# FAMILY PLANNING CLINICAL GUIDELINES

Guidance for Providing Title X Family Planning Services in Tennessee

Tennessee Department of Health
Bureau of Health Services
Women's Health Section

Title X Required Components January 2011
Family Planning Visit Types January 2011
Screenings and Required Counseling January 2011
Contraceptive Methods January 2011

**FAMILY PLANNING CLINICAL GUIDELINES**
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Office of Family Planning
Office of Population Affairs
U.S. Department of Health and Human Services
(Guidelines can be found at http://opa.osophs.dhhs.gov/titlex/2001guidelines/ofp_guidelines_2001.htm)

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**Program Guidelines For Project Grants For Family Planning Services**
**January 2001**
**Compliance Statement**

The Tennessee Title X Family Planning Program must comply with the federal program guidelines and any other released federal program instructions, annual legislative mandates, annual program priorities, and annual key issues as established by the U.S. Department of Health and Human Services, Office of Public Health, Office of Population Affairs, Office of Family Planning. The central office staff of the Tennessee Family Planning Program has made every effort to assure that a copy of the (current) Program Guidelines for Project Grants for Family Planning Services is in every copy of the Family Planning Clinical Guidelines. If a copy of the Clinical Guidelines does not have this document, a copy can be obtained at either the federal website, http://opa.osophs.dhhs.gov/titlex/2001guidelines/ofp_guidelines_2001.htm or by contacting the central office staff for the Tennessee Family Planning Program. Whenever new program instructions are released these are disseminated to the state regional family planning administrators by central office staff for incorporation into the guidelines. Annual legislative mandates, program priorities, and key issues are also disseminated (annually) to the field by the Tennessee Family Planning Director through the regional family planning administrators.

It is imperative that every family planning program administrator in the state be familiar with the federal guidelines, federal program instructions, annual legislative mandates, annual program priorities, and annual key issues. It is also imperative that every nurse, nurse practitioner, and physician read and comply with all of sections seven and eight of the federal guidelines. These sections of the federal guidelines are entitled, “Client Services and Required Services”. All health care providers must also be familiar with program instructions, legislative mandates, program priorities and key issues released by the federal office that relate to clinical services. It is essential that the state of Tennessee comply with all clinical services that the federal guidance states must be done. For those clinical services described as should be done or may be done, every consideration should be given to incorporating these services.

## PROGRAM STANDARDS

### POLICY

Services provided by the Tennessee Department of Health Title X Family Planning Program must comply with state and federal laws, regulations, and program guidelines. Title X laws and regulations are found in the current Program Guidelines For Project Grants For Family Planning Services, U.S. Department of Health and Human Services, Public Health Service. The central office staff of the Tennessee Family Planning Program has made every effort to assure that a copy of the (current) Program Guidelines for Project Grants for Family Planning Services is in every copy of the Family Planning Clinical Guidelines. If the local copy of the Clinical Guidelines does not have this document, a copy can be obtained at either the federal website, http://opa.osophs.dhhs.gov/titlex/2001guidelines/ofp_guidelines_2001.htm or by contacting the central office staff of the Tennessee Title X Family Planning Program.

The following list summarizes the state and federal program requirements hereafter referred to as Minimum Program Standards.

**MINIMUM PROGRAM STANDARDS** (as listed in OPA Program Guidelines for Project Grants for Family Planning Services, January 2001)

1. Before an entity can apply for Federal Title X funding, a needs assessment for family planning services must be conducted. The components of a needs assessment can be found in OPA Program Guidance section 3.2.
2. Entities must apply using the form required by the Department of Health and Human Services and submit their application as described in OPA Guidance section 3.3 and must address all points listed in section 59.7 of the Title X Family Planning regulations.
3. Family Planning clinics must adhere to section 59.5 of the Title X Family Planning regulations, to the requirements of the OPA Guidelines, and to any other federal regulation that applies to grants made under Title X. (Section 3.4)
4. All Title X grantees must comply with applicable legislative, regulatory and administrative requirements described in the Public Health Service Grants Policy Statement. (Section 3.5)
5. Individuals must not be coerced to receive family planning services or to use or not use a particular method of family planning. Acceptance of family planning services must be voluntary and not be a prerequisite to eligibility for any other service or assistance in any other program. (5.1)
6. Clinical staff must be informed that they are subject to prosecution under Federal law if they coerce any person to undergo abortion or sterilization. 5.1)
7. Every clinic must assure client confidentiality. Information obtained from clients cannot be disclosed without written consent from the client except as required by law or as necessary to provide services to the client, but with appropriate safeguards for confidentiality. (5.2)
8. Grantees must establish policies to prevent anyone within the local Title X program from using their position for private gain (i.e., conflict of interest). (5.3)
9. Any research using Title X clients as subjects must adhere to the legal requirements governing human subjects research at 45 CFR Part 46. (5.5)
10. Grantees must have written agreement with each delegate/contract agency with written standards and guidelines consistent with OPA Program Guidelines for Project Grants for Family Planning Services. No clinic site can subcontract services without written approval from the State. (6.1)
11. Every application for a Title X grant must include a plan with goals, measurable objectives consistent with Title X objectives, and an evaluation component. (6.2)
12. Grantees must maintain a financial management system that complies with Federal standards to safeguard the use of funds. Documentation of income and expenditures must be maintained. (6.3)
13. Clients must not be denied services due to inability to pay. (6.3)
14. Charges must be based on a cost analysis of all services provided by the clinic. (6.3)
15. Clients with fees must be given bills at the end of their visit. (6.3)
16. If the client has a third party payor, that payor must be billed. (6.3)
17. A schedule of discounts must be implemented so that inability to pay is never a barrier to service.
18. Fees must be waived for clients with incomes between 101% and 250% of the federal poverty level if it is deemed that they are unable to pay for their family planning services. (6.3)

19. Clients at or below 100% of the federal poverty level must not be charged although third party payors of such individuals must be billed. (6.3)
20. Eligibility for discounted fees must be documented in the record. (6.3)
21. Bills to third party payors must show total charges without applying discounts. (6.3)
22. Client bills must show total charges minus their discount. (6.3)
23. Confidential minors are billed for services based on the income of the minor. (6.3)
24. Reasonable efforts to collects charges without jeopardizing confidentiality must be made. (6.3)
25. A method for aging outstanding accounts must be established. (6.3)
26. Clients must not be pressured to make donations. (6.3)
27. The grantee and its delegate agencies must undergo audit to assure compliance with the law. (6.3)
28. All facilities providing Title X family planning services must meet applicable federal, state, and local standards and codes. (6.4)
29. Clinics must not discriminate on the basis of handicap. Facilities must be readily accessible to the disabled. Clinics must comply with the Americans with Disabilities Act. (6.4).
30. All clinics must have written plans for the management of emergencies. (6.4)
31. Clinics must be administered by a qualified director. (6.5)
32. Clinical care must be under the direction of a licensed physician with training or experience in family planning. (6.5)
33. Clinics must have protocols that direct client care. (6.5)
34. Personnel records must be confidential. (6.5)
35. The license of licensed staff must be verified prior to employment. (6.5)
36. The licenses of licensed staff must be kept current and documentation that the license is current must also be kept. (6.5)
37. Clinics must provide staff with orientation and in-service training. (6.6)
38. The State must comply with all federal financial reporting requirements. (6.7)
39. An advisory committee/informational and educational (I&E) committee must review all informational and educational materials used in the clinics. The factors the Advisory/I&E committee must consider are listed in section 6.8 of the OPA Program Guidelines.
40. The grantee must provide for community participation in the development of family planning services. (6.9)
41. The grantee must include a plan for community participation.
42. The Advisory/I&E committee can serve as the community participation committee. The committee must meet at least annually. (6.9)
43. The clinics must provide for community education programs. (6.9)
44. Clinics must have planned activities that make their services known to the community.
45. Brochures developed with Title X money must acknowledge Federal grant support. (6.10)
46. Clinics must comply with federal law regarding rights to inventions made under government grants, contracts, or agreements. (6.11)
47. Clinics must provide clinical, informational, educational, social and referral services relating to family planning. (7.0)
48. All clinics must offer a broad range of acceptable and effective medically approved family planning methods and services on site or by referral. (7.0)
49. Clinics must provide services stipulated by law or regulation or that is required by OPA Family Planning Program Guidelines. (7.0)
50. The clinics must have written plans for client education that are approved by central office and signed by the medical director. (7.1)
51. Clinical protocols must be consistent with OPA Family Planning Program Guidelines (7.1)
52. A request for a waiver from an OPA requirement must be made in writing and include supportive data to justify the request. (7.1)
53. All initial visits must include education, counseling, informed consent with a method specific consent form, Medical history of client and family, physical examination, laboratory testing as appropriate for the method, and a plan of care that includes medications or supplies, performance of any clinical procedures, mechanism for follow-up, provision of referral, if needed. (7.2)
54. Return visits except for routine re-supply must include history, examination, laboratory testing appropriate to the need and the method, and a plan of care that includes medications or supplies, clinical procedures, mechanism for follow-up and referral if needed. (7.2)
55. All clinics must have written plans for the management of the following emergencies: vaso-vagal reactions, anaphylaxis, syncope, cardiac arrest, shock hemorrhage, and respiratory difficulties. All staff must be familiar with these plans. (7.3)

