Services Provider name and agency name.
3. Name of prescribed medication.
4. Directions for use.
5. Lot number.
6. Quantity dispensed.
7. Expiration date.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Iowa Code, Section 234.22

C5.2 - ABSTINENCE

Policy

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

Abstinence is another form of sexual expression. The term "abstinence" has several meanings:

- Refraining from all sexually expressive behavior (Sexual Risk Avoidance).
- Refraining from sexual behavior involving genital contact (Sexual Risk Reduction).
- Refraining from penetrative sexual practices (Sexual Risk Reduction).

Procedure

Effectiveness

When used correctly and consistently, abstinence is 100% effective against pregnancy and STIs.

Contraindications

There are no known contraindications to abstinence.

Advantages

- Only form of birth control that is 100% effective when used consistently and correctly.
- May promote intimacy by discussing sexual choices with partner.
- Prevents STIs.

Disadvantages

There are no known disadvantages to abstinence.

Side Effects

There are no known side effects from abstinence.

Subjective

- Ask the client how they define abstinence and work with their definition.
- Primary abstainers have never had sexual intercourse with another person.
- Secondary abstainers are sexually experienced but for various reasons no longer engage in behaviors they consider as "having sex." Individuals may voluntarily abstain, not be in a current relationship, unhappy with a relationship or have an estranged relationship, be fearful of a STI, have the presence of others in the home, have a geographical separation from their partner, have poor health, an illness or injury, or be pregnant or had a recent childbirth.

- Abstinence may be involuntary in instances of loss of a partner, incarceration, medical reasons or other causes.

Objective

Clinical examination is not necessary.

Plan

- Support the individual's choice.
- Provide information about abstinence.
- Discuss EC and condom use.
- Recommend age-appropriate periodic assessment.

Client Education

1. Clients must receive:
   a. Information about all types of contraceptive options.
   b. Information about ECs including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
2. Discuss with client:
   a. They should make decisions about abstinence when they are clearheaded and sober, not in the heat of the moment. Decide with their partner about the right time to have intercourse which should be a mutual decision without coercion or pressure.
   b. Discuss and decide with their partner, in advance, what sexual activities they will and will not do.
   c. Avoid high-pressure sexual situations (drunk or high).
   d. Always have condoms on hand if they change their minds.
   e. Learn more about their body and how to keep it healthy.
   f. Learn about contraception and safe sex.
   g. 100% abstinence, 100% of the time is 100% effective against pregnancy and STIs.
   h. Abstinence is free and always available to everyone.
   i. Abstinence requires a high level of motivation.
3. Recommend the use of condoms, barrier method or initiation of contraceptive method to prevent pregnancy and STI/HIV if/when they are no longer abstinent.
4. In instances of involuntary abstinence, counseling about relationships or other forms of sexual expression can be offered.

Fertility Return

Absitince does not cause any disruption to fertility.

Referral

Referred services are not Title X funded.
As indicated by history, physical examination or lab findings.

Date Revised	September 2023
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html) Title X Program Handbook (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf)
Additional Resources	

C5.3 – ETONOGESTREL SUBDERMAL CONTRACEPTIVE IMPLANT

Policy

The etonogestrel 68mg subdermal implant (Nexplanon®) is an implantable form of birth control that is completely reversible. It is a single flexible, radiopaque, soft, thin plastic rod that is placed under the skin of the client's upper arm (ideally, non-dominant arm). Per FDA requirements, all Clinical Services Providers performing insertions and/or removals of the contraceptive subdermal implant should receive instructions, training and certification by the manufacturer prior to inserting or removing the implant. Clinical Services Providers should see Warnings and Precautions on current Prescribing Information follow manufacturer information for removing the implant. Counsel clients about back-up contraception as appropriate. Recent data on duration of action, show that the etonogestrel subdermal implant is efficacious for up to the end of the 4th year (see citation below), however it is FDA approved for up to 3 years of use. Please engage in discussion with the patient about the difference in FDA approval versus evidence-based efficacy as well as access to removal. It is vital that patients understand how to access removal of a LARC device prior to insertion.

Clients should be given information about the risks of implant insertion as part of the informed consent process. It is also very important to discuss the changes that can result in menstrual bleeding as a result of implant placement.

Procedure

Mode of Action

Etonogestrel 68mg sub-dermal implant has two main mechanisms of action:

1. Primarily, it effectively inhibits ovulation.
2. It increases the viscosity of cervical mucus making it more difficult for sperm to enter the uterus.

Effectiveness

The pregnancy rate is less than 1 per 200 women, which translates to an effectiveness of >99%.

Contraindications

Absolute Contraindications

- Pregnancy.
- Current breast cancer.
- Known hypersensitivity to any components of Nexplanon®-plastic (Ethylene Vinylacetate copolymer) rod, core of Ethylene Vinyl Acetate and Etonogesterol.

Strong Relative Contraindications

Exercise caution when providing/monitor for side effects:

- Undiagnosed vaginal bleeding.
- Malignant and benign liver tumors or hepatocellular adenoma.
- Current and/or history of ischemic heart disease.

- Past history of breast cancer with no evidence of disease for 5 years.
- Use of certain anticonvulsants that can decrease the efficacy of Nexplanon®:
- Phenytoin, carbamazepine, barbiturates, primidon topiramate, and oxcarbazepine.
- Cirrhosis – severe.
- Systemic lupus erythematosus **with** positive (or unknown) antiphospholipid antibodies.
- History of stroke

Other Considerations

The advantages of using the subdermal progestin implant generally outweigh the theoretical or proven risk. Please review the CDC medical eligibility criteria summary chart.

Advantages

- No action is required for contraception after insertion.
- It is always there when needed and is effective up to the end of the 4th year of use for contraception.
- Progestin is considered to be estrogen–friendly, therefore no impact on bone density.
- Can be inserted at any time if it is reasonably certain that the client is not pregnant.
- Has no impact on lactation and milk production, even when placed immediately after delivery.
- Overall reduction in menstrual bleeding.

Disadvantages

- Must be changed every 4-5 years (see citations below).
- Unpredictable bleeding patterns after placement that can range from infrequent to prolonged
- Requires Clinical Services Provider to insert and remove.
- Does not protect from STIs

Side Effects possible related to the implant

- Irregular and unpredictable bleeding ranging from infrequent to prolonged.
- Headache.
- Acne.
- Emotional lability
- Breast tenderness
- Weight gain is not associated with the implant. Average gain is 2.8 pounds at 1 year and 3.7 pounds at 2 years, which is not significantly dissimilar from non-users

Warning Signs

- Any subjective symptoms of pregnancy.
- Any sign of a blood clot, including sharp chest pain, sudden shortness of breath, persistent calf pain, crushing chest pain, heaviness in the chest, sudden severe headache, vomiting, dizziness or fainting with visual problems.
- Sudden partial or complete blindness.
- Yellowing of skin and whites of the eyes.
- Severe pain, swelling or tenderness in the abdomen.
- Breast lumps.
- Signs of severe depression.
- Heavy vaginal bleeding
- Complications with insertion or removal of device

Potential Complications Associated with the subdermal contraceptive implant

- Pain, irritation, swelling, hematoma or bruising at insertion site.
- Scarring, including a thick scar called a keloid.
- Infection.
- Implant breaks make removal difficult.
- Rarely expulsion of implant.
- Rarely need for surgery to remove an implant.
- Migration of the implant into surrounding or farther structures
- Ectopic pregnancy risk is not increased with the implant, but in the unlikely event that a pregnancy occurs while the implant is in situ, it must be ruled out.
- Interactions with other medicines (see website).
- Headache.
- Acne

Interactions with Other Medications

Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal and implantable contraceptives. Antiretroviral medications (such as efavirenz and fosampenavir) may impact etonogestrel levels but are not felt to be contraindications to implant use. Anti-epileptic medications can also interact with systemic hormonal contraceptives, such as the subdermal contraceptive implant. Please review all client medications thoroughly prior to insertion.

Instructions to the Client

The only maintenance of the subdermal contraceptive implant involves:

- Client aware of danger signs.
- Annual exam to assess problems and check position of Nexplanon® as well as provide other reproductive health cares.
- Client aware of when it should be replaced and how to access removal services.
- Call the clinic with any problems related to the method

Fertility Return

Clients should be aware of the variable lengths of time for fertility return after discontinuing any contraceptive, however, vast majority of women have rapid return to fertility after subdermal implant removal with average ovulation being 3 weeks after removal. Immediate use of an alternative contraceptive is recommended after removal if the client is not seeking pregnancy. Encourage prenatal vitamin initiation at time of removal if not switching to a different highly or moderately effective contraceptive method.

Hormone Contraception and HIV

The CDC has affirmed the safe use of hormone contraception in women who are HIV positive.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014]

	(https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf) Thaxton L and Lavelanet A. Systematic review of efficacy with extended contraceptive implant duration. International Journal of Gynecology and Obstetrics. 21 October 2018. https://doi.org/10.1002/ijgo.12696 McNicholas C, Maddipati R, Zhao Q, Swor E, Peipert JF, Use of etonogestrel implant and levonorgestrel iontrauterine device beyond the US FDA-approved duration. Obstetrics and Gynecolog. 125(3):599. 2015 Ali M, Akin A, Bahomondes L, Brache V, Habib N, Landouylsi S, Hubacher D, WHO study group on subdermal implants for women. Extended use up to 5 years of the etonogestrel-releasing subdermal contraceptive implant: comparison to levonogestrel implant. Human Reproduction. 31(11):2491. 2016

C5.4 – LEVONORGESTREL-RELEASING INTRAUTERINE DEVICE

Policy

There are multiple levonorgestrel-releasing Intrauterine Devices (LNG IUD) available in the United States. The prescribing information is similar for all the LNG IUDs, but Clinical Services Providers are expected to know the specific indications and prescribing information for each method. The policy below is generalized. The LNG IUDs are T-shaped polyethylene frame compounded with barium sulfate and with a drug reservoir around the vertical stem. The reservoir contains the LNG and allows for sustained release over the duration of action. The barium sulfate allows the IUD to be visible on x-ray imaging. The typical dose LNG IUD contains 52mg of levonogestrel (Liletta® and Mirena®) that is released initially at a rate of 20mcg per day. This rate decreases progressively to approximately 6.5mcg per day at 8 years. Thus, the average release rates over 8 years are approximately 13.5 mcg per day.

Misoprostol is **not** recommended for routine use before LNG IUD insertion. Misoprostol at the time of insertion might be helpful in select circumstances (e.g., in women with a recent failed insertion). Paracervical block with lidocaine might reduce patient pain during LNG IUD insertion in nulliparous clients. Insertion should not be delayed to allow for patients to be on their menses, unless pregnancy cannot be reliably excluded. Insertion during menses does not improve pain with insertion or decrease risk of failed insertion. Clients should be given information about insertion risks, expected bleeding changes, and other risks/benefits of the LNG IUD as part of the informed consent process. It is vital that patients understand how to access removal of a LARC device prior to insertion.

Procedure

Mode of Action

It is not known exactly how the LNG IUD works; the following are hypotheses:

- The most likely way that the IUD prevents pregnancy is by thickening cervical mucus, which interferes with sperm motility and function.
- A weak local foreign body inflammatory response is noted with the IUD, but is less pronounced than with copper IUDs.
- Prevents endometrial proliferation-full suppression noted after about 3 months with substantial (70-100%) decrease in menstrual flow with the 52mg LNG IUD (Liletta® and Mirena®). The amount of menstrual bleeding reduction is less with the lower dose LNG IUD (19.5mgLNG IUD/Kyleena®).

Effectiveness

Theoretical and actual effectiveness rate are 99.9%.

Contraindications

Absolute Contraindications

Unacceptable Health Risk (method should not be used):

- Known or suspected pregnancy.

- Acute, active pelvic infections/STI, current pelvic inflammatory disease, including immediate postpartum uterine infection/sepsis.
- Gestational Trophoblastic Disease with persistently elevated beta HCG levels or malignant disease **with** evidence or suspicion of intrauterine disease.
- Uterine abnormalities, including a distorted uterine cavity such as bicornuate uterus, other Mullerian anomalies, or fibroid(s) distorting the cavity.
- Cervical cancer, awaiting treatment.
- Immediately post-septic abortion.
- Pelvic tuberculosis.
- Unexplained vaginal bleeding.
- Current pregnancy (unless being used as EC) or inability to rule out pregnancy.
- Breast cancer, current.