56. All clinics must have written plans for emergency transport, after hours management of contraceptive emergencies, and clinic emergencies. All staff must be familiar with these plans also. (7.3)
57. All services required by Title X that are provided by referral must establish formal arrangements with the referral agency(ies). (7.4)
58. Clinics must have written policies for the follow-up of referrals that are sensitive to client's confidentiality needs. (7.4)
59. As regards referrals, clinics must make arrangements for the transfer of pertinent information and obtain client consent unless there are laws to the contrary. In those cases, confidentiality should be safeguarded as much as possible. (7.4)
60. Clients must be advised to comply with the referral being counseled as to the importance of the referral and the method of follow-up. (7.4)
61. Clinics must maintain a list of health care providers and other agencies to be used for referral purposes. (7.4)
62. The client's written informed voluntary consent to receive services must be obtained prior to receiving any clinical services. (8.0)
63. For all prescription methods (non-over the counter) of contraception, a method specific consent form must be used.
64. Clinics must have written plans for client education and that education must documented in the client record. (8.1)
65. Education must provide clients with the information needed to make informed decisions, use their method, identify adverse effects, perform breast or testicular exam, reduce HIV risks, understand the range of available services, understand the purpose/sequence of care in the clinic, understand the importance of screening tests and other procedures involved in the family planning visit. (8.1)
66. Written informed consent specific the method must be signed before a prescriptive method is given (8.1)
67. Consent forms must be written in a language understood by the client or translated and witnessed by an interpreter. (8.1)
68. Clients must receive information on benefits, risks, effectiveness, side effects, complications, discontinuation, and danger signs of the method. (8.1)
69. Specific education and consent forms for the method must be a part of the service plan. (8.1)
70. The signed consent form must be a part of the client's record. (8.1)
71. Clinics must comply with federal sterilization regulations. (8.1)
72. The counselor who counsels the clinic on family planning methods must be sufficiently knowledgeable to provide accurate information regarding all aspects of the various contraceptive methods. (8.2)
73. Contraceptive counseling must be documented in the record. (8.2)
74. All clients must receive thorough and accurate counseling on STDs and HIV. (8.2)
75. Clients with high risk behavior must be counseled in risk reduction measures and the importance of HIV testing. (8.2)
76. Clinics must offer education about HIV/AIDS, information on risks and prevention and referral services. (8.2)
77. Where clinics do not provide HIV testing, referral sites must be available. (8.2)
78. A comprehensive medical history must include significant illnesses, hospitalizations, blood transfusions, chronic and acute medical conditions, allergies, current medications, and immunizations including Rubella status, review of systems, family medical history, partner history, past contraceptive use, menstrual history, sexual history, obstetric history, and gynecologic history, STDs including HBV, HIV, Pap history, DES status, and urologic conditions. (8.3)
79. A physical exam must include blood pressure, breast exam, pelvic exam, Pap test, colo-rectal screening beginning at age 50, STD/HIV screening. (8.3)
80. All counseling must include information about the possible health risks associated with delaying or declining preventive screening tests. (8.3)
81. All physical examination and laboratory test requirements stipulated in the prescribing information for the method must be followed. (8.3)
82. Reasons for deferring a physical exam must be documented in the record. (8.3)
83. Pregnancy testing must be provided at all clinic sites. (8.3)
84. Laboratory tests that are required for the provision of the method must be provided. (8.3)
85. A procedure must be in place to notify clients of abnormal lab results while at the same time safeguarding confidentiality. (8.3)
86. Revisits to the clinic must be individualized. (8.3)
87. The counseling and consent process for sterilization must assure that the client's decision is completely voluntary and fully informed and be in compliance with federal sterilization regulations. (8.4)

88. Grantees must make basic infertility services available to clients including an initial infertility interview, education, physical examination, counseling, and referral. (8.5)
89. Clinics must provide pregnancy diagnosis and counseling. (8.6)
90. Women with positive pregnancy tests must be counseled as to the importance of a physical exam as soon as possible and preferably within 15 days. (8.6)
91. If ectopic pregnancy is suspected, the client must be referred immediately for emergency services. (8.6)
92. Clinics must offer pregnant women neutral, factual, non-directive options counseling as needed including prenatal care, delivery, parenting; adoption or foster care; pregnancy termination. (8.6)
93. Adolescents must be informed about all methods. (8.7)
94. Adolescents must be counseled on safer sex to reduce STDs/HIV. (8.7)
95. Adolescents must receive abstinence counseling. (8.7)
96. Adolescents must be assured of confidentiality. (8.7)
97. Adolescents must receive counseling regarding the importance of family involvement in their decision to seek family planning services. (Long term Legislative Mandate)
98. Adolescents must receive education and counseling on how to identify and avoid sexual coercion. (Long term Legislative Mandate)
99. All clinics must be in compliance with the State of Tennessee law requiring notification of child abuse, child molestation, sexual abuse, rape, or incest. (Long term Legislative Mandate)
100. As regards STDs, all clinics that provide STD treatment must also provide appropriate follow-up. (9.2)
101. Gonorrhea and chlamydia tests must be available for clients requesting IUD insertion. (9.2)
102. Clinics must comply with state and local STD reporting requirements. (9.2)
103. Clinics must have equipment and supplies appropriate to the type of care being offered. (10.0)
104. Clinics must be operated in accordance with federal and state laws regarding security and record keeping of drugs and devices. (10.2)
105. Inventory, supply, and provision of pharmaceuticals must be in accordance with state pharmacy laws and regulations. (10.2)
106. Clinics must create a medical record for each client. (10.3)
107. Medical records must be complete, legible, and accurate and include telephone encounters. (10.3)
108. Medical records must be signed by the health care provider or other appropriate health professional including name, title and date. (10.3)
109. Medical records must be readily accessible, systematically organized, and confidential. (10.3)
110. Medical records must be safeguarded against loss or abuse by unauthorized personnel. (10.3)
111. Medical records must be secured by lock when not in use. (10.3)
112. Medical records must be available upon request to the client. (10.3)
113. Medical records must contain sufficient information to identify the client, indicate how to contact the client, justify the diagnosis, and warrant the treatment, i.e., plan of care. (10.3)
114. Medical records must include personal data, medical history, physical exam, laboratory test orders, results, and follow-up, treatment and instructions, scheduled re-visits, informed consent, refusal of services, allergies and untoward reactions to drugs (in a prominent and specific location.) (10.3)
115. Medical records must contain reports of clinical findings, diagnostic and therapeutic orders, and documentation of continuing care, referral and follow-up. (10.3)
116. Medical records must allow for entries by counseling and social service staff. (10.3)
117. Medical records must contain a confidentiality assurance statement. (10.3)
118. Medical records must be available to clients who are transferring their care another provider upon the client's request. (10.3)
119. A quality assurance system must be in place that provides for ongoing evaluation of clinic personnel and services. (10.4)

**Other Minimum Program Standards**

1. Family planning services must be offered in all 95 counties.
2. All Title X federal laws, rules, regulations, mandates, program priorities, key issues, and guidelines must be followed.
3. All state family planning clinical guidelines (this document) representing the minimum required services, must be followed.
4. Any person of reproductive age is eligible for family planning services.

5. All family planning services must be provided by appropriate personnel in accordance with current standards of medical practice, U.S. Medical Eligibility Criteria for Contraceptive use, ACOG guidelines and standards, and the guidelines and program directives of the Department of Health.
6. Abortion is not a method of family planning. No clinic shall pay for the procedure or any related costs.

## FAMILY PLANNING GUIDELINES FOR CLINIC VISITS
## MINIMUM REQUIREMENTS

### POLICY

The Tennessee Department of Health Family Planning Program policy states that the content of the various types of family planning visits shall be guided by federal requirements as stated in the *Program Guidelines for Project Grants for Family Planning Services, January 2001*. All clinics must offer a broad range of acceptable and effective medically approved family planning methods and services either on-site or by referral. Federal guidance for visits can be found in section 7 entitled Client Services and section 8 entitled Required Services of the above named document. A copy of this document is located in the front of the Family Planning Clinical Guidelines. Contact your regional Family Planning Administrator or Central Office staff if you need more copies of this document. Or you may access a copy by going to http://opa.osophs.gov/gov and click on Office of Family Planning, then OFP References, then on Program Guidelines (January 2001).

### PERSONNEL

The persons working in clinics in the Tennessee Department of Health System have been hired in accordance with the State of Tennessee's extensive rules and regulations regarding employment. Entities, such as local health department clinics, within a state personnel system are heavily monitored for compliance with state and federal laws regarding hiring practices including federal Title VII regulations. The department of health publishes extensive job descriptions for nurses and physicians. The Department requires education, medical and nursing licensure and certification, and job experience for each position. A performance review system is in place for ongoing assessment of staff performance including adherence to federal Title VI regulations.

All nurses in Tennessee who have expanded there nursing role to include medical duties must be in compliance with the rules and regulations of the Board of Nursing; this authority being given to the Board by the State Legislature. The Board of Nursing writes, "Registered nurses, duly licensed by the State of Tennessee who practice nursing in this state are not prohibited from expanding their roles by the Nursing Practice Act. However, RNs functioning in an expanded role assume personal responsibility for all of their acts. RNs who manage the medical aspects of a patient's care must have written medical protocols, jointly developed by the nurse and the sponsoring physician(s). The detail of medical protocols will vary in relation to the complexity of the situations covered and the preparation of the R.N. using them." [Rule 1000-1-.04(3)(b)]

### PROTOCOLS

To be in compliance with the above quoted Board of Nursing rule, all Title X Family Planning nursing personnel who have expanded their role to include the medical aspects of patient care work within protocols jointly written by the nurse(s) and sponsoring physician(s). These protocols vary in relation to the complexity of the situation and the preparation of the RN using them.

The following table describes the nurses and their protocols in Tennessee:

Nurses and Protocol Status

| Type of Nurse by preparation | Protocol status |
|---|---|
| Advanced Practice Nurse (a master's level nursing preparation and national certification) Licensure and certification is RN, APN Approved Board of Nursing (BON) titles include nurse practitioner, nurse anesthetist, nurse midwife or clinical nurse specialist | Broadly written protocol letters of agreement written and signed with their physician agreeing to work within the scope of their training (usually as a family nurse practitioner) while using designated resources as well as consult with the physician in making diagnoses and providing treatments. |
| Advanced Practice Nurse without a Master's degree. Graduate of a certificate program in advanced nursing practice and having national certification and licensure in the state of TN prior to July 1, 2005. Licensure and certification is RN, APN No approved BON title other than RN, APN | Most work under broadly written protocol letters of agreement for family planning services only plus minor gyn services. This is written and signed with their physician agreeing to work within the scope of their training while using designated resources as well as consult with the physician in making diagnoses and providing treatments. |
| Registered Nurse graduate of a certificate nursing program in advanced nursing practice but without national certification. Has RN licensure only. No approved BON title other than RN | Protocols are written in detail to reflect standard of care for each method of contraception and minor gyn complaints. Also uses physician or APN consult to guide diagnoses and treatments. |
| Public Health Nurse with in-house training in family planning service. Has RN licensure only. No approved BON title other than RN | Detailed protocol for the provision of each method of contraception. Minor gyn problems or contraception side effects require consult with MD or APN. Also provides the standard nursing services authorized under the statewide public health nurse protocol (described below) for family planning services. |
| Public Health Nurse Has RN licensure only. No approved BON title other than RN. | Public Health Nurse protocols reflect standards of nursing care plus standing orders for routine treatments such as immunizations, treatment of positive STD tests, etc. |

**FAMILY PLANNING APPOINTMENTS**

The regions/metros/agencies have different approaches to the scheduling of family planning clients. Some clinics see clients on a standard classic appointment system; some clinics use a modified walk-in approach called "same-day, next-day". Whatever system a region/metro/agency uses for an appointment, it is strongly recommended that an appointment system not become a barrier to service due to the complexity of the system or due to the wait time for an appointment. As a guideline, it is recommended that family planning clients be scheduled within 10 business days and preferably sooner if possible. It is recommended that adolescent clients be given special scheduling consideration. It is recommended that clients be asked if they have special scheduling needs (i.e., a certain day off from work or a certain day when there is transportation). Since Tennessee has a pregnancy unintendedness rate of 49.6% (PRAMS, 2008), the Family Planning Program must not create barriers to service via appointment systems that may serve staff well but do not meet the needs of all clients who call or walk-in to schedule family planning services.