Strong Relative Contraindications

Theoretical or proven risks usually outweigh the advantages:

- Complicated solid organ transplantation.
- Breast cancer in the past with no evidence of disease for the past 5 years.
- Malignant Hepatoma, hepatocellular adenoma or severally decompensated cirrhosis/liver failure.
- Systemic lupus erythematosus with unknown or positive anti-phospholipid antibodies.

Other Considerations

The advantages of using the IUD generally outweigh the theoretical or proven risk.
Refer to the Appendix for the CDC Medical Eligibility Criteria Summary Chart

Advantages

- No action is required for contraception
- The LNG IUD should not be noticeable during intercourse.
- It is always there when needed.
- Reduction in menstrual bleeding and related anemias.
- Reduction in dysmenorrhea.
- Reduction in ectopic pregnancies through an overall reduction in pregnancies.
- Can be inserted at any time if it is reasonably certain the client is not pregnant.
- Rapid return of fertility when removed.
- Does not alter breast milk production.

Disadvantages

- Must be changed periodically as indicated by the manufacturer
- May be expelled without the client's knowledge.
- Does not protect against STIs.
- Require cervical inspection and bimanual exam before insertion.

Side Effects possible related to the implant

- Irregular periods for 3 to 6 months post-insertion. Discuss the immediate return of fertility following discontinuation. Immediate use of alternative contraception after removal of IUD is recommended if the client is not desiring pregnancy.
- Amenorrhea in 1/5 of women.
- Possible hormonal side effects (mood changes, acne, headache, breast tenderness, nausea, hirsutism) however, these are typically temporary.

Warning Signs

- A late or missed period is seldom related to pregnancy unless accompanied by other signs and symptoms of pregnancy, but should be evaluated if new onset.
- Abdominal pain or pelvic pain or pain with intercourse (suggests perforation, partial expulsion, or infection).
- Fever/Chills (suggests infection) accompanied by pelvic pain.
- Foul vaginal discharge (suggests infection).
- Missing or change in length of LNG IUD strings (suggests expulsion or displacement).
- Severe or prolonged vaginal bleeding or spotting.
- Yellowing of skin or eyes.

Potential Complications Associated with Levonorgestrel IUD

- Uterine perforation, although this is very rare.
- Vaso-vagal response with insertion/removal (hypotension, pallor, brachycardia, feeling faint etc).
- Intra-uterine infection risk is increased in the first 3 weeks after IUD placement, but then returns to baseline. Risk of STI's is not increased with LNG IUD placement and STI can be treated with IUD in place.
- Rejection/expulsion of device (rate of expulsion may be increased with nulliparous women).
- Pregnancy.
- Risk of possible spontaneous abortion if conception occurs (chances are 25% risk if IUD removed, and 50% if LNG IUD left in place).
- The FDA approved lifespan for each LNG IUD is variable. See prescribing information. Use of any IUD beyond the approved lifespan is considered off-label use.
- LNG IUD are very effective in preventing pregnancy, so there is an overall decreased risk of pregnancy. Increased risk of ectopic pregnancy in the unlikely event a pregnancy occurs; women should be encouraged to seek immediate care with known or suspected pregnancy.

STI Testing

If a client has not been screened for STIs according to CDC STI screening guidelines, screening must be performed at the time of insertion. STI can be treated with an IUD in place.

Instructions to the Client

The only maintenance of the LNG IUD involves:

- Client checking devise string monthly if the client finds these reassuring, but it is not necessary.
- Client aware of danger signs including those of infection, expulsion and bleeding/cramping expectations after LNG IUD insertion.

- Annual exam for preventative care, also able to assess problems and check position of the IUD.
- Clients should be aware of type of IUD and duration of action to ensure timely removal and replacement. Please ensure that the client knows how to access removal services.
- Counsel about the need for back-up contraception as appropriate.
- Call the clinic with any problems related to method.

Fertility Return

Return to fertility after removal is typically rapid. Immediate use of an alternative contraceptive is recommended after removal if the client is not seeking pregnancy. Encourage prenatal vitamin initiation at time of removal if not switching to a different highly or moderately effective contraceptive method.

Interactions with Other Medications

Not applicable.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)

C5.5 - COPPER T380-A INTRAUTERINE DEVICE (IUD)

Policy

The Copper T-380A Intrauterine Device (ParaGard®) is a small T-shaped device made of polyethylene with added barium sulfate for x-ray visibility. The T-shaped device has fine copper wire wound around the vertical stem. The horizontal arms of the T have a sleeve of copper around them. The bottom of the T has a white knotted loop of polyethylene string. Clients should be given information about the risks of insertion as part of the informed consent process. Clients should be adequately counseled about the bleeding and cramping expectations after placement of a copper IUD, which often increases menstrual bleeding and cramping by about 30%.

Procedure

Mode of Action

It is not known exactly how the Copper IUD works, however it is thought that the main mechanism of action is the prevention of fertilization through a cytotoxic inflammation that is spermicidal. Copper IUD is also thought to work via the following mechanisms:

- Local foreign body inflammatory response causing lysis of the blastocyst and/or prevention of implantation, although evidence suggests that fertilization occurs in less than 1% of cycles.
- Copper interferes with estrogen uptake and its intracellular effects on the endometrium.
- Copper concentration in cervical mucous is high. The copper inhibits sperm motility and is spermicidal.

Effectiveness

Theoretical and actual effectiveness is 99.0-99.4%.

Contraindications

Absolute Contraindications

Unacceptable Health Risk (method should not be used):

- Known or suspected pregnancy.
- Acute, active pelvic infections/STI, including immediate postpartum uterine infection.
- Gestational trophoblastic disease with persistently elevated beta HCG Levels or malignant disease with evidence or suspicion of intrauterine disease, uterine abnormalities (a distorted uterine cavity such as bicornuate uterus or fibroid distorting the cavity).
- Cervical cancer, awaiting treatment.
- Endometrial cancer.
- Severe dysmenorrhea (if has not tolerated the Copper IUD previously).
- Immediately post-septic abortion.
- Pelvic tuberculosis.
- Unexplained vaginal bleeding.
- Current pregnancy (unless being used as EC) or inability to rule out pregnancy.

Strong Relative Contraindications

Theoretical or proven risks usually outweigh the advantages:

- Complicated solid organ transplantation.

Other Considerations

The advantages of using the IUD generally outweigh the theoretical or proven risk.
Refer to the Appendix for the CDC Medical Eligibility Criteria Summary Chart

Advantages

- No action is required for contraception
- The Copper IUD should not be noticeable during intercourse.
- It is always there when needed.
- It contains no hormones.
- Its duration of action is 10-12 years.
- Users should continue to have a regular menstrual cycle.

Disadvantages

- Must be changed periodically as indicated by manufacturer (10 years).
- May make menses heavier and more painful.
- May be expelled without the client's knowledge.
- Does not protect against STIs.

Side Effects

- Increased dysmenorrhea.
- Heavier menstrual flow.
- Mid-cycle bleeding (may be a symptom of infection).
- Spotting (not unusual in the first 3 months).

Warning Signs

- A late or missed period and/or feelings of pregnancy.
- Abdominal pain, pelvic pain or pain with intercourse (suggests perforation or infection).
- Fever/Chills (suggests infection).
- Foul vaginal discharge (suggests infection).
- Missing or change in length of IUD strings (suggests expulsion or displacement).
- Severe or prolonged vaginal bleeding (suggests dislocation or perforation).

Potential Complications Associated with Paragard®

- Uterine perforation, although this is rare. Difficulty removing the Copper IUD.
- Infection secondary to placement (this risk only is present for the first 21 days after placement).
- Expulsion of device (rate of expulsion may be increased with nulliparous women).
- Intra-uterine infection risk is increased in the first 3 weeks after IUD placement, but then returns to baseline.

Risk of STI's is not increased with IUD placement and STI can be treated with IUD in place.

- If a pregnancy occurs, there is a substantial risk of possible spontaneous abortion if intra-uterine conception occurs (chances are 25% risk if IUD removed, and 50% if IUD left in place).
- The FDA approved lifespan for each IUD is variable. The Copper T380-A is FDA approved for 10 years, but is efficacious for up to 12 years. Clinical providers should discuss the difference between FDA approved duration of action and evidence-based duration of action.
- IUD are very effective at preventing pregnancy, so there is an overall significant decreased risk of pregnancy. However, if a conception occurs, and in the unlikely event the fertilized egg implants and a pregnancy begins, it is more likely that the pregnancy is ectopic. Patients with an IUD and known or suspected pregnancy, should be encouraged to immediately seek care.

STI Testing

If a client has not been screened for STIs according to STI screening guidelines, screening must be performed at the time of insertion. STI can be treated after insertion, with the Copper IUD remaining in place.

Instructions to the Client

The only maintenance of the Copper IUD involves:

- Client checking IUD strings at end of each menses (if this is reassuring to the client, if not, it is not necessary).
- Client aware of danger signs.
    - i) A late or missed period. Periods should continue to be monthly/regular with a Copper IUD. Periods often are heavier and crampier with Copper IUD. If you miss a period, do a pregnancy test right away.
    - ii) Abdominal pain or pelvic pain or pain with intercourse (may suggest infection or abnormal location of the IUD). You see your IUD, because it has fallen out (expulsion)
    - iii) Fever/Chills (suggesting infection) accompanied by pelvic pain—especially if in the first month after insertion.
    - iv) Foul vaginal discharge (suggests infection) or new exposure to any sexually transmitted infection
    - v) Missing or change in length of strings
    - vi) Severe or prolonged vaginal bleeding
- Annual exam for preventative care, also able to assess problems and check position of the IUD.
- Client should be aware of type of IUD to insure timely replacement.
- Client should be aware of how to access removal services.
- Call the clinic with any problems related to method.

Fertility Return

Return to fertility after removal is typically rapid/immediate. Immediate use of an alternative contraceptive is recommended after removal if the client is not seeking pregnancy. Encourage prenatal vitamin initiation at time of removal if not switching to a different highly or moderately effective contraceptive method.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of

	Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)

C5.6 - STERILIZATION

Policy

Sterilization is a permanent method of birth control and must be considered irreversible. There are generally two accepted types of permanent sterilization available in the US:

- Vasectomy - Interruption of the vas deferens tubes in the penis/testicles prevents sperm from being ejaculated in the semen.
- Bilateral Tubal Ligation/salpingectomy - Interruption or removal of the fallopian tubes in the pelvis prevents the ovum from descending the tube and from coming in contact with the sperm

Federal regulations must be met if sterilization procedure is performed or arranged by Title X. Sterilization of clients as part of Title X must be consistent with 42 CFR part 50 subpart B, ("Sterilization of Persons in Federally Assisted Family Planning Projects").

Procedure

The Iowa HHS Title X Program does not allocate funding for sterilization services. If an individual is interested in pursuing sterilization services, the SR shall provide a referral.

Date Revised	September 2023
References	Title X Program Handbook (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf) Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	

C5.7 - PROGESTIN HORMONE INJECTION-DEPO-MEDROXYPROGESTERONE ACETATE (DMPA)

Policy

Depo-medroxyprogesterone acetate (DMPA), which is marketed as Depo-Provera® may be administered by either deep intramuscular injection (150mg/1 ml) or subcutaneously (104mg/0.65 ml) based on the manufacturer's instructions. The only difference between these formulations is the route of administration and dose. The duration of action, mechanism of action, return to fertility, side effects and pain with administration are all similar or the same. The decision to use intramuscular or sub-cutaneous DMPA should be based on client preference, available supply, and cost.

Procedure

Mode of Action

When administered at the recommended dose to women every 12 weeks, DMPA inhibits the secretion of gonadotropin, which in turn prevents follicular maturation and ovulation and results in endometrial thinning. These actions produce its contraceptive effect.

Effectiveness

Theoretical use effectiveness is 99%, when administered every 12 weeks.
Typical use effectiveness is 96% and depends on punctuality of injections.

Indications for Use

- Clients who have developed estrogen-related complications while taking combined OCs or have medical conditions where estrogen is not recommended.
- Clients request.

To increase assurance that the client is not pregnant at the time of the first administration, it is recommended that Depo-Provera be administered only:

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

Contraindications

Absolute Contraindications

- Known or suspected pregnancy.
- Undiagnosed vaginal bleeding.
- Known or suspected malignancy of the breast.
- Known sensitivity to DMPA.

Strong Relative Contraindications

Theoretical or proven risks usually outweigh the advantages:

- Diabetes longer than 20 years or if accompanied by vascular disease, neuropathy or retinopathy.
- Hypertension (systolic ≥ 160 or diastolic ≥ 100)
- Plans pregnancy within 1 year.
- Inability to tolerate irregular, frequent bleeding which may occur with DMPA.
- Inability to tolerate amenorrhea, which is common with DMPA.
- History of breast cancer with no evidence of current disease for 5 years.
- Liver tumor or hepatocellular adenoma
- History of CVA.
- Ischemic heart disease (current or history of) Systemic lupus erythematosus with positive antiphospholipid antibodies or severe thrombocytopenia.
- Multiple risk factors for cardiovascular disease or atherosclerosis (i.e., older age, smoking, diabetes, hypertension, low HDL, high LDL or high triglyceride levels).
- Epilepsy treated with medications that can lower the effectiveness of systemic hormonal contraception, including but not limited to phenytoin, carbamazepine, barbiturates, primidon topiramate, and oxcarbazepine.

Relative Contraindications

The advantages of using the DMPA generally outweigh the theoretical or proven risk.
Refer to the Appendix for the CDC Medical Eligibility Criteria Summary Chart

The CDC has affirmed the safe use of hormone contraception in clients who are HIV-positive. Clients should be strongly advised to always use condoms. There are no contra-indications to any hormonal contraceptive in HIV positive women.

Advantages

- May be used for clients who cannot or prefer not to take estrogen.
- Convenient; not related to sexual intercourse.
- Provides relatively long-term protection.
- Because of decreased menstrual flow, may decrease menstrual cramps, PMS and ovulatory pain.
- When initiated at 6 weeks after delivery, there is no impact on lactation.

Disadvantages

- Bleeding irregularity, principally amenorrhea. Possible delay in resumption of menses after discontinuing method.

- Bone mineral density changes. Bone density measurements or testing is not indicated at any time due solely to DMPA use.
- Fluid retention.
- Weight changes (average 8.1 lb. in 2 years).
- Delayed return of fertility (median time is 10 months following the last injection, but can be up to 18 months in some patients).
- Decrease in glucose tolerance, which is typically not clinically significant unless patient has risk factors for diabetes.
- Must be repeated every three months for optimal effectiveness.

Side Effects

- Irregular bleeding patterns/amenorrhea (delayed return of menses after discontinuing method).
- Weight gain.
- Delayed fertility (discuss return of fertility after discontinuation with client).
- Mood swings.
- Decreased libido.
- Hair loss.
- Bloating.
- Breast tenderness.
- Possible loss of bone density.

Instructions to the Client

1. No back-up method is needed if administered at the proper time. If DMPA is started greater than 7 days after a menstrual period, then the client must abstain from intercourse for 7 days after the injection or use additional contraceptive protection for the next 7 days.
    a. Back-up is not needed if DMPA is administered less than one month postpartum or within the first 7 days after a spontaneous or induced abortion.
    b. If switching from an IUD and the patient has had intercourse since the start of most recent menses, advise the client to retain the IUD for 7 days after injection. This is due to the theoretical possibility that sperm may remain alive in the genital tract after intercourse and lead up to fertilization if ovulation occurs.
2. Does not provide protection against STIs.
3. Encourage adequate calcium intake.
4. Efficacy is diminished if more than three months elapses between shots.
5. May be given early when necessary.
6. If a client is >15 weeks from the date of the last injection, they can have the injection if it is reasonably certain that she is not pregnant (See US SPR for guidelines below for determining with reasonable certainty that a client is not pregnant).
7. Document counseling about maintaining bone density:
    - Increase Vitamin D in diet or take supplements.
    - Adequate weight bearing exercise.
    - Not smoking.

8. Implants, DepoProvera, POP, CHCs: Certain drugs to treat cystic fibrosis (e.g., lumacaftor) or HIV anti-retroviral medications might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal and implantable contraceptives. Please check all drug interactions.

Return Injections

1. At each injection visit:
    a. Check BP
    b. Check weight
    c. If the patient reports heavy bleeding, check Hgb. or Hct.
    d. Update LMP or bleeding patterns.
    e. Review Side Effects:
        i. Changes in bleeding pattern.
        ii. May delay return to fertility.
        iii. Weight changes.
        iv. Possible bone mineral changes.
        v. Decreased libido.
        vi. Review next injection date and provide calendar outlining next due date according to schedule.
2. Per CDC recommendations, there are no restrictions when early administration is requested or needed.
3. If return visit is <15 weeks since the last DepoProvera (DMPA) injection, the repeat injection can be given without requiring additional contraceptive protection. If return visit is >15 weeks since the last DMPA injection, the injection can be given if it is reasonably certain the client is not pregnant. The client must abstain from intercourse or use a backup method for 7 days after the injection. The client may consider using EC if appropriate.
    a. Reasonably rule out pregnancy.
        i. Assure clients are informed of the increased risk of pregnancy with very late injection (>15 weeks).
        ii. Reinforce the importance of timely injections.
    b. If unable to reasonably rule out pregnancy at 15 week visit:
        i. Have client return when an accurate pregnancy test can be done.
        ii. Give a barrier to use until next Depo shot.
4. Counsel about return of menses after discontinuing method.

Same Day Start

- Same day start of DMPA is best, if pregnancy can reliably be ruled out (see above).
- Clinicians need to obtain a thorough history of unprotected intercourse since the last menstrual period to determine the need for pregnancy testing.
- Clients who have had unprotected intercourse in that time frame should have a sensitive urine pregnancy test to determine their status.

- If clients have had unprotected intercourse in the last five days, they should be provided EC.
- Review back-up recommendations as above
- Clients will need to repeat the pregnancy test two to three weeks after the injection if they have had any recent unprotected intercourse.

If Wanting to Change To Oral Contraceptives While on Dep-Provera

- Start oral contraceptives pills no later than the beginning of the 13th week after last DMPA injection. This will allow coverage for the first cycle.
- If starting oral contraceptive pills >14th week after last DMPA injection:
    - Rule out pregnancy.
    - Start pills with instructions to use a barrier or other back up method also for the first week.

Fertility Return

Return to fertility after discontinuation may be prolonged for some, while for most fertility returns quickly or within a few months. There may be menstrual irregularities for up to 18 months post cessation. Pregnancy can occur prior to return of menses.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)

C5.8 - COMBINED ORAL CONTRACEPTIVE PILLS

Policy

This policy outlines the use of combined oral contraceptive pills, containing estrogen and progestin to prevent pregnancy.

Procedure

Mode of Action

The primary mechanism of action is hormonal inhibition of ovulation by suppressing the release of gonadotropins. Also, progesterone alters cervical mucous inhibiting sperm motility into the uterus.

Effectiveness

Theoretical effectiveness rate is 99.7%.
Typical use effectiveness rate is 91%.

Contraindications

Absolute Contraindications

- Thrombophlebitis, thromboembolic disorders, cerebral vascular disease, coronary occlusion, or a past history of these conditions
- Acute/current DVT and/or PE.
- Any history of VTE (venous thromboembolism) including DVT or PE with higher risk of recurrence.
- Major surgery planned with prolonged immobilization
- Markedly impaired liver function (steroid hormones are contraindicated in patients with acute viral hepatitis or during a flare) such a severe cirrhosis.
- Known or suspected breast cancer.
- Undiagnosed abnormal vaginal bleeding.
- Known or suspected pregnancy.
- Smokers over the age of 35 who smoke more than 15 cigarettes daily (see CDC US Medical Eligibility Criteria).
- Complicated solid organ transplantation
- Poorly controlled hypertension (systolic ≥140 or diastolic ≥90 or as indicated by The American Heart Associations most recent guidelines)
- Migraines headaches **with** aura
- Diabetes with complications i.e., nephropathy, retinopathy, neuropathy, other vascular disease or diabetes >20 years duration.
- Known or suspected carcinoma of the endometrium or other estrogen-dependent cancer.
- Liver cancer or hepatocellular adenoma.
- Peripartum cardiomyopathy with moderately or severely impaired cardiac function.
- Within 6 months of peripartum cardiomyopathy with normal or impaired cardiac function.
- Less than 21 days postpartum in both breastfeeding and non-breastfeeding clients.

Strong Relative Contraindications

- Gallbladder disease that is being medically managed or is currently active/symptomatic.
- Previous cholestasis on combined hormonal contraceptives.
- Well controlled hypertension with resting BPs Systolic reading of 130-139 and Diastolic reading between reading of 80-89 on three different occasions (or as indicated by The American Heart Associations most recent guidelines)
- Chronic renal disease with hypertension.
- Clients over 35 who smoke less than 15 cigarettes/day (see CDC US MEC Criteria).
- History of a malabsorptive procedure type of bariatric surgery (this includes Roux-en-Y), however restrictive procedures are not a contraindication. Other administration methods for estrogen containing contraception (such as the ring or patch) is acceptable for mal-absorptive procedures.
- See specific drug interaction information for antiretroviral, anticonvulsants and antimicrobial (specifically rifampin or rifabutin) medication.
- More than six months after peripartum cardiomyopathy with normal or impaired cardiac function.
- Clients 21-30 days postpartum with other risk factors for VTE (age >35, history of VTE, BMI >30, smoking and others).
- Breastfeeding clients up to 30 days postpartum with or without other risk factors for VTE.
- Breastfeeding clients 30-42 days postpartum with other risk factors for VTE.

Relative Contraindications

Refer to the Appendix for the CDC Medical Eligibility Criteria Summary Chart

Combined Oral Contraceptives for Women in Later Years

- Clients aged 35 and older may continue to use oral contraceptives in the absence of risk factors.
- Clients who have current or past history of thrombophlebitis or thromboembolic disorder, or cardiovascular disease, diabetes with vascular involvement, smoke more than 15 cigarettes daily, or are hypertensive, should not use combined oral contraceptives. The risks to clients with hyperlipidemia who use combined oral contraceptives usually outweigh the advantages.

Advantages

- Reliable method of contraception when used properly.
- There is no interference with the normal sequence of sexual relations.
- There are no requirements for preparation or disposal.
- Patient controls starting and stopping the method

Definitely Beneficial

- Improved uterine bleeding (lighter and more predictable).
- Decreased dysmenorrhea.
- Decreased ovulatory symptoms (i.e. Mittelschmerz).
- Suppression of endometriosis.
- Improved acne and hirsutism.
- Prevention of menstrual porphyria.

Probably Beneficial

- Prevention of functional ovarian cysts.
- Decrease in premenstrual symptoms.
- Control of bleeding (dyscrasia, anovulation).

Noncontraceptive Benefits

- Decreased endometrial cancer.
- Decreased ovarian cancer.
- Decreased benign breast disease.
- Fewer ovarian cysts.
- Fewer uterine fibroids.
- Fewer ectopic pregnancies.
- More regular menses, decreased menstrual flow, decreased dysmenorrhea, decreased anemia.
- Decreased salpingitis.
- Decreased incidence of sickle cell crisis

Disadvantages

- Increased risk of venous thromboembolism (VTE).
- Must remember to take pill every day at the same time.
- Does not protect against STIs.
- Possible decreased libido.

Side Effects

- Nausea, typically resolves.
- Fluid retention, breast fullness, or tenderness.
- Breakthrough bleeding (common in first three months of use).
- Decreased menstrual flow (not always a nuisance).
- Missed periods.
- Melasma.
- Libido alterations.
- Interaction with other drugs.
- If history of epilepsy, diabetes, hyperlipidemia, liver impairment, client should inform Clinical Services Provider if hormonal contraception is planned.
- Use of certain anticonvulsants can alter the effectiveness of oral contraceptives. These include, but is not limited to the following: phenytoin, carbamazepine, barbiturates, lamotrigine, primidon topiramate, and oxcarbazepine.

Possible Complications

Possible Life-Threatening

- Venous thromboembolism: blood clots in the legs, pelvis, lungs or brain (see Initial Pill Selection).
- Liver tumors (hepatocellular adenomas).

Serious, but rare

- Gallbladder disease.
- Hypertension.