**CLINIC FLOW**

The way that a client moves through the clinic is called clinic flow. The goal is to move the client through her visit smoothly and efficiently. Efficiency includes using client time and staff expertise optimally. The goal is to have no client waiting more than 30 minutes for a clerk, nurse assistant, nurse, NP or physician. It should also be the goal to use the NP and physician time wisely. It is best to minimize staff down time as much as possible.

In order to achieve good clinic flow, it is recommended that the client herself complete, as much as possible, a self-history form. The client moves from the clerk to an individual who collects the basic labs such as blood pressure, height, weight, etc. This may be a nurse or a nurse assistant. This is a very brief visit and the client then moves into the exam room. The examiner will review the history, perform the exam, and write the plan of care.

The public health nurse will then receive the client. She will have the client review and sign a method specific consent form. She will carry out the orders in the plan of care including dispensing the ordered method. She will discuss confidentiality and record how the client wants to receive information from the clinic. She will arrange any ordered referrals or labs; and provide the needed health teaching. The client then returns to the clerk who will exit the client.

This particular pattern of flow through the clinic is given as an example only but it is highly recommended. Clinics need to establish optimal clinic flow, and use staff time wisely.

## INFORMED CONSENT

Federal requirements for method-specific informed consent can be found in section 8.1 of the federal Program Guidelines. Informed consent is a process as well as a form. A consent form cannot replace the exchange of information between the provider and the client that culminates in the client accepting or refusing a specific procedure or treatment. The consent form is intended to record this process. It becomes a part of the medical record. The informed client also has the right to refuse to undergo any of the treatments or procedures. The method-specific consent form, documenting the client's voluntary consent to receive the program's services, must be signed by the client. In order to give informed consent for contraception, the client must receive education on the benefits and risks of the various contraceptive methods. On the contraceptive of choice, the client must receive education on the safety, effectiveness, potential side effects, complications, and danger signs of the contraceptive method of choice. The consent form does not need to be signed yearly or upon readmission, unless indicated in the list below. Signing an informed consent form is required for:

- All new clients (clients who are already on an established method of contraception are considered new to the Family Planning Program and should sign a consent form).
- Clients who change methods, even if the change is to a method that the client used at a previous time.
- Clients with whom the provider believes there is a need to review information.
- Clients for whom there is a major change in health status.

Often times a client may enter the Family Planning Program for a method that cannot be provided that day such as the implant or an IUD. If the client leaves with a non-prescriptive method such as male condoms, it is recommended that she sign the Consent for Non-prescriptive Method Consent Form. Then she would sign the consent form for the IUD or implant on the day that the method was provided.

## HISTORY

At the initial comprehensive clinical visit, a complete medical history <u>must be obtained</u> on all female and male clients. Pertinent history <u>must be updated</u> at subsequent clinical visits. The comprehensive medical history <u>must address</u> at least the following:

- Acute or chronic medical conditions, significant illnesses; hospitalizations; surgery; blood transfusions or exposure to blood products
- Allergies
- Current use of prescription and over-the-counter medications
- Extent of use of tobacco, alcohol, and other drugs
- Immunizations, annual influenza vaccination, and rubella status (inquire regarding rubella status and request records if necessary to document rubella vaccination; teach client about the risks of rubella in pregnancy; document inquiry and teaching)
- Review of systems as relates to the current subjective symptoms perceived by the client
- Pertinent history of immediate family members

- Partner history including partner use of injectable drugs, multiple partners, risk of STDs and HIV, and bisexuality.
- Contraceptive use past and current including adverse effects (females)
- Menstrual history (females
- Sexual history including HIV risks and all other high risk sexual behaviors (males and females)
- Obstetric history (females)
- Gynecological conditions (females)
- Sexually transmitted diseases, including HBV (males and females)
- HIV (males and females)
- Pap smear history including date of last Pap, any abnormal Pap, treatment (females)
- In utero exposure to diethylstilbestrol (DES) (males and females)

**PHYSICAL EXAMINATION**

Male clients requesting temporary methods of contraception are not required to undergo physical examination, but should be offered this service.

Females using prescriptive methods of contraception must have a general physical examination. Females using non-prescriptive methods or diaphragms should have a general physical examination at least every two years. The examination for males and females should include at least the following:

- Height and weight for BMI
- Blood pressure
- Thyroid
- Heart
- Lungs
- Extremities
- Breasts, including review of instruction in self breast exam
- Abdomen
- Pelvis
- Digital prostate exam in males over age 50 with instruction in self-exam of the testes for males of any age
- Rectum (Colorectal screening begins at age 50 for males and females as noted in OPA Program Instruction Series, OPA 03-01: *Screening for Cervical and Colorectal Cancer and Sexually Transmitted Diseases (STD), November 2003.*)

Clinics must provide and encourage all clients to use health maintenance screening procedures including immunizations and influenza vaccination. Clinics must provide and stress the importance of the following to their female clients and should stress and provide the following to their male clients:

- Blood pressure evaluation
- Breast examination
- Pelvic examination that includes vulvar evaluation, speculum exam, and bimanual exam (females)
- Genital examination including prostate examination age 50 and older or as needed (males)
- Cervical cancer screening for women (Pap smear) (females)
- STD and HIV screening as indicated
- Rectal examination (Colorectal screening to begin at age 50 as stated above)

**The Deferred Exam Visit**

A provision has been made within the *Program Guidelines for Project Grants for Family Planning Services, January 2001* to allow for the delay of the physical examination. Physical Examination and related prevention services should not be deferred beyond 3 months after the initial visit, and in no case may be deferred beyond 6 months, unless, if in the provider's judgment, there is a compelling reason for extending the deferral. All deferrals, including

the reason(s) for deferral, must be documented in the client record. For definitions and requirements of the components of an initial visit, refer to all of section 7, entitled Client Services, and all of section 8, entitled Required Services, within *Program Guidelines for Project Grants for Family Planning Services, January 2001.*

The exception to the rule regarding only 3-6 month delay of examination and related preventive services is made in the case of an adolescent who has been sexually active less than three years. In this case, the cervical cancer screening component (Pap smear test) may be delayed until the client has been sexually active three years or becomes 21 years of age (which ever comes first). Only the Pap smear is delayed in this instance and the rest of the required exam components will be completed. (For more information, see Cervical Cancer Screening Guidelines found within this document.)

The plan of care for a deferred exam visit be considered preliminary or temporary and will include:

- An explanation for the deferral
- A comprehensive medical history for the initial client. The history must be negative for contraindications as listed in this protocol.
- Updated medical history for the annual client who needs new orders for her method but either she has missed or the clinic cannot provide the exam visit at this time. The history must be negative for contraindications as listed in this protocol. See the PTBMIS codes manual for the coding of this visit.
- For annual visits (or supply visits), consult for Pill side effects that have not responded to standard treatments (i.e., Pill at bedtime for nausea), complications, or warning signs. Record consultant instructions in chart.
- Blood pressure measurement,
- hemoglobin or hematocrit as indicated
- Name, dosage, route, and frequency of the contraceptive chosen
- The number of cycles given or covered (up to 3 cycles)
- Informed consent
- Necessary health teaching to use method correctly and consistently
- Document health teaching/counseling in chart.
- Offer condoms and/or contraceptive foam or film for use as back-up protection against unintended pregnancy.
- Date of the exam appointment

**The Exam Visit**

The plan of care for an exam visit will include:

- Name, dosage, route, frequency of the contraceptive chosen; the number of cycles to be dispensed and/or when to return to be re-supplied.
- Initial patients may receive 3-4 cycles with 9-10 cycles on re-supply or be re-supplied as required by the method
- Whenever possible, depending upon the method, established clients should receive 13 cycles (Clients, who have been on their contraceptive method for some time from another provider and are having no problems, may also receive 13 cycles)
- Provide or continue health teaching at the exam visit (see below). PHN can be directed to provide this.
- Document which health teachings were provided.
- Offer condoms and/or contraceptive foam or film for use as back-up protection against unintended pregnancy
- Provide ECPs in advance of need or educate client on the availability of ECPs
- Stress making appointment for re-supply or annual exams before method runs out
- Other treatments as may be indicated from the examination and assessment
- Referrals for blood pressure 140/90 or greater, resting, on three visits with each visit no more than one week apart, or a diastolic measurement of 100 or more on a single visit
- Referral, testing, consult and/or treatment for urinalysis positive for glucose, or 2+ or greater for protein or other abnormal laboratory tests
- Refer or consult for problems not covered by the Family Planning Program
- Clients are returned annually, for re-supply, and as needed for problems.

## LABORATORY

The following laboratory procedures must be provided to clients if required in the provision of a contraceptive method and may be provided for the maintenance of health status and/or diagnostic purposes either on-site or by referral. A procedure that addresses client confidentiality must be established to allow for client notification and follow-up of abnormal laboratory results.

- Hemoglobin or Hematocrit
- Pap smear
- Sickle cell screening
- Mantoux tuberculin test
- Pregnancy test
- Gonorrhea and chlamydia screening (See required restrictions to screening in the Chlamydia section of this document)
- Vaginal wet prep
- Diabetes testing
- Cholesterol and lipids
- Hepatitis B testing
- Syphilis serology
- Rubella titer
- Urinalysis
- HIV testing (CDC recommends that HIV testing be a part of routine medical care. Follow current Tennessee STD Program guidance.)

**OPTIONAL LAB TESTS**: may be provided as needed.

## TYPES OF VISITS IN FAMILY PLANNING IN TENNESSEE

### Preconception Health and Pregnancy Planning

All visits to the family planning program are an opportunity to teach clients about the importance of preconception health and pregnancy planning. Together these are sometimes referred to as the reproductive health plan. Begin with the questions found on the medical history including:

1. When if ever would you like to become pregnant or become pregnant again?
2. How many children would you like to have?

Proceed by learning the client's history of and desire for a type of contraception. Then review the client's answers to the sexual behavior questions in the history. Proceed to provide the clients with basic reproductive health information that she may need including:

1. The importance of avoiding high risk sexual behavior
2. The importance of adopting positive health habits prior to any future conception
3. The importance of a visit to a health care provider for health assessments prior to any future conception

Finally, remind clients that from time to time all women feel ambivalent about avoiding pregnancy. Wanting to conceive, be pregnant and become a mother is normal even when it is not the best time to have a child. Waiting to become pregnant until a woman is in good health is best for the woman and the desired child. Teaching clients about preconception health and pregnancy planning promotes healthy mothers and babies.