Warning Signs

- Call the clinic or report to the ER if any of the following warning signs should occur:
  - **A**..... Abdominal Pain (severe)
  - **C**..... Chest Pain (shortness of breath)
  - **H**..... Headaches (severe)
  - **E**..... Eye Problems (blurred or loss of vision)
  - **S**..... Severe Leg Pain (calf or thigh)

Lactation Concerns and the Combination Pill

- Mini-pill (progestin only) is preferred for clients immediately after delivery due to the increased risk of VTE in the immediate postpartum period.
- A combination oral contraceptive pill may be prescribed after 1 month postpartum (U.S. Medical Eligibility Criteria), under the following conditions:
  - Shared decision-making about the risk of unplanned, short interval pregnancy, and theoretical risk of decreases in lactation with initiation of combined hormonal contraception.
  - Client understands that small amounts of hormone may be present in breast milk, and that this is safe for baby.
- Breastfeeding clients who do not have additional VTE risk factors may reasonably begin combination oral contraception at 30 days postpartum. However, breastfeeding clients with additional VTE risk factors should delay CHC initiation until at least 42 days (six weeks) postpartum. Please refer to CDC MEC for additional guidance: https://www.sciencedirect.com/science/article/abs/pii/S0010782415004825

Instructions to the client

Instruct client that oral contraceptive pills do not protect against acquiring STIs/HIV. A barrier contraceptive should be used in combination with pills to help reduce the risk of STIs.

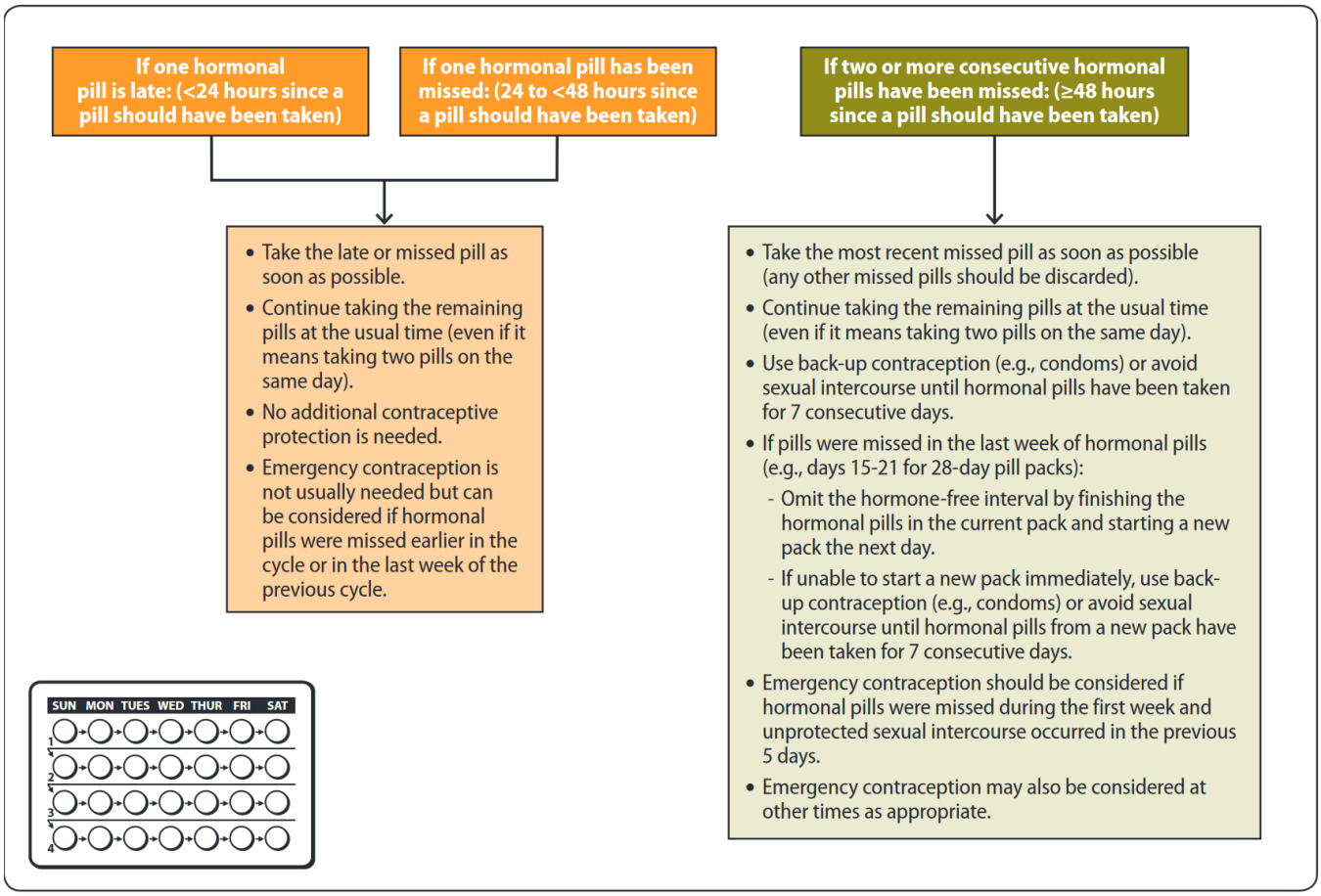
1. When to initiate pills for a new or restart FP client (not postpartum, not post-abortion, and not currently on pills):
   a. Day 1 Start (28 day regimen): One tablet is taken daily from the first day of the menstrual cycle through day 28, counting the first day of the menstrual flow as "Day 1".
   b. Sunday Start (28-day regimen): The first pill is taken on the Sunday after the start of menses. If menses starts on Sunday, the first pill should be taken on that day, and continued throughout the 28 days. With either the same day or Sunday start, the client should be encouraged to use a back-up method of condoms for seven (7) consecutive days.
   c. Quick Start: If there is no suspicion of pregnancy, take the first pill in the clinic. Count the day the first pill is taken as day 1. Counsel that client is not fully protected until pills are taken for seven (7) days. Offer condoms as a back-up method. Document that condoms were offered.
2. Postpartum in a non-breastfeeding client:
   a. Clients 21-42 days postpartum without other risk factors for VTE. Rule out pregnancy and begin pills per normal initiation protocol. Counsel that client is not fully protected until pills have been taken for 7 days.
3. Post-abortion:
   a. Up to 2 weeks if no risk of pregnancy, initiate pills per normal pill initiation protocols. Client is not fully protected until pills are taken for seven (7) days. Offer condoms for a back-up method, document.

b. Initiate pills per normal protocol after menses. Client is not fully protected until pills have been taken for 7 days. Offer condoms, and document.

Making Up Missed Pills (See diagram following)

1. If you MISS one "active" pill:
    a. Take as soon as you remember. Take the next pill at your regular time if it has been less than 24-hours since you missed it. You do not need to use a back-up birth control method.
2. If you missed pills early in the cycle or during the last week of the previous cycle, you may want to use EC. If you MISS two or more "active" pills in a row:
    a. Take the most recent missed pill as soon as possible. This means you will take two pills on the day you remember them. Discard any other missed pills.
    b. Then take 1 pill a day until you finish the pack.
    c. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills. You MUST use another birth control method (such as male condoms, female condoms, foam, contraceptive sponge or abstinence) until you have taken the pills correctly for 7 days in a row.
    d. Offer EC. *Reference Emergency Contraception policy.*
    e. If you miss pills in the last week of the hormonal pill, do not take the hormone free pills, simply finish the rest of any hormone pills and then immediately start a new pack. If you are unable to start a new pack right away, use a back-up method of birth control or abstain from intercourse until you can start the new pack and have taken 7 consecutive pills from the new pack.
3. If you forget any of the seven "reminder" pills in Week 4:
    a. THROW AWAY the pills you missed.
    b. Keep taking 1 pill each day until the pack is empty.
    c. You do not need a back-up method.
    d. Make sure to start a new pack no more than 7 days after completing the active pills.
4. Client should call the clinic if one of the following situations should occur:
    a. If one or more pills is missed and no menses occur.
    b. If two (2) consecutive menses are missed (regardless of whether any pills were missed).
    c. If intermenstrual spotting occurs for 3 or more cycles.

Recommended Actions After Late or Missed Combined Oral Contraceptives



Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

For the full recommendations, see the US Selected Practice Recommendations for Contraceptive Use, 2013 (http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf).

Extended Cycle OCP Use

- Up to 91-day cycle or 13 week cycle, 84 days of active pills/7 days of inactive pills with up to four withdrawal bleeds per year.
- It is also an option for continuous use during which the client takes an active pill every day without any pill-free/inactive pill interval.
- Unless prescribing a pill formulation specifically designed for extended cycle use (ie seasonale®), the client will need 15-17 packs per year.
- Additional advantages of extended cycle dosing include overall decreased bleeding, reduction in headaches, premenstrual symptoms and mood changes that occur during the inactive pill period.
- Same mechanism of action as regular combined contraceptive pills and same effectiveness.
- Same contraindications as regular combined contraceptive pills.
- Same advantages and disadvantages as regular combined contraceptive pills with an additional advantage of only four withdrawal bleeds per year instead of 13.
- May allow for improved ovulatory suppression in obese patients.

- Same side effects as combined contraceptive pills with the additional side effect of increased likelihood of break through bleeding during the first few cycles.
- Same instructions as regular combined contraceptive pills except that it is up to a 91 day/ 13 week regimen not 28 day/4 week regimen.

Fertility Return

Return to fertility after discontinuation of oral contraceptive pills is typically rapid (within 4 weeks), although variable, and clients should be encouraged to initiate alternative contraception immediately if they are not desiring pregnancy.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)

C5.9 - PROGESTIN ONLY ORAL CONTRACEPTIVES

Policy

This policy outlines the use of the progestin only oral contraceptive pill (POP) or drospirenone only to prevent pregnancy.

Procedure

Mode of Action

Primary mechanism of action for norethindrone pills (35mcg) of action is by the thickening of cervical mucus and thus decreased sperm penetration. Given this mechanism, taking the pills at the same time daily is vital for effectiveness.

Drospirenone (4mg) only progestin contraception (DSP 4mg) primarily works by inhibition of ovulation via suppression of gonadotropin levels. Drospirenone also alters cervical mucus making it less penetrable to sperm.

Effectiveness

Typical use, 91% effectiveness over one year for NET 35mcg.
Typical use, 91-96% effectiveness over one year for DSP 4mg.

Contraindications

Absolute Contraindications

- Breast cancer - current.

Strong Relative Contraindications

- History of breast cancer with no evidence of current disease for 5 years.
- Severe cirrhosis of the liver.
- History of a malabsorptive procedure type of bariatric surgery (ie Roux-en-Y), however restrictive procedures are not a contraindication. Other administration methods for estrogen containing contraception (such as the ring or patch) is acceptable for mal-absorptive procedures.
- Ischemic heart disease.
- Liver malignancy or hepatocellular adenoma.
- Unexplained vaginal bleeding
- Stroke.
- Systemic lupus erythematosus, if positive antiphospholipid antibodies.
- See specific drug interaction information for antiretroviral, anti-seizure and antimicrobial medications.

Relative Contraindications

The advantages of using progesterone-only oral contraception generally outweigh the theoretical or proven risk.
Refer to the Appendix for the CDC Medical Eligibility Criteria Summary Chart

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Advantages

- Can be taken by women who cannot take estrogen.

- Does not have the serious but rare complications of estrogen.
- Can be started at any time if it is reasonably certain the individual is not pregnant, including immediately postpartum.
- Client controls when to stop and start the method.
- Clients take the same pill every day (same color and hormone content and no pill free week).
- Decrease in pelvic inflammatory disease because of less penetrable cervical mucus.
- Does not suppress lactation, even when initiated immediately following delivery.

Disadvantages

- Lack of protection against STIs.
- Menstrual cycle disturbances, irregular menstruation and amenorrhea.
- Breast tenderness.
- NET 35mcg is less likely to improve menstrual bleeding than other hormonal contraception due to the very low dose. DSP 4mg does result in improved bleeding.
- NET 35mcg pills are very low-dose and must be taken daily at the same time each day or the effectiveness is decreased. DSP 4mg is more forgiving, but should also be taken at the same time daily
- Some medications decrease effectiveness.

Side Effects

- Severe lower abdominal pain, contact a clinic and/or Clinical Services Provider immediately.
- Delayed period after several months of regular cycles may be a sign of pregnancy.
- Repeated, very severe headaches.
- There may be a delay of return to normal menses after method discontinuation, however return of fertility is typically rapid.

Instructions to the client

Norethindrone 35mcg:

Instruct client that oral contraceptive pills do not protect against acquiring STIs/HIV. A barrier contraceptive should be used in combination with pills to help reduce the risk of STIs.

1. Start the first pill on the day of the visit to the clinic or on the first day of the next period.
2. Take one pill per day until all pills from pack are finished. Try to take pills at the same time every day. Choose a time and take the pill at that time or within three hours after that time. If you take the pill more than three hours late, use condoms or a back-up method or abstain from intercourse for the next 48 hours. Never miss a day.
    a. NET 35mcg does not have a placebo week and clients should take an active pill daily
    b. DSP 4mg should be taken once daily for 24 days and then a 4 day pill-free interval should be observed to allow for withdrawal bleeding.
3. When each pill pack is finished, start a new pill pack the next day.
4. Use a back-up method for the first 2 days on POPs unless you have started your pills within the first five days of menstrual bleeding.
5. Use a condom if at risk on STIs/HIV.
6. Instruct on Emergency Contractives and provide a package or prescription (Plan B or Ullipristal (Ella®)).

Less than 3 hours late (or less than 12 hours for a DSP 4mg)

- Take the missed pill as soon as you can/remember
- Take the next pill at the usual time
- You do not need extra contraception and do n ot necessarily need emergency contraception

More than 3 hours late (or more than 12 hours for a DSP 4mg)

- Take the missed pill as soon as you can remember. Only take 1 pill.
- Take the next pill at the usual time (which might mean taking two pills in the same day)
- Continue taking remaining pills each day at the usual time.
- Use extra contraception such as condoms for the next two days (48 hours) after remembering to take the missed pill or avoid intercourse.
- If you have unprotected sex during the two days after you miss your pill, consider using emergency contraception.

Discontinuing Pills

- If pills are discontinued, start another method of contraception immediately.
- If the client desires pregnancy, discuss return of normal menses and provide preconception information.
- Fertility returns very quickly after discontinuation.

Fertility Return

Return to fertility after discontinuation reestablishes quickly. Immediate use of an alternative contraceptive is recommended after discontinuation if the client is not seeking pregnancy. Encourage prenatal vitamin initiation at time of discontinuation if not switching to a different highly or moderately effective contraceptive method.

Hormone Contraception and HIV

The CDC has affirmed the safe use of hormone contraception in women who are HIV positive.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)

C5.10 - COMBINED HORMONAL CONTRACEPTIVE PATCH (XULANE®)

Policy

This policy outlines the use of the combined hormonal contraceptive patch. It is easy to use and works like the pill, but only needs to be changed once a week. The patch contains both estrogen, in the form of ethinyl estradiol, and progestin, in the form of norelgestromin.

Procedure

Mode of Action

The primary mechanism of action for combined hormonal contraceptive patch is inhibition of ovulation and forming thickened cervical mucus that inhibits sperm mobility.

The patch contains the same hormones as combined birth control pills, but the hormones are delivered through the skin. This is why there is likely a decrease in efficacy for patients who weigh more than 90kg (198lbs). The hormones from the patch get into the bloodstream and are processed by the body differently than hormones from birth control pills - they are not metabolized in the liver. Women are exposed to about 60% more estrogen using the patch than a typical birth control pill containing 35 micrograms of estrogen. Theoretically, increased estrogen may increase the risk of side effects, including blood clots - however, studies comparing combined hormonal contraceptive methods are lacking.

See full prescribing information. The FDA has issued this black box warning for the contraceptive patch:
WARNING: CARDIOVASCULAR RISK ASSOCIATED WITH SMOKING, RISK OF VENOUS THROMBOEMBOLISM, AND PHARMACOKINETIC PROFILE OF ETHINYL ESTRADIOL.

Cigarette Smoking and Serious Cardiovascular Risks

Cigarette smoking increases the risk of serious cardiovascular events from hormonal contraceptive use. This risk increases with age, particularly in individuals over 35 years of age, and with the number of cigarettes smoked. For this reason, hormonal contraceptives, including the patch, should not be used by individuals who are over 35 years of age and smoke. This is true for all combined hormonal contraceptive options.

Risk of Venous Thromboembolism

The risk of venous thromboembolism (VTE) among individuals aged 15 to 44 who used the norelgestromin and ethinyl estradiol transdermal system compared to women who used several different oral contraceptives was assessed in five U.S. epidemiologic studies using electronic healthcare claims data. The relative risk estimates ranged from 1.2 to 2.2; one of the studies found a statistically significant increased relative risk of VTE for current users of norelgestromin and ethinyl estradiol transdermal system.

Pharmacokinetic (PK) Profile of Ethinyl Estradiol

The Pharmacokinetic (PK) profile for the norelgestromin and ethinyl estradiol (EE) transdermal system is different from the PK profile for oral contraceptives in that it has a higher steady state concentration and a lower peak concentration. It is not known whether there are changes in the risk of serious adverse events based on the differences in PK profiles of

EE in individuals using norelgestromin and EE transdermal system compared with women using oral contraceptives containing 30 mcg to 35 mcg of EE. Increased estrogen exposure may increase the risk of adverse events, including VTE.

Effectiveness

Theoretical effectiveness is 99% effective.

Typical use effectiveness is thought to be 91%. The patch may not be as effective in women weighing more than 198 lbs (90 kg).

Indications for Use

Any individual who is a candidate for combination oral contraceptives may use the patch with the limitations identified in the black box warning. See contraindications below.

Contraindications for Use

Please review guidelines for combined hormonal contraceptive pills.

Advantages

- The same as for oral contraceptives.
- The patch only needs to be placed once per week.
- The patch does not interfere with intercourse.
- The client controls starting or stopping this method. Discontinuation of the method is controlled by the client.
- The patch does not require a daily regimen.

Side Effects

The same side effects as oral contraceptives. Review warning label.

Risks

Risks are the same as for combined oral contraceptive pills. In general, increased estrogen may increase the risk of side effects, including blood clots, however studies directly comparing the patch to oral combined hormonal contraception are lacking.

Precautions

Precautions are the same as for combined oral contraceptive pills.

Hormonal birth control methods help to lower the chances of becoming pregnant. They do not protect against HIV infection (AIDS) and other STIs.

Drug Interactions

See complete prescribing information. Examples include Hepatitis C drug combinations; itraconazole, voriconazole, fluconazole, grapefruit juice, or ketoconazole may increase plasma hormone concentrations; HIV/Hepatitis C Virus (HCV) Protease Inhibitors and Non-Nucleoside Reverse Transcriptase Inhibitors.

Certain anti-microbial, anti-epileptics and anti-retrovials as well as certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal and implantable contraceptives.Initiation

No Hormonal Contraceptive Used in the Last Month

- Begin on or before day 5 of the menstrual cycle. Apply even if not done bleeding.
- Use back-up method until patch has been in place for 7 consecutive days.

Switching from Combination Oral Contraceptives

- Apply on or before start of the new pill cycle and back-up method need not be used.
- Use back-up method for 7 consecutive days if applied after oral contraceptive restart day.

Switching from Progestin Only Method

- Use a back-up method until patch has been in place for 7 days.
- Progestin only pills may apply on any day. Do not skip any days between pills and patch application.
- Apply on the same day as removal of the progestin implant.
- Apply on the same day as removal of LNG IUD.
- Apply prior to the 14th week or 98 days from last Depo-Provera injection. If applied after the 14th week or 98th day, use a back-up method until patch has been in place for 7 consecutive days.

Use

1. Initiate the patch:
    a. Begin the patch within the first 24 hours of menses and no back-up is needed. If the patch is started after the first 24 hours of the menses, a back-up is required for 7 days.
2. Apply one patch weekly for 3 weeks to the upper outer arm, upper torso, lower abdomen or buttocks (any hairless part of the body, avoiding the breasts). Recommend changing patch location each time it is changed. Then the patient observed a patch-free interval of 1 week.
3. Reinforce importance of not going longer than 7 days without a patch which would increase the risk for pregnancy
4. If the patch becomes partially detached for 24 hours or less, reattach it or reapply a new patch. The patch change day will remain the same.
5. If the patch has been detached for more than 24 hours, apply a new patch and that day is now the patch change day. A back-up method should be used for 7 days.
6. If it has been more than 48 hours since a patch detached and unprotected intercourse occurred in the last 72 hours, consider offering EC.
7. Advise client to observe for skin irritation at the patch removal site. Encourage rotation of site application.
8. Call the clinical or report to the ER if any of the following warning signs should occur:

A Abdominal Pain (severe)
C Chest Pain (shortness of breath)
H Headaches (severe)

E Eye Problems (blurred or loss of vision)

S Severe Leg Pain (calf or thigh)

9. Discuss return of normal menses and fertility after discontinuation of method.

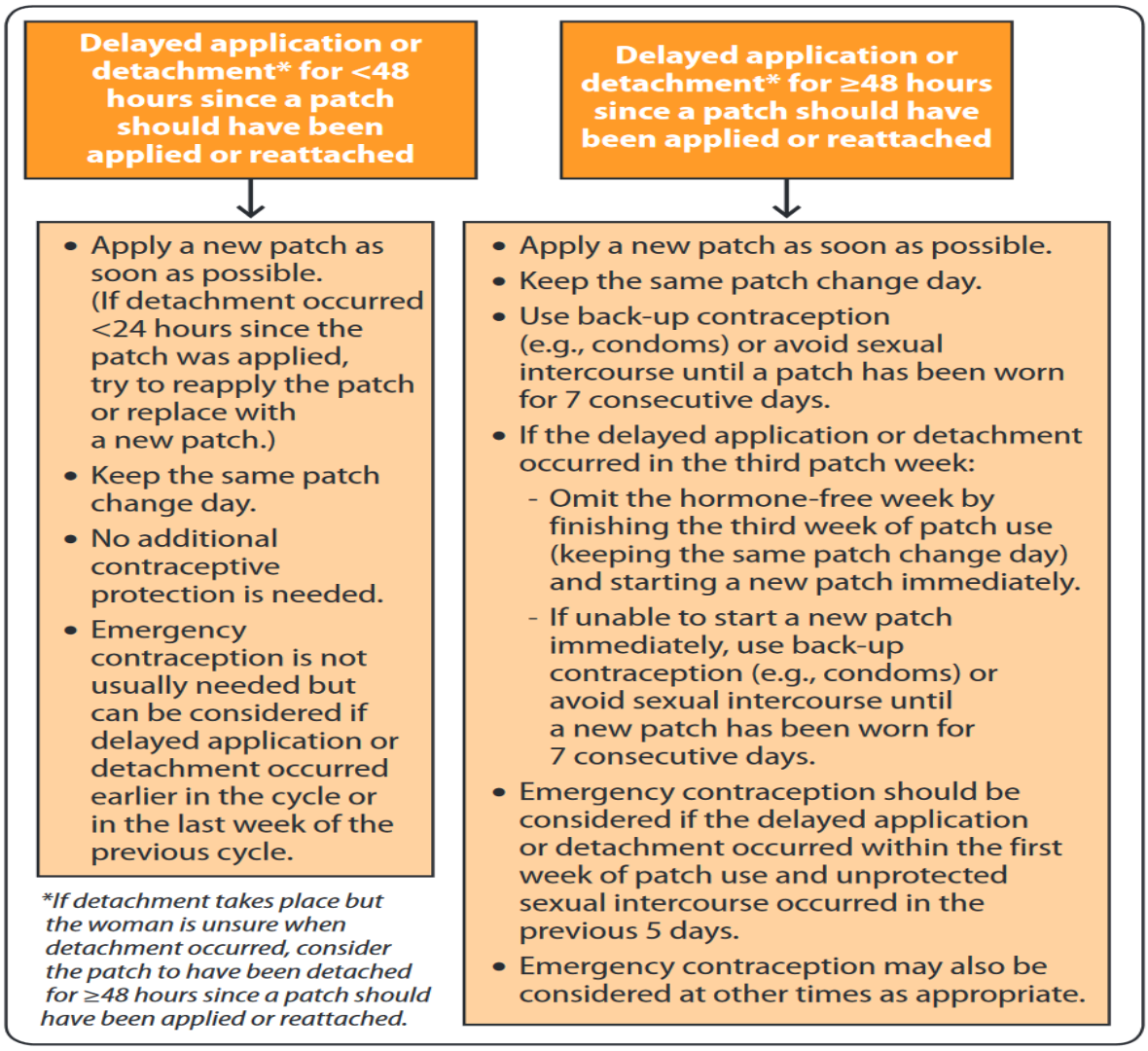
Fertility Return

Return to fertility after discontinuation reestablishes quickly. Immediate use of an alternative contraceptive is recommended after removal if the client is not seeking pregnancy. Encourage prenatal vitamin initiation at time of removal if not switching to a different highly or moderately effective contraceptive method.

Hormone Contraception and HIV

The CDC has affirmed the safe use of hormone contraception in women who are HIV positive.