A client who schedules a preconception health visit between exam visits is coded, "no exam-counseling".

## INITIAL VISIT

For definitions and requirements of the components of an initial visit, refer to all of section 7, entitled Client Services, and all of section 8, entitled Required Services, within *Program Guidelines for Project Grants for Family Planning Services, January 2001.*

An initial family planning visit for a male or female client occurs the first time a client presents to a family planning clinic in Tennessee (see deferred physical examination next paragraph). An initial visit for a male or female client must consist of education and counseling, informed consent (signed consent form females only), history, physical examination (females only and offer to males), appropriate laboratory tests, provision of a method of contraception (see the specific method guidelines included in this manual), and plans for follow-up and referral as needed.

A provision has been made within the *Program Guidelines for Project Grants for Family Planning Services, January 2001* to allow for the delay of the physical examination and related preventive health services. Physical examination should not be deferred beyond 3 months after the initial visit, and in no case may be deferred beyond 6 months, unless if in the provider's judgment there is a compelling reason for extending the deferral. All deferrals, including the reason(s) for deferral, must be documented in the client record. A deferred exam initial visit is coded as a supply visit in PTBMIS.

**RETURN VISITS**

A return family planning visit for a male or female client must be individualized based upon the client's need for education, counseling, and clinical care. Clients selecting hormonal contraceptives, intrauterine devices, or diaphragms for the first time should be scheduled for a revisit as appropriate after initiation of the method to reinforce its proper use, to check for possible side effects, and to provide additional information or clarification. A new or established client who chooses to continue a method already in use is not required to return for this early visit. See the PTBMIS codes manual for coding information.

**MEDICAL REVISIT**

A family planning medical revisit occurs when the client is returning for follow-up care and receives one or more of the medical services which requires placing her on the exam table. The medical visit should include history of the presenting complaint, update of the general history, perform necessary physical evaluation, perform laboratory tests as indicated, and treat or refer according to protocol. Provide counseling and education as needed. See the PTBMIS codes manual for coding information.

**ANNUAL EXAM**

An annual exam describes a continuing client who receives her/his annual physical examination within the family planning program. Regions/agencies have the option to schedule clients using non-prescriptive methods or diaphragms for services every two years rather than annually. Annual exams include: education and counseling, history, physical examination, appropriate laboratory tests, continuation of a method of contraception or method change (see the specific method guidance included within this document), method specific informed consent form if there is a method change, and plans for follow-up or referral if needed. See the PTBMIS codes manual for coding information.

A provision has been made within the *Program Guidelines for Project Grants for Family Planning Services, January 2001* to allow for the delay of the physical examination. Physical examination and related prevention services should not be deferred beyond 3 months after the annual visit, and in no case may be deferred beyond 6 months, unless if in the provider's judgment there is a compelling reason for extending the deferral. All deferrals, including the reason(s) for deferral, must be documented in the client record. A deferred exam annual visit is coded as a supply visit in PTBMIS.

**SUPPLY VISIT**

A supply visit occurs when a client is returning to the clinic for a re-supply of his or her contraceptive. Supply visits should include reproductive health education and counseling. Supply visits also include: brief history update since the last visit of new problems or concerns, blood pressure for hormonal contraceptive users or for other methods as indicated, weight as needed, optional lab tests may be provided as indicated.

**PREGNANCY TEST VISIT**

Pregnancy testing must be provided to all clients in need of this service. (See Pregnancy Test Guidelines within this document for further information.) Pregnancy testing is important as an entry point for providing education and counseling about reproductive life planning, family planning, and preconception health. When a woman presents to the health department requesting a pregnancy test, one should be provided on the day of request, even if family planning clinic services are not normally available on that day. Pregnancy testing is a high priority.

**OTHER VISIT**

The "other" visit category is used any time the client is in the clinic for a reason other than an initial, medical, annual or supply visit. For example, a family planning client who returns to the clinic for special counseling or for any medical services that do not require a table exam such as a blood pressure check would be considered an "other visit".

As always, for those Title X sites that are on the PTBMIS system, please refer to the most current PTBMIS codes manual for information on how to code Family Planning visits. The PTBMIS codes manual can be found on the Health Services Administrations (HAS) intranet web site.

## REFERENCES


1. American College of Obstetricians and Gynecologists, Committee on Professional Liability, *ACOG Committee Opinion*, Number 166, "Informed Refusal", December 1995.
2. American College of Obstetricians and Gynecologists, Department of Professional Liability, *The Assistant,* Number 4, "Informed Consent", 1997.
3. U.S. Department of Health and Human Services, Office of Public Health and Science, Office of Population Affairs, Office of Family Planning, *Program Guidelines for Project Grants for Family Planning Services*, January 2001, (latest edition).
4. U.S. Department of Health and Human Services, Public Health Service, Office of Population Affairs, *OPA Instruction Series, OPA 03-01: Screening for Cervical and Colorectal Cancer and Sexually Transmitted Diseases (STD), November 3, 2003.*
5. U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services*, Third Edition, Agency for Health Care Research and Quality, publication number 02-500, September 2002.

## EDUCATION AND COUNSELING PLAN

Education is the presentation of relevant information and educational materials, based upon client needs and knowledge. Title X clinics must have written plans for client education that include goals and content outlines to ensure consistency and accuracy of information provided. Client education must be documented in the client record. The statement, "Education provided per protocol" is not acceptable documentation per Title X guidelines. Topics covered at any family planning visit must be documented by name and be provided in accordance with a standard Title X curriculum. A family planning education documentation table has been provided on the Initial History form. Return to this area to document client education at every visit. The education provided should be appropriate to the client's age, level of knowledge, language, and socio-cultural background and be presented in an unbiased manner. A mechanism to determine that the information provided has been understood should be established. Details of federal education requirements can be found in section 8.1 of *Program Guidelines for Project Grants for Family Planning Services, January 2001.*

Counseling is an interactive process in which a client is assisted in making an informed choice. Federal guidance on counseling can be found in section 8.2 of the above referenced document. The primary purpose of counseling in the family planning clinic is to assist clients in reaching an informed decision regarding the choice and continued use of family planning methods and services. The counseling process is designed to help clients resolve uncertainty, ambivalence, and anxiety in relation to reproductive health and to enhance their capacity to arrive at a decision that reflects their considered self-interest.

The goal of a Family Planning education and counseling plan is to assure that the client receives accurate information and support when choosing her contraceptive method. This includes knowing how to use her method correctly, what common side effects to expect, how to manage these side effects, what are the danger signs for the method, and who to call if danger signs develop. It also includes helping the client explore how she feels about a method and whether or not the client sees herself as being able to be use her chosen method correctly and consistently.

To accomplish this goal, the following tools, guidelines, and protocols are used in all Title X family planning clinics in TN:

- Family planning method specific consent form with teaching tool.
- Family planning method specific client instruction sheets.
- Family planning Quick Reference Guide to services, counseling and education.
- Family planning initial history form with counseling and education documentation.
- Primary care health questionnaire form with counseling and education documentation.
- PHN Protocols
- Family Planning Clinical Guidelines (this document in total)
- Local family planning protocols for the APNs.

Every client contact is an opportunity to improve health through counseling and education. To that end, many topics could be presented to the client during her family planning visit. Since it is commonly accepted that clients will remember approximately three points per visit, staff should make every effort to prioritize topics presented with emphasis on the current Title X family planning program priorities. Over time, from one visit to the next, the client should eventually receive all of the following information:

**Required counseling/education topics:**

- Purpose and sequence of clinic procedures including the return visit schedule
- Health Department services (can be given in writing)
- Importance of recommended tests and screenings
- Information necessary to be able to give informed consent
- Information about all contraceptive methods, including fertility awareness-based methods and abstinence, (can be given to the client in writing)
- Information necessary to be able to use the chosen contraceptive method correctly and consistently including how to discontinue the method, back-up methods, and ECPs.

- Information necessary to be able to identify adverse reactions, common side effects and possible complications of the method selected and what to do in case any of these occur
- Education regarding safer sex, STDs and the importance of HIV/AIDS testing
- Reproductive Life Planning
- The importance of family involvement (all adolescents on first visit)
- How to recognize and resist sexual coercion (all adolescents on first visit)
- Self breast exam for females and self-testicular exam for males (can be given in writing)
- Emergency contraception (ECPs)
- Results of the history, physical examination, laboratory studies or instructions as to when test results will be available
- Emergency 24-hour telephone number and where emergency services can be obtained
- Appropriate referrals for additional services as needed

**Optional counseling topics:**

- Nutrition
- High-risk sexual behaviors related to STDs
- Pap smear testing and cervical cancer
- Disease prevention and maintenance of health
- Instructions regarding calcium supplementation as a precaution against osteoporosis (adolescents and young adults, 1200-1500 mg day; adults aged 25-50, 1000 mg day; post menopausal women, 1000-1500 mg day)
- Instructions regarding folic acid supplementation (400 mcg daily)
- Counseling regarding avoidance of tobacco products
- Counseling regarding the adverse effects of alcohol and drug abuse
- Domestic violence and personal safety
- Unintended pregnancy prevention and its value in maintaining individual, child and family health
- Basic female and male anatomy and physiology (can be given in writing)

## CONTRACEPTIVE METHOD COUNSELING

Contraceptive method counseling must be provided to:

- Assure that the client knows results of the history, physical examination, and laboratory studies
- Assure that the client knows how to use the contraceptive method selected and is comfortable with its use
- Assure that the client knows common side effects and possible complications of the method selected and what to do in case they occur
- Assure that the client understands the return visit schedule and mechanism for obtaining next appointment
- Assure that the client knows the emergency 24-hour telephone number and location where emergency services can be obtained
- Assure that the client receives appropriate referral for additional services as needed.

## HIV AND SEXUALLYTRANSMITTED DISEASES (STD) COUNSELING AND EDUCATION

All clients must receive thorough and accurate counseling on STDs and HIV including assessment of individual risk. The Center for Disease Control and Prevention (CDC) has developed national HIV/AIDS Prevention Strategies which include HIV testing as a routine part of medical care. The CDC recommends that a routine general consent form be considered as covering HIV testing. CDC also recommends that only clients who “opt out” of HIV testing would not be tested. In Tennessee, follow the most current recommendation for HIV testing as directed by the Tennessee STD Program. Clients found to be at risk for HIV must receive risk reduction counseling. All clinics must offer education about HIV infection and AIDS, information on risks and infection prevention, and referral services. When a clinic does not offer HIV risk assessment, counseling and testing, the clinic must provide the client with a list of health care providers who can provide these services.

## SPECIAL COUNSELING

Clients should receive special counseling regarding future planned pregnancies, sterilization, and other individual issues (e.g., genetic, nutritional, sexual, preventive health) as indicated. Clients exposed to DES in utero should be made aware that they are at risk for certain conditions.

## REFERENCE


1. U.S. Department of Health and Human Services, Office of Public Health and Science, Office of Population Affairs, Office of Family Planning, Program Guidelines for Project Grants for Family Planning Services, January 2001
2. U.S. Department of Health and Human Services, Public Health Service, Office of Population Affairs, *OPA Program Instruction Series, OPA-87-4: AIDS Education, Counseling and Testing in Title X*, December 8, 1987.
3. U.S. Department of Health and Human Services, Public Health Service, Office of Population Affairs, *OPA Program Instruction Series, OPA 98-1: Certifications for Encouraging Family Participation and Counseling to Minors on How to Resist Coercive Attempts to Engage in Sexual Activities,* February 24, 1998.

## ENCOURAGING FAMILY PARTICIPATION IN FAMILY PLANNING

### FAMILY PARTICIPATION IN FAMILY PLANNING

### POLICY

The federal Office of Population Affairs (OPA) *Program Guidelines for Project Grants for Family Planning Services, January 2001*, section 8.7, page 25, last paragraph, states:

"Adolescents must be assured that the counseling sessions are confidential and, if follow-up is necessary, every attempt will be made to assure the privacy of the individual. However, counselors are to encourage family participation in the decision of minors to seek family planning services and provide counseling to minors on resisting attempts to coerce minors into engaging in sexual activities. Title X projects may not require written consent of parents or guardians for the provision of services to minors. Nor can the project notify a parent or guardian before or after a minor has requested and received Title X family planning services."

Staff persons are to be aware of these requirements and ensure that family involvement counseling for adolescents is integrated into the clinic setting while client confidentiality is respected.

### DEFINITION

Family involvement includes, but is not limited to, parental awareness of a minor's decision to seek family planning services, discussion of family planning options, and encouragement of responsible sexual decision-making.

### CONFIDENTIALITY

Adolescents are entitled to confidential services and counseling. Historically, the states have determined whether parental consent is necessary for the treatment of minors. In Tennessee, there is no parental consent required for family planning, prenatal, HIV/AIDS, or sexually transmitted disease services.

According to The Alan Guttmacher Institute, most teens seeking services at Title X clinics are already sexually active. Fear of parental discovery is a concern that may prevent or delay sexually active teens from seeking contraceptive services, placing them at an increased risk for unintended pregnancies and sexually transmitted diseases (STDs).

### COUNSELING ISSUES

Adolescents have special needs requiring extra counseling, patience and attention to emotional problems, as well as needs for information and education. Adolescents may require more visits to the clinic than older clients. Visit schedules should be individualized according to the adolescent's ability to assimilate the information. Counseling will emphasize the need for the involvement of a supportive family member in the adolescent's health care decisions.

### PROVIDER TASKS

By integrating encouragement of family involvement into the family planning visit, the staff will help adolescents develop the interpersonal skills necessary to involve their families. Adolescents will need information about contraception, safer sex, abstinence, teen pregnancy, STDs, and HIV/AIDS. Adolescents often need to be introduced to the concept of responsible decision-making as regards their sexuality. Whenever possible, adolescents should receive this counseling prior to initiating sexual intercourse. It is important that providers always:

- Listen to adolescents.
- Encourage responsible decisions.
- Encourage communication with parents or other adult family member in their reproductive health decisions.
- Assure the adolescent of confidentiality.
- Develop a plan to contact the client without jeopardizing confidentiality.

## RESISTING COERCION TO ENGAGE IN SEXUAL ACTIVITY

## POLICY

Counseling concerning sexual coercion must be provided to all minors who present to Title X Family Planning Clinics. The initial visit is an excellent time to counsel and provide literature regarding this issue. The frequency of counseling shall be based on client needs.

## DEFINITION

Sexual coercion is the act of persuading or coercing a person into engaging in an unwanted sexual activity through verbal pressure (i.e., "everyone's doing it"), physical force, threat of physical force, or emotional manipulation (i.e., insincere complements, expensive gifts, put downs, guilt trips). It differs from rape in that the coerced individual feels it is easier to consent to sexual activity than to decline, because of an imbalance in power. Coercive situations may not be obvious, even to the coerced individual.

## PROVIDER TASKS

By integrating counseling on resisting sexual coercion into the family planning visit, the provider will help adolescents develop the interpersonal skills necessary to resist coercion. Adolescents will need information about contraception, safer sex, abstinence, teen pregnancy, STDs, and HIV/AIDS. Adolescents may need to be introduced to the concept of responsible decision-making as regards their sexuality. Whenever possible, adolescents should receive this information prior to initiating sexual intercourse. It is important that the provider always:

- Listen to adolescents.
- Encourage responsible decisions.
- Assess adolescents for evidence of sexual abuse or sexual violence.
- Assess adolescents for evidence of sexual coercion.
- Document all counseling and information provided.
- Ensure that sexual coercion counseling of adolescents is integrated into the clinic setting.

Providers can recommend the following tips for resisting sexual coercion:

- Trust your feelings. If it feels wrong, say no firmly and leave.
- Plan ways to respond to verbal pressure.
- Avoid alcohol and drugs. Alcohol and drugs alter the ability to resist coercion.

Contact the regional/metro/agency Family Planning Administrator to request a copy of *Preventing Sexual Coercion Among Adolescents: A Training Guide for the Family Planning Provider*.

## REFERENCES


1. Office of Population Affairs, Office of Family Planning, U.S. Department of Health and Human Services, *Program Guidelines for Project Grants for Family Planning Services, January 2001.*
2. Office of Population Affairs, Program Instruction Series OPA 99-1, *Compliance with State Reporting Laws,* January 12, 1999.
3. Risisky, D., Turner, K., Stolbach, J., *Preventing Sexual Coercion Among Adolescents: A Training Guide for the Family Planning Provider,* Emory University Regional Training Center, Atlanta, Georgia, 1999.
4. Tennessee Department of Health, Bureau of Health Services, Office of Nursing, *Public Health Nursing Statewide Protocol*.
5. Tennessee Code Annotated (TCA), The Official Tennessee Code, Prepared under the Supervision of the Tennessee Code Commission: TCA Section 68-34-101-111, Family Planning Act; TCA Code Sections 37-1-601 through 37-1-616, Child Sexual Abuse; TCA Section 37-1-401, Mandatory Child Abuse Reports.
6. http://www.tennessee.gov/youth/cps/index.htm (cps stands for child protective services which is a division of the Department of Children's Services)

## Child Abuse Reporting in Tennessee

Every year since FY 1999, the federal spending bill for Title X family planning services has contained the following legislative mandate:

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

In Tennessee, the Department of Children’s Services (DCS) has the responsibility of investigating suspected child abuse including child sexual abuse. To that end, DCS has published the following toll-free number where all citizens of Tennessee, including all health care professionals, are to report suspected child abuse and child sexual abuse. That number is 1-877-237-0004. Anyone who “suspects” is to report. DCS will determine whether or not an investigation is merited. This guidance is in compliance with Department of Health Bureau policy 8.8. Staff persons are not required to seek the permission of their supervisor before reporting suspected abuse, but should notify their supervisor as soon as possible. The report is documented on form PH 2947 and forwarded to DCS after the call. A copy of this form is kept in the clinic in a confidential file separate from the client’s chart. A copy of the form (marked confidential) is also sent to the regional nursing director.

## REFERENCE

1. http://tennessee.gov/youth/childsafety.htm

## HIV PREVENTION COUNSELING

Over the past two decades, the Centers for Disease Control and Prevention (CDC) has focused on helping uninfected persons at high risk for contracting the human immunodeficiency virus (HIV) to change and maintain behaviors such that they might remain uninfected. Despite these efforts the number of new HIV infections remains about the same each year while newer more effective treatments have increased the number of persons living with HIV.

There are approximately 850,000-950,000 Americans living with HIV today. One-fourth of these persons do not know they are infected. There are approximately 40,000 new cases of HIV each year. The majority of these new infections are transmitted by persons who do not know they are infected. Forty-one percent of persons who are HIV positive find out their HIV status less than one year before progressing to AIDS (Autoimmune Deficiency Syndrome). Of those who test positive at a CDC-funded HIV testing site, 31 percent do not return for their test results.

In April 2003, the CDC launched a new initiative aimed at reducing barriers to early diagnosis of HIV infection and to reducing barriers to referral to quality care services. This effort entitled “Advancing HIV Prevention” (AHP) focuses on four new strategies for HIV prevention:

- HIV testing as a part of routine medical care
- Implement new models for diagnosing HIV outside the medical care setting
- Prevent new infections by working with persons living with HIV and their partners
- Further decrease perinatal HIV transmission

The overall goal is to reduce barriers to early HIV diagnosis and increase access to state-of–the-art medical care, treatment, and ongoing prevention services for persons living with HIV. The four strategies of the initiative should give every HIV-infected individual the opportunity to be tested, have access to quality medical care and to prevention services needed to prevent further HIV transmission.

In September 2006 the CDC revised its recommendations for HIV testing in health care settings. The recommendation includes the concept of test unless the client “opts out”. That is, HIV testing is recommended by the CDC for all clients in health care settings after the client is informed that the testing will be performed unless the client declines. This applies to health care settings (which includes public health clinics) only. Separate consents for HIV testing are not required.

The CDC also reports that, “The number of persons in the United States who report ever being tested for HIV is increasing, and fewer persons are being diagnosed late in their infection. However, nearly <u>one third</u> of diagnoses still occur late. Increased testing efforts are needed, particularly among populations that account for most HIV diagnoses.

The CDC notes, “All health-care providers should expand routine HIV screening so that all adults are tested. Members of populations with higher rates of HIV diagnoses and living in geographic areas with high HIV prevalence should be screened more frequently than others. Persons likely to be at high risk for HIV infection (e.g., gay, bisexual, and other men who have sex with men) should be tested at least annually. Public health officials should emphasize the importance of HIV testing and allocate resources to increase testing among populations with the highest rates of HIV diagnoses.”

Within the family planning clinic setting, staff can support the CDC by promoting HIV testing as a part of routine medical care. Staff can offer onsite testing at the time of the family planning visit or encourage timely testing at a nearby location. Clients require counseling regarding the importance of returning for test results.