Recommended Actions After Delayed Application or Detachment With Combined Hormonal Patch



Date Revised	September 2023
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)

C5.11 - CONTRACEPTIVE VAGINAL RING

Policy

This policy outlines the use of the Contraceptive vaginal ring, a flexible, transparent ring containing progesterone (etonogetrel) and estrogen (ethinyl estradiol). The ring is marketed as NuvaRing® or EluRyng®. The contraceptive ring is a polymeric ring that releases on average 0.12mg/day of etonogestrel and 0.015mg/day of ethinyl estradiol. The hormone is absorbed by the mucosal surfaces of the vagina.

Procedure

Mode of Action

The vaginal ring works by inhibiting ovulation and forming thickened cervical mucus that inhibits sperm mobility. The mechanism of action is the same as for combined hormonal contraceptive pills.

Effectiveness

Theoretical effectiveness 98%-99%.
Typical use effectiveness is likely 93%.

Indications for Use

Any individual who is a candidate for combination oral contraceptives may use the vaginal ring. See oral combined hormonal contraception above.

Contraindications for Use

Contraindications for use of the contraceptive vaginal ring are the same as those for oral contraceptives.

Advantages

- The same as for oral contraceptives.
- The vaginal ring only needs to be placed once per month, although hormone levels remain therapeutic for 35 days after insertion.
- The vaginal ring does not interfere with intercourse. It can be removed for up to 3 hours during intercourse, but then needs to be replaced.
- IThe client controls starting and stopping this method.
- The vaginal ring does not require a daily regimen.
- The vaginal ring is easily reversible.

Side Effects

- The same side effects as oral contraceptives.
- Vaginal infection and irritation.

Contraindications, Precautions and Drug Interactions

Contraindications are the same as for combined oral contraceptive pills.

Risks

Risks are the same as for combined oral contraceptive pills except for increased vaginal discharge and irritation.

Use

Insert one ring per cycle and leave for three weeks. Position in the vagina is not important. Quick start method may be used.

Initiate If:

1. No hormonal contraceptive used in the last month:
   a. Begin on or before day 5 of the cycle. Insert even if not done bleeding.
   b. Use back-up method until ring has been in place for 7 consecutive days.
2. Switching from combination oral contraceptives:
   a. Insert ring on or before start of the new pill cycle and back-up method need not be used.
   b. Use back-up method for 7 consecutive days if inserted after oral contraceptive restart day.
3. Switching from Progestin only method. Use a back-up method until ring has been in place for 7 days:
   a. Progestin only pills – may insert the ring on any day. Do not skip any days between pills and insertion of the ring.
   b. Insert on the same day as removal of the progestin implant.
   c. Insert on the same day as removal of progestin containing IUD or IUS.
   d. Insert prior to the 14th week or 98 days from last Depo-Provera injection. If inserted after the 14th week or 98th day, use a back-up method until ring has been in place for 7 consecutive days.

Deviations from Recommended Regimen

1. Inadvertent removal, expulsion – The ring may be rinsed with lukewarm (never hot) water and replaced in the vagina. A back-up method should be used until the ring has been in place for 7 consecutive days. NOTE: The ring may be removed for periods of up to 3 hours or less without losing effectiveness.
2. If the ring is in place for more than 3 weeks up to 4 weeks, remove and observe the ring-free week. If ring is in place for more than 4 weeks, pregnancy must be ruled out and another method used until the ring can be reinserted. A back-up method must be used until the ring has been in place for 7 consecutive days.
3. Extended cycle dosing can be used. This would mean keeping the ring in place for 4 weeks and then immediately replacing with a new ring in order to "skip" a withdrawal bleed.

In the Event of a Missed Menses

1. If the regimen has been adhered to, the ring may be inserted at the prescribed time.
2. If regimen has not been adhered to (ring out more than 3 hours or ring free period was extended), pregnancy should be considered.
3. If the regimen has not been adhered to and two consecutive menses have been missed, pregnancy must be ruled out.
4. If ring has been retained longer than 4 weeks, pregnancy should be ruled out.

Client Instructions

1. This method does not protect against STI/HIV.

2. Dispose of the ring in the foil pouch away from pets or children.
3. Call the clinic or report to the ER if any of the following warning signs should occur:
   A Abdominal Pain (severe)
   C Chest Pain (shortness of breath)
   H Headaches (severe)
   E Eye Problems (blurred or loss of vision)
   S Severe Leg Pain (calf or thigh)
4. Discuss return of normal menses and fertility after discontinuation of method, especially with continuous cycle use.
5. Implants, DMPA, POP, CHCs: Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal, and implantable contraceptives.

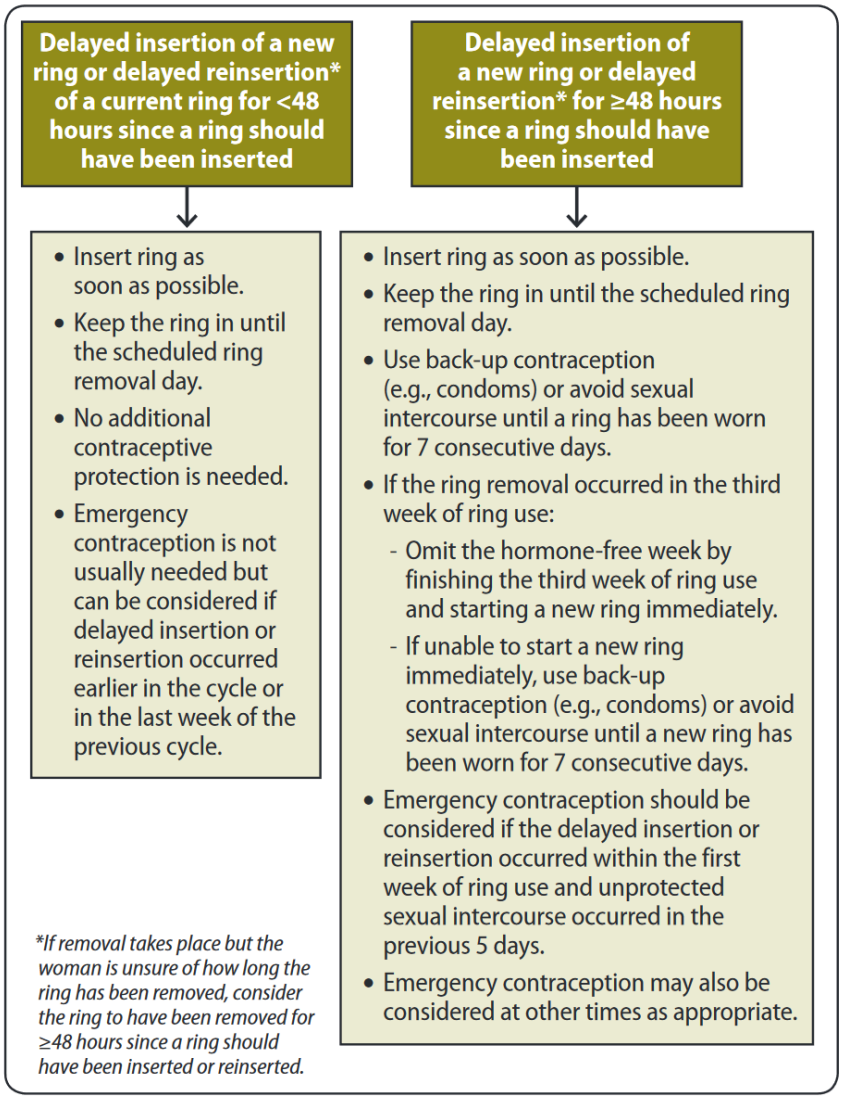
Fertility Return

Return to fertility after discontinuation reestablishes quickly. Immediate use of an alternative contraceptive is recommended after removal if the client is not seeking pregnancy. Encourage prenatal vitamin initiation at time of removal if not switching to a different highly or moderately effective contraceptive method.

Hormone Contraception and HIV

The CDC has affirmed the safe use of hormone contraception in individuals who are HIV-positive. Individuals with HIV should be strongly advised to always use condoms. There are no contra-indications to any hormonal contraceptive in HIV positive individuals. if using a progestin-only injectable contraceptive because of the inconclusive body of evidence on the possible increased risk for HIV acquisition.

Recommended Actions After Delayed Insertion or Reinsertion With Combined Vaginal Ring



Date Revised	September 2023
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)

C5.12 - DIAPHRAGM

Policy

This policy outlines the use of the diagragm Caya®, a contoured cup made of silicone that fits inside the vagina and covers the cervix. It must be used with a contraceptive gel or cream (Nonoxonol-9) to achieve maximum effectiveness. This diaphragm requires a prescription. This is a one-size diaphragm, which fits most, but not all women. The one-size diaphragm does not require fitting. The Caya® should be replaced every 2 years.

Procedure

Mode of Action

The diaphragm fits inside the vagina over the cervix. The dome forms a barrier between the cervix and the semen, preventing sperm entry into the uterus. The spermicidal cream or jelly is used with the diaphragm for additional protection, killing any sperm that accidentally go past the rim of the diaphragm.

Effectiveness

- Theoretical effectiveness rate is 97%.
- Actual use effectiveness rate is 87%.

Advantages

- There are no serious side effects with this device.
- Insertion may be incorporated into foreplay.

Disadvantages

- Some individuals may consider the diaphragm "messy" or cumbersome.
- It must be used every time intercourse occurs.
- Warn client of the risks of Nonoxonol-9.
- Using a diaphragm and spermicide is associated with increased urinary tract infections and vaginal infection.
- Rare instances of toxic shock syndrome have been reported.
- Less effective at pregnancy prevention than other methods.

Contraindications

Strong Relative Contraindications

- Allergy to spermicide.

Relative Contraindications

- Complete uterine prolapse.
- Vesico-vaginal fistula.
- Recto-vaginal fistula.
- Severe cystocele or rectocele.
- Small "button" cervix.

- Severe retroversion of the uterus (this varies from client to client).
- Inability of client to learn correct insertion technique.
- History of toxic shock syndrome or vaginal colonization of staph aureus.
- Vaginal septum that has not been repaired/removed.

There are no absolute contraindications to diaphragm use.

Side Effects

- Possible slight discomfort (bladder pressure, uterine cramps) especially if inserted improperly.
- Vaginal/vulvar irritation from spermicide.
- Foul smelling, profuse vaginal discharge if the diaphragm is forgotten or left in place too long.
- Toxic shock syndrome is rare but possible.

Instructions to the Client

To Apply Contraceptive Jelly or Cream

Hold the diaphragm with dome down (like a cup). Squeeze the contraceptive gel from the tube into the dome, usually about a teaspoon; then spread a little around the rim of the diaphragm with your finger. The contraceptive jelly or cream remains active for about 6 hours. If you inserted the diaphragm more than two hours before intercourse, you need to add more contraceptive gel.

To Insert Diaphragm

With one hand, hold the diaphragm dome down (spermicide in the dome) and fold the diaphragm using the "grip dimples" on the sides. Spread the labia with the other hand, and insert the folded diaphragm deeply into the vaginal canal. The cervix should be inside the cup. This can be done standing with one foot propped up (on the edge of a bathtub), squatting or lying on your back. Push the diaphragm downward and back along the floor of the vagina as far as it will go. Then tuck the front rim up behind the pubic bone. If it is uncomfortable, it may be incorrectly placed and should be removed and reinserted.

To Check the Placement of the Diaphragm

When the diaphragm is correctly placed, the back rim of the device is below and behind the cervix, and the front edge of the rim is tucked up behind the pubic bone. Often it is not possible to feel the back rim. The client should check to be sure the cervix can be felt through the soft rubber dome of the diaphragm and that the edge of the dome is securely behind the public bone. The contraceptive gel (in the dome of the diaphragm) should be on the inside, next to the cervix.

To Remove the Diaphragm

The diaphragm must be **left in place for at least 6 hours after intercourse,** but not longer than 24 hours. Place the index finger behind the front rim of the diaphragm and pull down and out. Be careful not to puncture the diaphragm with a fingernail. If it is hard to hook a finger behind the rim, try a squatting position and push downward with the abdominal muscles. After use, the diaphragm should be washed with soap and water, rinsed and then dried. It should not be heated. It should be examined after each use for any holes or thin spots.