Family planning staff can also participate in the discussion in their communities to promote testing outside of medical visits using the newer rapid test technologies such as those developed by OraSure Technologies, Inc.: OraQuick Rapid HIV-1 Antibody Test or OraSure HIV-1 Oral Specimen Collection Device. Possible non-medical sites include prisons, juvenile detention centers, university campuses, booths at music events, fairs, or other community activities.

As a part of the federal key issues for Title X clinics, Family planning staff should present the A-B-C Strategy for HIV Prevention to their clients who are negative for HIV. A client instruction sheet can be found in the appendix to use in discussing the following strategy:

*A* is for abstain. If you abstain from vaginal, anal, or oral sex you will not get HIV from sex.

*B* is for be faithful. If you and your sex partner are faithful to each other, you greatly reduce the risk of getting HIV.

*C* is for condom use. If you are sexually active, use condoms, especially if you have more than one partner.

Finally, Family Planning staff can screen clients for feelings of anger, depression, and hopelessness. People who believe their future holds no hope for happiness take more risks. These individuals need referral to resources in their community that can support them as they sort through these issues and behaviors.

## Appendix

1. ABC for HIV Client Instruction Sheet

## References


1. Morbidity and Mortality Weekly Report, "Advancing HIV Prevention: New Strategies for a Changing Epidemic", April 18, 2003.
2. Morbidity and Mortality Weekly Report, "Vital Signs: Hive Testing and Diagnosis Among Adutlts-United Stated, 2001-2009, December 3, 2010 / 59(47);1550-1555
3. Centers for Disease Control and Prevention, "AHP Initiative Quick Facts", www.cdc.gov.
4. Centers for Disease Control and Prevention, "Advancing HIV Prevention: Progress Fact Sheet April-December 2003, www.cdc.gov.
5. The Prevention Connection, A Newsletter from CDC's National Center for HIV, STD, and TB Prevention, "Letter from the Director, Dr. Harold Jaffe, Spring 2003.
6. The Prevention Connection, A Newsletter from CDC's National Center for HIV, STD, and TB Prevention, "New CDC Initiative: Advancing HIV Prevention", Dr. Julie Louise Gerberding, Director, Centers for Disease Control and Prevention, Spring 2003.
7. National Center for Policy Analysis, Daily Policy Digest, Health Issues/Public Health "Ugandan Model of AIDS Prevention, May 16, 2003.
8. Conference: The Call to Action on Sexual Health: Science and Belief Seeking Common Ground: Sexual Health and Responsible Sexual Behavior: Building Bridges and Finding Common Ground, Speaker: David Satcher, M.D., May 24, 2004, transcript at www.kaisernetwork.org.
9. Morbidity and Mortality Weekly Report, "Sexually Transmitted Diseases Treatment Guidelines, 2006, Volume 55, No. RR-11, pages 10-12, August 4, 2006.

## PREVENTING INTIMATE PARTNER VIOLENCE

Intimate partner violence (IPV), formerly referred to as domestic violence, can be defined as purposely causing harm to a person with whom you have a relationship. This harm includes physical abuse, psychological/emotional abuse, sexual assault, isolation, or economic abuse (controlling food, shelter, money etc.). This harm is committed by a husband, former husband, boyfriend, or ex-boyfriend. Sometimes the abuser is another female. In the case of abuse of the elderly, the abuser may be a son, daughter, or other relative. The victims of IPV are more often women.

Violence against another person is always wrong. The victim is never responsible for the violent behavior and does not cause the abuse to occur. Sometimes victims are not sure if they are being abused. The American College of Obstetricians and Gynecologists suggests the following list of questions to determine whether or not the client is a victim of abuse. Just one yes answer means the client is involved in an abusive relationship.

Does the person you love:

- Threaten to hurt you or your children
- Say it's your fault if he or she hits you, then promises it won't happen again (but it does)
- Put you down in public or keep you from contacting family or friends
- Throw you down, push, hit, choke, kick, or slap you
- Force you to have sex when you don't want to

The Tennessee Coalition Against Domestic and Sexual Violence suggest the following screening questions. If the client answers yes to even one of these questions, they are likely in an abusive relationship. When abuse is suspected, these questions, used carefully, can screen clients for IPV.

Does your partner:

- Embarrass you with bad names and put-downs
- Look at you or act in ways that scare you
- Control what you do, whom you see or talk to, or where you go
- Stop you from seeing or talking to friends or family
- Take your money or Social Security, make you ask for money, or refuse to give you money
- Make all the decisions
- Tell you you're a bad parent or threaten to take away or hurt your children
- Act like the abuse is no big deal, it's your fault, or even deny doing it
- Destroy your property or threaten to kill your pets
- Intimidate you with guns, knives, or other weapons
- Shove you, slap you, or hit you
- Force you to drop charges
- Threaten to commit suicide
- Threaten to kill you
- Monitor your time and make you account for every minute when you run errands, go to work, etc.
- Pressure you into sex
- Tell you no one will love you like they do

It is important that Family Planning staff know the shelter resources available in their community and be prepared to share information to clients in need.

Victims of IPV cannot always leave immediately. Therefore they should be encouraged to formulate a safety plan. Safety plans cannot guarantee safety. Nevertheless, a safety plan is important and may include the following:

- Having important phone numbers nearby for you and your children. Numbers to have are the police, hotlines, friends and the local shelter.

- Friends or neighbors you could tell about the abuse. Ask them to call the police if they hear angry or violent noises. If you have children, teach them how to dial 911. Make up a code word that you can use when you need help.
- How to get out of your home safely. Practice ways to get out.
- Safer places in your home where there are exits and no weapons. If you feel abuse is going to happen try to get your abuser to one of these safer places.
- Any weapons in the house. Think about ways that you could get them out of the house.
- Even if you do not plan to leave, think of where you could go. Think of how you might leave. Try doing things that get you out of the house - taking out the trash, walking the pet or going to the store.
- Put together a bag of things you use everyday (see the checklist below). Hide it where it is easy for you to get.
- Going over your safety plan often.

If you consider leaving your abuser, think about...

- Four places you could go if you leave your home.
- People who might help you if you left. Think about people who will keep a bag for you. Think about people who might lend you money. Make plans for your pets.
- Keeping change for phone calls or getting a cell phone.
- Opening a bank account or getting a credit card in your name.
- How you might leave. Try doing things that get you out of the house - taking out the trash, walking the family pet, or going to the store. Practice how you would leave.
- How you could take your children with you safely. There are times when taking your children with you may put all of your lives in danger. You need to protect yourself to be able to protect your children.
- Putting together a bag of things you use everyday. Hide it where it is easy for you to get.

ITEMS TO TAKE, IF POSSIBLE

- Children (if it is safe)
- Money
- Keys to car, house, work
- Extra clothes
- Medicine
- Important papers for you and your children
- Birth certificates
- Social security cards
- School and medical records
- Bankbooks, credit cards
- Driver's license
- Car registration
- Welfare identification
- Passports, green cards, work permits
- Lease/rental agreement
- Mortgage payment book, unpaid bills
- Insurance papers
- PPO, divorce papers, custody orders
- Address book
- Pictures, jewelry, things that mean a lot to you
- Items for your children (toys, blankets, etc.)

Review your safety plan often.

Victims of Intimate Partner Violence can also call the National Domestic Violence Hotline at: 1-800-799-7233 or 1-800-787-3224 (TTY) for help and support.

## References


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*Intimate Partner Violence, 1993-2001,* Bureau of Justice Statistics, U.S. Department of Justice, Office of Justice Programs, February 2003.

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*Domestic Violence Screening,* Sara Freeman, RN, CS, FNP, The Female Patient, Volume 29, page 6, , June 2004.

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## Reproductive Life Planning and Birth Spacing

Decreasing Infant mortality rates in Tennessee is an important Department of Health goal. Title X is also committed to improving the health of mothers and children.

The National Survey of Family Growth (NSFG) and the Pregnancy Risk Assessment Monitoring System (PRAMS) in the states are surveys that have revealed an important aspect to the birth of our children and that is that too often women are not planning their pregnancies. By helping women establish a reproductive life plan, we teach them how to have healthy babies and empower them to be able to decide when to have their children and how many children to have.

Nationally, the most common reason for not wanting to be pregnant but having unprotected sex is, “I didn’t think I could get pregnant.” In Tennessee, the most common reason for not wanting to be pregnant but having unprotected sex is, “I guess I didn’t mind if I got pregnant.” These two statements show that there is a need for reproductive health education and counseling.

When discussing a reproductive life plan with a client, the following should be covered:

1. Reproduction, the menstrual cycle, and fertility awareness
2. STD prevention to preserve fertility
3. When do you want to become pregnant or when do you want to become pregnant again?
4. How many children would you like to have?
5. Spacing each “birth to next conception” 18-23 months apart
6. Contraceptive options including emergency contraception
7. Pregnancy Ambivalence – It is normal for women of reproductive age to want to become pregnant and to fantasize about becoming pregnant. Even women who say they know that this is not a good time to get pregnant can feel this way from time to time. It is common for women to become ambivalent about using contraception as they begin to long for a pregnancy. This ambivalence can lead to an unplanned pregnancy which satisfies the longing but creates new problems associated with unintendedness. Women who become pregnant this way may say it was just an accident that they couldn’t have prevented when in reality they knew they were taking chances; chances that were driven by ambivalence.
8. Planning – Planning is the opposite of ambivalence. Planning means acknowledging your desire to become pregnant and acting on that desire in the most positive way for your health and for the health of the baby. Planned pregnancies are more likely to produce a healthy baby than an unplanned pregnancy.
9. The preconception health care visit is a part of planning. It will include general health examination and testing, counseling, updating any needed immunizations (including rubella status), counseling regarding any possible familial genetic disorders, and starting prenatal vitamins with folic acid prior to conception. Smoking cessation would be a part of this visit for women who smoke.

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1. Vital Health and Statistics, Series 23, Number 29, May 2010, Data From the National Survey of Family Growth, Use of Contraception in the United States: 1982-2008.

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4. Journal of Contraception, Volume 78, number 5, November 2008, No Such Thing as an Easy (or EC) Fix, Editorial, pages351-354.

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6. Journal of Contraception, Volume 75, number 5, May 2007, Reasons for Unprotected Intercourse: Analysis of the PRAMS Survey, pages 361-366.

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CERVICAL CANCER SCREENING GUIDELINES

POLICY

All federal (Title X) and state guidelines are to be followed when collecting Pap tests. Guidelines for Pap management and Pap test follow-up must also be followed. On November 3, 2003, the Office of Population Affairs released Program Instruction Series, OPA 03-01 entitled "Screening for Cervical and Colorectal Cancer and Sexually Transmitted Diseases (STD)". These instructions acknowledged the standards of the American Cancer Society (ACS), the American College of Obstetricians and Gynecologists (ACOG), and the United States Preventive Services Task Force (USPSTF) regarding onset and frequency of Pap testing. Through OPA Program Instruction Series 03-01, permission was given for agency medical directors to change their medical protocols and practice to reflect current national standards. Using the December 2009 ACOG recommendations, cervical cancer screening in Tennessee Health Department clinics is as follows:

1. According to the ACOG, December 2009, annual cervical cytology screening should begin at age 21 years.
2. Women ages 21-29 should undergo cervical cytology screening with conventional cytology or with liquid-based cytology every 2 years.
3. Women age 30 years and older who have had three consecutive (not to exceed 60 months) negative cervical cytology screening test results and who have no history of CIN 2 or CIN 3, are not immunocompromised, are not HIV infected, and were not exposed to diethylstilbestrol (DES) in utero will extend the interval between cervical cytology examinations to every 3 years.
4. Women with a history of CIN 2 or CIN 3, or who are immunocompromised, or who are HIV infected, or who were exposed to diethylstilbestrol (DES) in utero, are at increased risk of cervical cancer and will need annual or more frequent Pap testing.
5. Both liquid-based cytology and conventional cytology are acceptable for screening.
6. Women who have undergone hysterectomy with removal of the cervix for benign indications and who have no prior history of CIN 2 or CIN 3 or worse may discontinue routine cytology testing.

In addition, it can be noted that the 2006 Consensus Guidelines released October 1, 2007, recommended that women 20 years of age or younger have less aggressive Pap follow-up. This is because this age group almost always clears the cervical cancer precursors, i.e., high risk types of human papilloma virus (HPV). Also, cervical cancer is virtually nonexistent in this age group. By over treating cervical cytological changes such as ASC-US and LSIL, healthy childbearing can be compromised.

The 2006 Consensus Guidelines also stated that HPV testing should be limited to high risk types only. There is no merit in testing for low-risk HPV. Within Tennessee's Cervical Cancer Screening Guidelines, reference to HPV testing refers to high risk HPV only.

OPA Program Instruction Series 03-01 also noted that, "Clinical protocols should continue to take into account individual client risks, use of specific methods of contraception, as well as current national standards of care." Both ACOG 2009 and the 2006 Consensus Guidelines recognized the need for individualizing care. Guidelines should never be a replacement for clinical judgment.

Also, this guidance does not preclude the importance of a complete physical examination, STD screening, and preventive health teaching. Always educate and counsel clients to recognize and to avoid high risk sexual behavior.

**DEFINITIONS**

The Pap test is an effective screening test for cervical cancer and its precursors. It is safe, cost-effective, widely available, and can detect abnormal cervical cells long before the disease becomes invasive or progressive. There are two types of Pap tests: the conventional Pap smear and the liquid-based Pap test. Within these Guidelines, we will differentiate the two types for the reader. Conventional Pap smear will mean the standard classic Pap smear slide. Liquid-based Pap test will mean the use of a brush and cytology liquid to transport cervical material to the laboratory. Pap test will mean either test.

**FREQUENCY OF CERVICAL CANCER SCREENING**

Cervical cancer screening can be performed as needed during a family planning or a primary care women's health visit. The frequency of cervical cancer screenings is as follows:

1. Begin Pap testing at age 21
2. If a woman less than age 21 is inadvertently Pap tested or if screening took place before the release of these guidelines and if she has or had an abnormal result, conservative observational management should be the mainstay of care. Use the current recommendations of the Consensus Guidelines for Management of Women with Abnormal Cervical Cancer Screening Tests.
3. For women ages 21-29 with a normal Pap history and a negative medical history, test every two years with liquid-based or conventional cytology.
4. Women age 30 and older, who have had 3 consecutive (not to exceed 60 months) satisfactory and normal Pap tests (either conventional or liquid), will be tested every 3 years.
5. Women with an abnormal Pap result generally have special Pap frequency requirements. See the appropriate algorithm in this document.

**EXCEPTIONS TO THE CERVICAL CANCER SCREENING SCHEDULE**

1. Clients who have a documented Pap test (either type) with another provider within the appropriate age-based time frame.
2. Clients who are menstruating or who have douched or had sexual intercourse within the past 48 hours. In these situations, the Pap test (either type) can be delayed. An appointment for the Pap should be made within 3-6 months.
3. Clients who request to delay the physical exam and Pap test until a later date. The exam and Pap test can be delayed 3-6 months. An appointment should be scheduled for the exam and test.
4. Clients with obvious signs of infection should be treated first and receive their Pap test at another visit.
5. Always document why the Pap test was delayed.

For basic management of abnormal Pap tests or positive HPV results, see the attached algorithms. Clients who are returning to the health department after a colposcopy visit or cervical dysplasia treatment will be managed in accordance with the directions given by the colposcopist or the treatment provider.

**SCHEDULING AND TRACKING OF PAP TESTS AND HPV TESTS**

The following should be discussed with the client prior to the Pap test visit. The choice of staff member who provides this information is a regional decision.

1. Avoid douching for 2 days before the exam.
2. Avoid sexual intercourse for 2 days before the exam.
3. Avoid putting anything into the vagina for 2 days before the exam
4. Make appointment for Pap test 1-2 weeks after the end of menses.
5. Whenever possible, have any abnormal vaginal secretions treated before the Pap test is scheduled. (Health care provider may need to make this decision at the time of the exam.)

When a client gives a history of abnormal Pap tests results, send for these records. The client will need to sign the appropriate release of information in order for the health department to send for and receive these. Pap management will reflect consideration of these records, and may include (but is not limited to) consult with the assigned health officer and referral for further follow-up.

If a Pap test is not taken or an HPV test is not done when indicated (regardless of the reason), the client's chart should be flagged, and the reason noted in the chart. The nurse should indicate the scheduled return appointment date for continued cervical cancer screening.

Once the Pap test or HPV test has been taken, it should be documented in the client's record, entered into the tracking system, and the flag removed.

If the Pap test is not collected at the return visit, the flag remains on the chart. Be sure to document why the Pap test or HPV test was not taken. Assure that the client has another appointment. The flag will remain on the chart.

The Pap test should not be repeated before 6 months from the previous Pap test unless the Pap report was unsatisfactory. In this case, the Pap can be repeated as soon as possible allowing time for any needed treatment, but no longer than 4 months. However, colposcopy may be ordered or repeated anytime it is indicated.

TECHNIQUES FOR AVOIDING UNSATISFACTORY CONVENTIONAL PAP SMEARS

| Causes of an Unsatisfactory Pap Smear | Appropriate Responses |
|---|---|
| Smear too bloody (excess red blood cells) | Repeat Pap smear when client not bleeding; test for chlamydia. |
| Smear too inflammatory (excess white blood cells) | Diagnose & treat infection; repeat Pap smear as soon as practical but within 4 months. |
| Cells are air dried | Fix slide within 2-5 seconds, spraying from 10-12 inches. |
| Cells are cytolyzed | Avoid water from douching or overly moist speculum, |
| Scanty cellular material | Use firmer scrape to obtain more cellular material. |
| Cellular material too thick | Spread more evenly over slide or use 2 slides for heavy material. |
| Cells too atrophic | Prescribe vaginal estrogen cream. |
| Foreign material | Avoid medications, lubricants, swab fibers etc. |

**PAP TEST/HPV TEST REPORT PROCESS**

Upon return from the laboratory, all Pap test reports and HPV tests are reviewed by the designated local Public Health Nurse (PHN). The PHN will pull all abnormal findings for review by the APN or the MD. The APN or MD will write the plan for follow-up of the abnormal finding.

A tracking system is established by regional policy and maintained at each site for follow-up of abnormal Pap tests and HPV tests. If a region can demonstrate that a computerized tracking system is in place that facilitates assurance that Pap test results and HPV results are followed, that region will be exempt from the requirement of a manual tracking system. In this circumstance, written regional policies concerning the use of such a computerized tracking system must be in place and documentation must be made available upon request that would enable quality management staff to determine whether or not the system is being utilized in accordance with policy.

The attempts to contact the client may include phone calls, direct contact during a Family Planning clinic visit or a home visit, or by mail. Clients may also be contacted during any clinic visit, i.e., WIC visit, primary care visit, etc. Flag the chart or use the note field on the PTBMIS screen to alert staff that at the next clinic visit, Pap test or HPV follow-up is indicated. (It is suggested that when a letter is returned undeliverable, check the correctness of the address. If the address is correct, call the emergency contact to get a forwarding address. If a forwarding address is unavailable, flag the chart.)

The designated PHN is responsible for recording Pap test and HPV results in accordance with regional policy. “Negative for intraepithelial lesion or malignancy” laboratory results slips may be discarded once results are posted. HPV tests that are negative for high-risk HPV may also be discarded once results are posted. Refer to Policy and Procedures Manual, 5.3 C, Tennessee Department of Health, Bureau of Health Services. Disposal of negative slips should be a regional decision, covered by regional policy.

**MINIMUM REQUIREMENTS FOR PAP TEST AND HPV FOLLOW-UP**

Federal Title X Guidelines state, “a procedure must be established to allow for client notification and adequate follow-up of abnormal laboratory results.” Pap test and HPV follow-up guidelines are to be used when clients have stated that they may be contacted by phone or at home. Use the regional policy for notifying confidential clients.

Abnormal Pap test and positive HPV tests are reviewed by the nurse-practitioner or physician. Follow-up orders are given to the assigned public health nurse(s) for follow-up and tracking. Recommendations by the pathologist are taken into consideration. Follow-up and tracking must comply with regional protocols and must be documented in the chart and/or in the electronic record (i.e., tracking).

**CLIENT NOTIFICATION**

A regional policy must be established for notification of "negative for intraepithelial lesion or malignancy” or “negative for high-risk HPV”.

For Pap test results indicating the presence of an organism or condition that the practitioner or physician wishes to address or treat (such as yeast, numerous red blood cells or shift in bacterial flora), a minimum of two documented attempts to contact the client are required.
Clients, who have been referred to colposcopy and subsequently return to the health department, are managed in accordance with the instructions given by the colposcopist.

For Pap test results indicating the presence of an organism or condition that the practitioner or physician wishes to address or treat (such as yeast, numerous red blood cells or shift in bacterial flora), a minimum of two documented attempts to contact the client are required.

For Pap test reports indicating atypical squamous cells of undetermined significance or greater, two documented attempts to contact the client are required.