Instruct Client to Use the Diaphragm Each and Every Time They Have Intercourse

Each episode of intercourse requires a new application of jelly or cream. DO NOT remove or dislodge the diaphragm within a 6-hour timeframe. Use the contraceptive gel applicator to insert additional gel in front of the diaphragm if intercourse occurs more than once during the 6-hour timeframe. If additional spermicide is too messy, condoms may be used for subsequent intercourse. DO NOT remove the diaphragm, however, until six hours after last intercourse. For more information client can be directed to https://www.bedsider.org/birth-control/diaphragm or https://www.caya.us.com/wp-content/uploads/2023/09/IFU_caya_US_210923-EN.pdf

Instruct the Client That After Intercourse

The diaphragm should be left in place for 6 hours after intercourse. After the 6-hour minimum time--the diaphragm may be removed whenever it is convenient. If subsequent intercourse is anticipated, the individual may wash the diaphragm, apply new spermicide and re-insert it. It should be removed and washed at least once every 24 hours to avoid developing an unpleasant odor. But remember, stick to the 6-hour minimum after intercourse for leaving the diaphragm in place.

Care of the Diaphragm

Always follow care instructions that come with the diaphragm. After use, the diaphragm should be washed with mild soap and water, thoroughly rinsed, dried with a towel and then stored in its plastic container.

Inspect the Diaphragm

Each time it is used for defects or holes. Vaseline should not be used with the diaphragm since it may cause deterioration. If a lubricant is needed, K-Y jelly may be used without harming the diaphragm. The diaphragm should be stored away from heat. and will normally discolor (darker brown) over time.

Warn Client of the Risks of Nonoxonol-9

Possible increased risk of acquiring HIV, vaginal irritation among others.

Douching is Always Discouraged:

If an individual thinks they must douche, they should be instructed to wait six hours after intercourse or more to douche.

Fertility Return

There is no disruption to fertility. Given lower efficacy of diaphragm for contraception, please recommend users also take a prenatal vitamin or folic acid supplement.

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References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)

C5.13 - MALE/EXTERNAL CONDOM

Policy

This policy outlines the use of male/external condoms, a thin rubber latex, polyurethane or lamb caecum sheath (Lambskin condoms are not reliable at prevention of STI) which is put on an erect penis to prevent ejaculated sperm from being deposited inside the vagina.

Procedure

Mode of Action (Barrier Method)

Ejaculation can occur while the covered penis is in the vagina, the ejaculate being contained within the condom.

Effectiveness

Theoretical effectiveness rate is 98%.
Typical/ACTUAL use effectiveness rate is 87%.

Must be used for each act of anal, vaginal or oral intercourse when any risk of infection exists.

Contraindications

Allergic reaction to rubber/latex condoms and/or pre-lubricated condoms. If this occurs, synthetic condoms are an alternative.

Advantages

- Condoms do not require a prescription and are easily accessible.
- Condoms are relatively inexpensive.
- May be kept as "reserve" or "back-up" method if not prepared for other methods or if supplies run out.
- Encourages male participation in contraception.
- Can be used as dual method to increase effectiveness or to reduce risk of STIs.

Disadvantages

- Putting on the condom may interrupt foreplay unless efforts are made to incorporate it into a part of foreplay.
- In rare instances, condoms may break.
- Use of Nonoxynol–9 lubricated condoms does not reduce the risk of STI and may increase exposure to HIV and herpes virus. If lubrication is desired to enhance the pleasure of intercourse, only water-based or silicone-based lubricants should be used.
- Must be used with each act of intercourse.

Side Effects

Use of the condom may reduce glans sensitivity for the male.

Instructions to the Client

- Since sperm are present in pre-ejaculatory semen, the condom should be placed on an erect penis before the penis comes into contact with the vulvar area. Unroll the condom all the way to the base of the penis, leaving about one-half inch of empty space, not filled with air, at the tip (or buy condoms with nipple tips to hold the semen). Lubrication may be used on the outside of the condom (some are lubricated to aid the penis in entering the vagina). Petroleum jelly (Vaseline) or any oil-based product should not be used because it may cause the rubber to deteriorate. Water based lubricants (K-Y liquid or jelly) and saliva are excellent lubricants.
- After intercourse, hold onto the condom, as the penis is withdrawn, taking care not to spill semen anywhere near the opening of the vagina. The penis should be withdrawn shortly after ejaculation occurs. As the erection subsides, the condom could slip off, spilling semen into the vagina and pregnancy could result. At this time it is recommended both hands and the penis are washed with gentle soap.
- If the condom tears or comes off in the vagina, insert contraceptive foam or jelly immediately and emergency contraception is recommended.
- Condoms should be used only once and then thrown away.
- Heat may cause deterioration of the condom. Do not keep condoms in your wallet, glove compartment or any area where they are exposed to heat.
- Use of condoms lubricated with Nonxynol-9 does not reduce the risk of STI and may increase the risk of HIV and herpes virus.
- Clients should be instructed not to use a condom that has been worn during anal intercourse for vaginal intercourse. A new condom should be used every time a change occurs from vaginal to anal or from anal to vaginal intercourse.

Fertility Return

There is no disruption to fertility. Given lower efficacy of barrier methods for contraception, please recommend users also take a prenatal vitamin or folic acid supplement.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020

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C5.14 - FEMALE/INTRAVAGINAL CONDOM

Policy

The purpose of this policy is to outline the use of the female/intravaginal pouch is a thin condom designed to provide individuals with protection against pregnancy and to reduce the risk of AIDS and other STIs. It consists of a soft, loose-fitting sheath and two flexible rings. One of the rings is used to insert the device and to hold it in place. The other ring remains outside the vagina after insertion. The condom covers the labia and the base of the penis during intercourse. Upon insertion, it lines the vagina. It is disposable and can be used only once.

Procedure

Mode of Action (Barrier Method)

Ejaculation can occur while the penis is in the vagina, since the ejaculate is contained within the vaginal pouch.

Effectiveness

- Theoretical effectiveness is 95%.
- Actual use effectiveness is 79%.

Advantages

- Does not require a prescription.
- May be used as a back-up method of birth control.
- Reduces the risk of STIs.
- Enables individual to use protection when their partner will not.
- May be inserted several minutes or hours before intercourse.
- May enhance pleasure for individuals.

Disadvantages

- More expensive than the external condom. Can be used only once and then must be discarded.
- Easily torn by sharp object like a ring or fingernail.
- Must be used with each act of intercourse.

Contraindications

None

Side Effects

No allergic reactions have been reported.

Instructions to the Client

- Should not be used in conjunction with an external condom.
- Follow insertion instructions on the package.

Fertility Return

There is no disruption to fertility. Given lower efficacy of barrier methods for contraception, please recommend users also take a prenatal vitamin or folic acid supplement.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)

C5.15 - WITHDRAWAL

Policy

The purpose of this policy is to outline the use of withdrawal ("pull out") refers to the removal of the penis from the vagina before ejaculation to prevent sperm from entering the vaginal canal.

Procedure

Mode of Action

Ejaculation occurs outside the vagina and away from the vulva, decreasing the possibility of conception.

Effectiveness

With typical use, 22-24% of couples relying on withdrawal will conceive within one year
Typical/actual effectiveness of withdrawal 78-80%.

Advantages

- Withdrawal requires no devices, involves no chemicals and is available in any situation at no cost.
- It is more effective than the use of no method at all.

Disadvantages

- Interrupts the excitement or plateau phase of sexual response and can diminish the pleasure for a couple. It can be difficult to do correctly all of the time.
- The ejaculate, which may contain sperm, may be emitted from the penis prior to climax or ejaculation, exposing the client to pregnancy.
- Offers no protection against STIs.

Contraindications

There are no absolute or strong relative contraindications.

Side Effects

Interruption in the excitement or plateau of sexual response, diminishing the sensation of pleasure.

Instructions to the Client

- Low effectiveness rate makes a second method in addition to withdrawal advisable.
- Care should be taken to see that ejaculation does not take place until the penis is clear of the vulva.

Fertility Return

There's no disruption to fertility. Given lower efficacy of withdrawal for contraception, please recommend users also take a prenatal vitamin or folic acid supplement.

Date Revised	September 2023
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)

C5.16 - CONTRACEPTIVE SPONGE

Policy

The purpose of this policy is to outline the use of the contraceptive vaginal sponge (Today®) is a soft, disposable polyurethane foam sponge containing Nonoxynol-9, which kills sperm on contact. Insertion is similar to diaphragm.

Procedure

Mode of Action

The sponge prevents pregnancy in three ways:

1. The spermicide contained in the sponge kills sperm before they reach the egg (spermicidal).
2. The sponge blocks the cervix (barrier).
3. The sponge traps and absorbs sperm (absorption).

Effectiveness

Theoretical effectiveness is 89-91%.

Actual/typical use effectiveness is 73-86%.

Contraindications

You should NOT use the Today® Sponge if you:

- Are menstruating.
- You and/or your partner has a sensitivity to:
  - Sulfa drugs.
  - The spermicidal nonoxynol-9 (contraceptive gel).
  - Polyurethane [medical grade].
- Have a vaginal abnormality such as a septum.
- Currently have a vaginal infection.
- Have ever had toxic shock syndrome.
- Have recently had a vaginal delivery (within 6 weeks), miscarriage or other termination of pregnancy, and have not been examined by your Clinical Services Provider.

Advantages

- No prescription or special fitting is required.
- Conveniently packaged (portable).
- Disposable.
- May be inserted immediately before intercourse or up to 16 hours prior to intercourse and therefore doesn't interfere with intercourse. Protection lasts for up to 24 hours. Leave sponge in place an additional 6 hours after intercourse before removing it.
- The sponge may be retained in place for up to 24 hours allowing for multiple acts of intercourse. If you have intercourse when sponge has been in place for 24 hours, leave it in place an additional 6 hours after intercourse before removing it. Today® Sponge must not be left in place for more than 30 hours.

- The sponge will be effective even if you swim or bathe after intercourse.

Disadvantages

- May decrease sexual spontaneity if not inserted in advance.
- Some reports of difficulty removing device.
- With frequent intercourse, may be more costly than other methods.
- Associated with possible increased risk of toxic shock syndrome.
- Does not provide protection against STIs or HIV.

Side Effects

- Possible vaginal burning or itching.
- Allergic reactions.

Warning Signs of Toxic Shock Syndrome

Report to the ER or clinic immediately if one or more warning signs of toxic shock syndrome should occur including:

- Fever.
- Vomiting.
- Diarrhea.
- Muscular pain.
- Dizziness.
- Rash similar to sunburn.

How to Use the Contraceptive Sponge

1. Sponge must be inserted before penis enters vagina.
2. Wash hands and wet the sponge with water and squeeze it gently. This activates the spermicide. (You will notice suds.)
3. Fold the sponge in half (the loop must be on the outside) and insert it into the vagina.
4. Push it deep into the vagina to cover the cervix.
5. You can have sex immediately after you put the sponge in, or you can wait up to 24 hours to have sex. If you have intercourse when the sponge has been in place for 24 hours, leave it in place an additional 6 hours after intercourse before removing it. Today® Sponge must not be left in place for more than 30 hours.
6. Sexual intercourse may be repeated without adding contraceptive gel.
7. To remove the sponge, grasp the loop and pull down gently and slowly.
8. Check to make sure the entire sponge has been removed.
9. Throw the sponge away. It can be used only once.

Fertility Return

Return to fertility should be immediate after removal. Given lower efficacy of the contraceptive sponge for pregnancy prevention, please recommend users also take a prenatal vitamin or folic acid supplement.

Other

A higher degree of protection against pregnancy will be afforded by using another method of contraception in addition to a spermicidal contraceptive. This is especially true during the first few months, until the client becomes familiar with the method. Clinical studies have demonstrated that approximately one-half of all accidental pregnancies occurred during the first three months of use.

After childbirth or spontaneous or induced abortion, the effectiveness of the sponge may be decreased. Do not use until bleeding has stopped, after delivery or abortion

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)

C5.17 - NATURAL FAMILY PLANNING

Policy

The purpose of this policy is to outline the use of Natural family planning (NFP) which is a means of either achieving or avoiding a pregnancy based on a couple's knowledge of their cycle of fertility and infertility. It is an educational means of FP, as opposed to the use of a device, barrier or hormonal method, such as the pill, IUD, etc.

There are several methods of NFP currently being taught and promoted. The first of these is called the Sympto-thermal Method (ST). This combines the observation of three different ovulation-related events: the production of mucus by the cervix (the mucus symptom), a change in the consistency of the cervix itself (which can be noted by placing the fingers inside the vagina to feel the cervix directly), and a change in basal body temperature. Couples who use the ST Method often feel greater security with its triple-check technique.

The second of these NFP methods is the Ovulation Method (OM). This method depends only upon the client's observation and interpretation of the mucus symptom to determine that ovulation is approaching, and that it has passed. Couples who choose this method like its simplicity.

Another variation is the use of cycle beads. Cycle beads are color-coded beads that represent the days of a client's cycle. A rubber ring is placed on the red bead on the first day of a menses. The rubber ring is then moved daily in the direction of the arrow. When the ring is on a red bead or a dark bead, there is little chance of conception occurring if intercourse occurs. When the ring is on a white bead, there is a high chance of conception occurring if unprotected intercourse occurs. Cycle beads work best in women with 26-32 day cycles.

Procedure

Mode of Action

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

Effectiveness

The effectiveness of either method is measured in three different categories:

To Avoid Pregnancy

Typical/actual use effectiveness of this method is between 76-88%.

To Achieve Pregnancy (normal fertility)

If a couple of normal fertility utilizes days of fertility (as determined by NFP) their chances of achieving pregnancy in the very first cycle are quite high: 75-80%.

To Achieve Pregnancy (previously infertile)

Some couples, who have previously been considered infertile, are able to achieve a pregnancy by learning and using NFP. Many couples trying to achieve pregnancy without success, can be referred to a NFP center, and thus may avoid expensive infertility testing.

Advantages

- It is safe. There are no medical side effects associated with its use.
- It is natural. The use of NFP does not interfere with the body's natural reproductive processes, nor does it interfere with any of its other normal metabolic processes.
- It can be used in all stages of reproductive life: regular cycles, long cycles, following childbirth (breastfeeding or not breastfeeding), during perimenopause or discontinuing another form of birth control. It is also gaining popularity as an initial approach to infertility.
- NFP methods are basically easy to learn and use.
- NFP is morally acceptable to all major world religions.
- NFP is the responsibility of both partners; NFP is a shared method of FP.

Disadvantages

There are two disadvantages frequently mentioned regarding NFP. The first of these is the fact that, if these methods are to be used to avoid pregnancy, they require the avoidance of all genital contact (abstinence, continence) for a variable number of days each cycle. As a means of preventing pregnancy, it is less effective than other methods with actual use effectiveness betweens 76-88%. The second disadvantage often discussed is that NFP methods take a lot of time and energy in order to be learned and used properly. If an individual's menstrual cycle is irregular, then NFP is very difficult and will have reduced effectiveness. In that case, an additional method may be recommended.

Factors Which Influence the Effectiveness of NFP

Mutual motivation by both partners has long been recognized as a very important factor in the success of NFP. However, it is now also recognized that the NFP teacher is nearly as important, and in some cases even more important, than the initial motivation of the couple being taught. There is no doubt that the teachers who themselves use NFP, produce the best success statistics in their clients.

A couple of words of caution are in order: Self-taught NFP (e.g., from a book, from a well-meaning friend) has a notably higher unplanned pregnancy rate than that learned from qualified teachers.

Older Methods of NFP

Rhythm

This was the earliest of the natural methods of FP. Its use is based on anticipating when ovulation is likely to occur in the present menstrual cycle, calculated from the longest and shortest lengths in the previous 6-12 cycles. It is no longer recommended.

Basal Body Temperature

There is usually .4 to .5 degree body temperature rise following ovulation, which is then maintained until the onset of the next menstrual period. This is a very effective method of determining post-ovulatory infertility. Although satisfactory to some couples, many feel the basal body thermometer used alone to avoid pregnancy is too restrictive. In general, using it alone is no longer recommended.

Plan

- Provide back-up method of contraception as indicated.
- Discuss EC and folic acid supplements.
- Return for age appropriate periodic assessment

Client Education

Clients Must Receive:

1. Information about all types of contraceptive options if they are new or undecided.
2. Information about NFP methods including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, etc.
    a. NFP or Fertility Awareness may incorporate one or more of these methods to help predict when ovulation might occur.
    b. To Prevent Pregnancy, use a barrier method or avoid sexual intercourse when ovulation or fertile times are identified
    c. Clients should be counseled about the advantages, disadvantages of NFP (as described above).
    d. Instruct client about health promotion and disease prevention (especially STI/HIV).
    e. Advise client that NFP methods do NOT provide STI/HIV protection.
    f. Correct and consistent use of condoms is recommended for STI/HIV protection.
    g. Refer client for additional information if requested. A list of training or education resources should be provided.

Fertility Return

There's no disruption to fertility. Given lower efficacy of the NFP pregnancy prevention, please recommend users also take a prenatal vitamin or folic acid supplement.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020

	(https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)

C5.18 - SPERMICIDAL FOAM & SUPPOSITORIES

The purpose of this policy is to outline the use of spermicidal foam and suppositories are chemical substances which are toxic to sperm, and will decrease likelihood of implantation.

Procedure

Mode of Action

The foam or suppositories are placed in the vagina, as close as possible to the cervical opening, allowing the chemical action to kill sperm on contact. Some suppositories must dissolve over a period of 10-30 minutes after placement in the vagina, prior to intercourse.

These methods should be used in combination with other methods (i.e., condoms) to increase protection.

Effectiveness

Theoretical effectiveness rate is 97%.
Actual use effectiveness rate is 85.1%.

Advantages

- An effective, safe method of contraception if used correctly.
- May be purchased at a drugstore without a prescription and is readily accessible.

Disadvantages

- Some women consider the use of foam as "messy".
- Must be used consistently with each act of intercourse.
- May cause irritation.
- May increase exposure to HIV and does not protect from STI.

Contraindications

There are no absolute or relative contraindications except allergy to foam or suppositories.

Side Effects

- Possible irritation or burning. If this occurs, change to a different brand.
- Couples having oral-genital sex have noted that foam has an unpleasant taste, although odorless and tasteless preparations are available.

Instructions to Client

Foam

1. Several brands of foam come in pre-loaded applicators, ready for use. If the foam comes in a separate container from the applicator, the applicator is filled to a designated mark by pressure applied directly on the top of the container or by tilting the applicator (instructions differ with brands).
2. Shake the can at least 20 times before using to insure adequate mixing of the spermicide and foam.
3. The filled applicator should be inserted as far as possible into the vagina and withdrawn about 1/2 inch. Then push the plunger to deposit the foam.
4. Foam protection lasts about 30 minutes. The foam should not be inserted more than 30 minutes prior to intercourse. If more than 30 minutes has elapsed, another applicator full of spermicide should be used. Insert a new applicator full of foam before every act of intercourse.
5. Douching is always discouraged; however, if an individual thinks they must douche, they should be instructed to wait 6- 8 hours after the last act of intercourse.
6. Wash the applicator with soap and lukewarm water.

Suppositories

1. Foil or plastic wrapper must be removed.
2. Slide the suppository into the vagina as far as it will go and as close to the cervix as possible to obtain maximal protection as it melts and foams.
3. After insertion, wait for the correct amount of time to elapse before having intercourse (times may vary with brands).
4. Use one suppository for each act of intercourse. If more than 1/2 hour has elapsed since insertion, insert another suppository to insure protection.
5. Douching is discouraged. If an individual thinks they must douche, they should be instructed to wait 6- 8 hours after the last act of intercourse.

Fertility Return

Return to fertility should be immediate after use. Given lower efficacy of the contraceptive sponge for pregnancy prevention, please recommend users also take a prenatal vitamin or folic acid supplement.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)

C5.19 - VAGINAL CONTRACEPTIVE FILM (VCF)

Policy

The purpose of this policy is to outline the use of vaginal contraceptive film (VCF) is a 2.5 by 2.5-inch water-soluble square containing the spermicide Nonoxynol-9, a chemical substance that is toxic to sperm.

Procedure

Mode of Action

VCF is folded over the finger and placed as close to the cervix as possible. It dissolves quickly, but unlike foam, does not liquefy, but becomes a coating gel. VCF must be inserted at least five (5) minutes, and not more than one hour, prior to intercourse.

VCF should be used in combination with condoms for increased protection.

Effectiveness

Theoretic effectiveness equal to foam 97%.
Actual effectiveness is similar to foam 82-85%.

Effectiveness increased when used in conjunction with condoms.

Advantages

- Readily available over-the-counter without a prescription.
- An effective, safe contraceptive if used correctly.
- Very portable.
- No hormonal side effects.
- Does not have to be removed.

Disadvantages

- Must be used with each act of intercourse.
- May cause vaginal irritation and/or increased vaginal discharge.
- May increase exposure to HIV and does not protect from STIs.

Contraindications

No absolute or relative contraindications.
Allergy to known ingredients.

Side Effects

- Possible irritation/burning/vaginal discharge.
- May be unpleasant to the taste for clients having oral-genital sex.

Instructions to Client

1. Fold film in half over the index finger and insert into the vagina as close to the cervix as possible.
2. VCF should be inserted at least five minutes prior to intercourse to allow it to liquefy. If more than one hour elapses between insertion and intercourse, another film should be inserted.
3. Additional film should be used with each subsequent act of intercourse.
4. VCF does not need to be removed. Its residual gel is flushed from the vagina by vaginal and cervical fluids.
5. Douching is discouraged. If an individual thinks they must douche, they should be instructed to wait six hours or more to douche.
6. Does not protect from exposure to STI and may increase exposure to HIV.

Fertility Return

Return to fertility should return immediately after use. Given lower efficacy of the vaginal contraceptive film for pregnancy prevention, please recommend users also take a prenatal vitamin or folic acid supplement.

Potential Complications

None.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)

C6.1 – USE OF 340B MEDICATIONS

Purpose

The purpose of this policy is to have each SR describe their process for ensuring compliance with the expectation that all clinic locations enroll in the 340B Program and comply with all 340B Program requirements, including annual recertification and avoiding diversion or duplicate discounts. 340B Program requirements are available at https://www.hrsa.gov/opa/program-requirements/index.html. (FY22 Notice of Award Special Terms and Requirements)

Policy

All SRs must enroll in the 340B Program and comply with all 340B Program requirements, including:

- initial certification
- annual recertification
- avoiding diversion or duplicate discounts

Each SR is responsible for annual recertification of all clinic sites where 340B purchased medications are used. Failure to recertify will result in the agency being unable to use 340B medications in any clinic sites that are not certified.

Procedure

Each SR will be responsible for the following:

- Identify the staff member responsible for enrolling and recertifying the project.
- Recipient's process for monitoring SRs and service sites to ensure compliance with this expectation.
- Each SR must certify that reasonable safeguards are in place to assure compliance with the provisions of Section 340B of the PHS Act that prohibit Drug Diversion and Double Discounts/Rebates.
- Each SR will have a policy clearly describing their safeguards for Drug Diversion and Double Discounts/Rebates in their FP manual. SRs will describe how they will maintain control over their inventory of 340B medications.

Iowa HHS will confirm that each SR and service site are updated and certified via the Office of Pharmacy Affair electronic forms system. Enrollment and agency's system for tracking medications stored and dispensed is reviewed as part of the annual site visit and documented.

Date Revised	September 2023
References	340B Requirements and Program Participation (https://www.hrsa.gov/opa/program-requirements) Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)

	Title X Program Handbook, (https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.pdf
Additional Resources	IME Information Letter 699

C6.2 – EMERGENCIES (MEDICAL AND NON-MEDICAL) & CONTRACEPTIVE ACCESS

Purpose

The purpose of this policy is to ensure that all SRs have written plans for management of on-site medical and non-medical emergencies. Written plans should comply with all applicable local, state, and federal law.

Policy

All Title X SR staff must be familiar with plans specific to medical and non-medical emergencies. Emergency guidelines are developed with input from Clinical Service Providers and should reflect local resources.

Procedure

Natural and manmade disasters may occur that result in displacement of persons and loss of access to contraceptive methods. SRs will develop an emergency plan to assure the availability of prescription and nonprescription contraceptive methods for their clients in the event of a natural disaster (tornado, flooding, earthquake, ice storms, for example) or manmade disaster (hazardous waste spills and terrorism, for example). SRs must replace, per the client's last refill history, supplies equivalent to the number that the client had on hand when the disaster occurred. If the client has FPP, Medicaid or another third-party payer, the agency must provide supplies equivalent to the number needed until the agency is able to bill for another refill of contraceptives.

SR staff must develop plans specific to medical and non-medical emergencies:

Medical Emergencies

- Vaso-vagal reactions.
- Anaphylaxis.
- Syncope.
- Cardiac arrest.
- Shock.
- Hemorrhage.
- Respiratory difficulties.

Non-Medical Emergencies

- At a minimum, written protocols must address:
- Severe weather (tornado, flood).
- Fire.
- Intruder in the building.
- Intoxicated patient or client.
- Lost or abducted child.
- Bomb threat guidance.
- Chemical spill.
- Power failure.

Protocols must also be in place for emergencies requiring:

- Transport.
- After-hours management of contraceptive emergencies.
- Clinic emergencies

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	