For Pap test reports or HPV tests indicating the need for referral to colposcopy, a minimum of two documented attempts to contact the client are required. The sequence of attempts to contact the client proceeds as follows:

1. First attempt: Phone call, letter sent by first class mail, or direct contact during a clinic or home visit.
2. Second attempt: Registered letter or direct contact in clinic or by home visit.
3. Document all phone calls and letters in the chart or the electronic record. Regional policy determines the type of documentation related to the sending of the letters. Also regional policy determines whether further follow-up should occur if the client does not respond. However further follow-up including extra phone calls and letters and possibly a home visit, are encouraged as may be needed.
4. Extra effort should be made to contact clients with epithelial cell abnormalities of high grade squamous intraepithelial lesion (HSIL), squamous cell carcinoma, atypical glandular cells, endocervical adenocarcinoma in situ, or any other malignant neoplasm. These clients are to be contacted within 5 working days from the receipt of the lab report or the call from lab. Clients in this category who do not respond to phone call or registered letter, should receive a home visit if at all possible.
5. Within 6 weeks of the date the Pap test or the HPV test was reported by the lab, clinics should have an appropriate referral in place (client informed and appointment made). Clinics are to document and facilitate any recommended follow-up. Clinics must not coerce clients to undergo any consultation or procedure. However, clients must understand the importance of follow-up and the possible consequences of failure to comply with recommendations.

**INTERPRETATION OF PAP TESTS**

The Bethesda System 2001 for Reporting Cervical Cytology

The Bethesda System, first developed in 1988, was designed to be a uniform system of terminology that would provide clear guidance for clinical management. It was modified in 1991 after actual laboratory and clinical experience with the Bethesda System itself. In 2001 the system was modified again to adjust for increased utilization of new technologies and recent findings from research studies. As of April 2002, more than 20 national and international societies have endorsed the 2001 Bethesda System.

On every Pap test report, the Bethesda System addresses the following categories:

1. Specimen Adequacy
2. General Categorization (optional)
3. Interpretation/Result
4. Automated Review and Ancillary Testing
5. Educational Notes and Suggestions (optional)

The following statements can be found under each category:

1. Specimen Adequacy

   a. Satisfactory for evaluation (note the presence/absence of endocervical/transformation zone component)
   b. Unsatisfactory for evaluation because (specify reason)
   c. Specimen rejected/not processed because (specify reason)
   d. Specimen processed and examined, but unsatisfactory for evaluation of epithelial cell abnormality because of (specify reason)

5. General Categorization (optional)

   a. Negative for intraepithelial lesion or malignancy
   b. Epithelial cell abnormality (see below)
   c. Other

6. Interpretation/Result

   a. Negative for Intraepithelial Lesion or Malignancy
   b. Organisms: Trichomonas, fungal organisms, shift in flora suggestive of bacterial vaginosis, bacterial changes consistent with Actinomyces, cellular changes consistent with herpes simplex virus
   c. Other non-neoplastic findings (optional): reactive cellular changes associated with inflammation including typical repair, radiation, intrauterine contraceptive device, glandular cells status post-hysterectomy, atrophy
   d. Epithelial cell abnormalities
      - Atypical squamous cells of undetermined significance (ASC-US)
      - Atypical squamous cells cannot exclude high grade squamous intraepithelial lesion (ASC-H)
      - Low-grade squamous intraepithelial lesion (LSIL) encompassing human papillomavirus/mild dysplasia/ cervical intraepithelial neoplasia (CIN 1)
      - High-grade squamous intraepithelial lesion (HSIL) encompassing moderate and severe dysplasia, carcinoma in situ, CIN 2 and CIN 3
      - Squamous cell carcinoma
      - Atypical glandular cells (AGC) (specify endocervical, endometrial, or “not otherwise specified” – NOS)
      - Atypical glandular cells, favor neoplastic (specify endocervical or NOS)
      - Endocervical adenocarcinoma in situ (AIS)
      - Adenocarcinoma
      - Other such as endometrial cells in a woman > age 40

a. Automated Review and Ancillary Testing

   a. Statement will define what type of automated review or ancillary test was used

5. Educational Notes and Suggestions (Optional)

   a. Statement will be self-explanatory

TennCare clients may have MCOs that require Pap tests collected on their clients be sent to particular laboratories with which they have contracts. Some grantees contract with a laboratory of their choice. It should be noted that

some laboratories use a modified Bethesda System. Regions should be aware of minor differences in their systems (mainly descriptive) and have on file the exact wording of the laboratory's alternative/modified Bethesda System.

## ATTACHMENTS

Management of Pap Findings – These decision algorithms are intended to provide public health staff with a simple visual tool for Pap test follow-up.

## REFERENCES


1. American College of Obstetricians and Gynecologists, ACOG Practice Bulletin, Cervical Cytology Screening, Number 45, August 2003.
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3. American College of Obstetricians and Gynecologists, ACOG Committee Opinion Number 300, October 2004.
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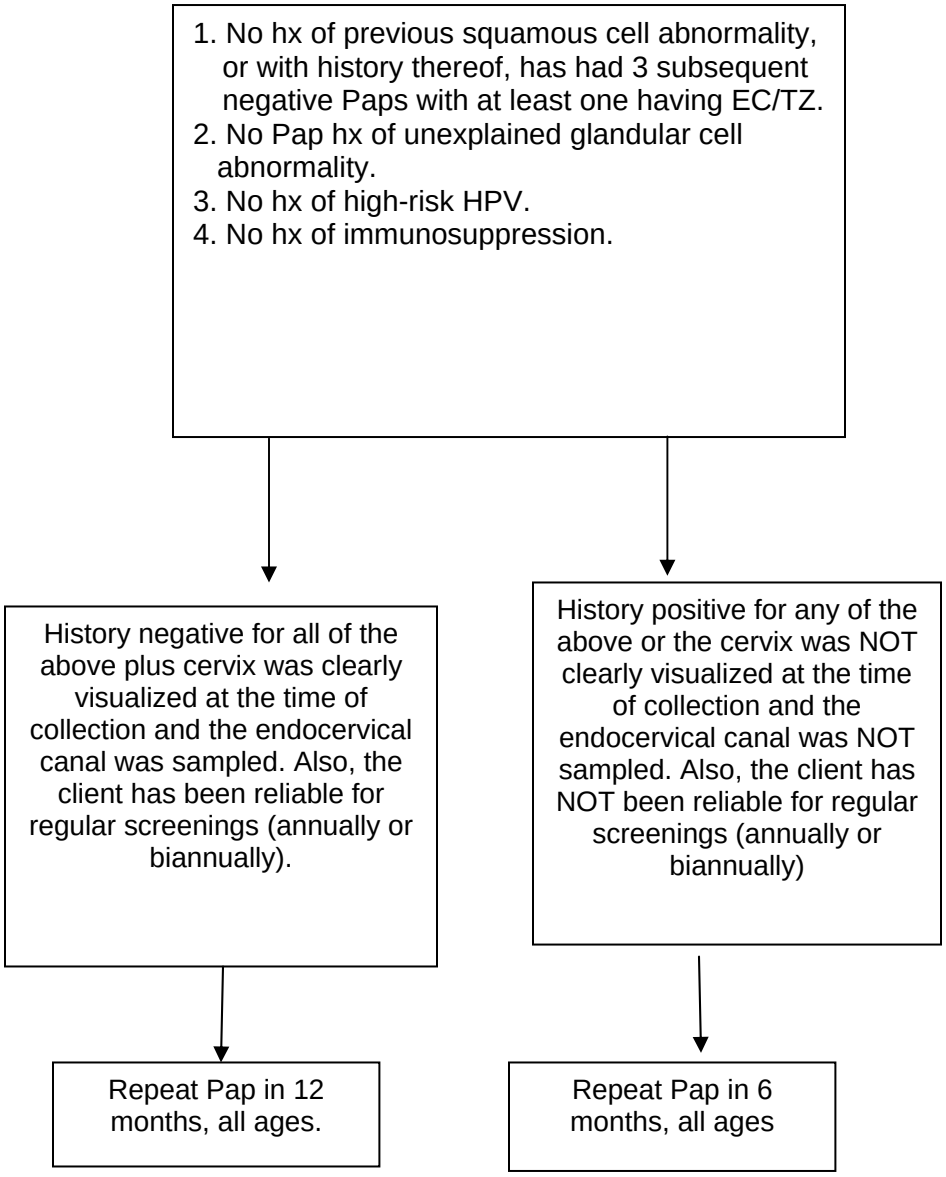
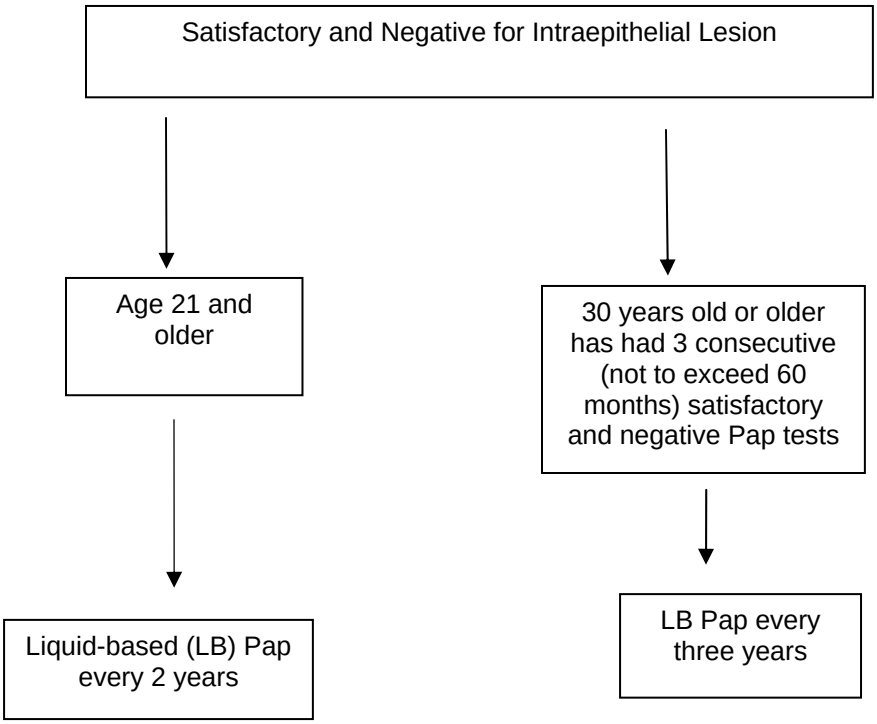
8. U.S. Preventive Services Task Force, Screening for Cervical Cancer – Recommendations and Rational, www.ahrq.gov , January 2003.
9. American Journal of Obstetrics and Gynecology, 2006 Consensus Guidelines for the Management of Women with Abnormal Cervical Cancer Screening Tests, pages 346-355, October 2007.

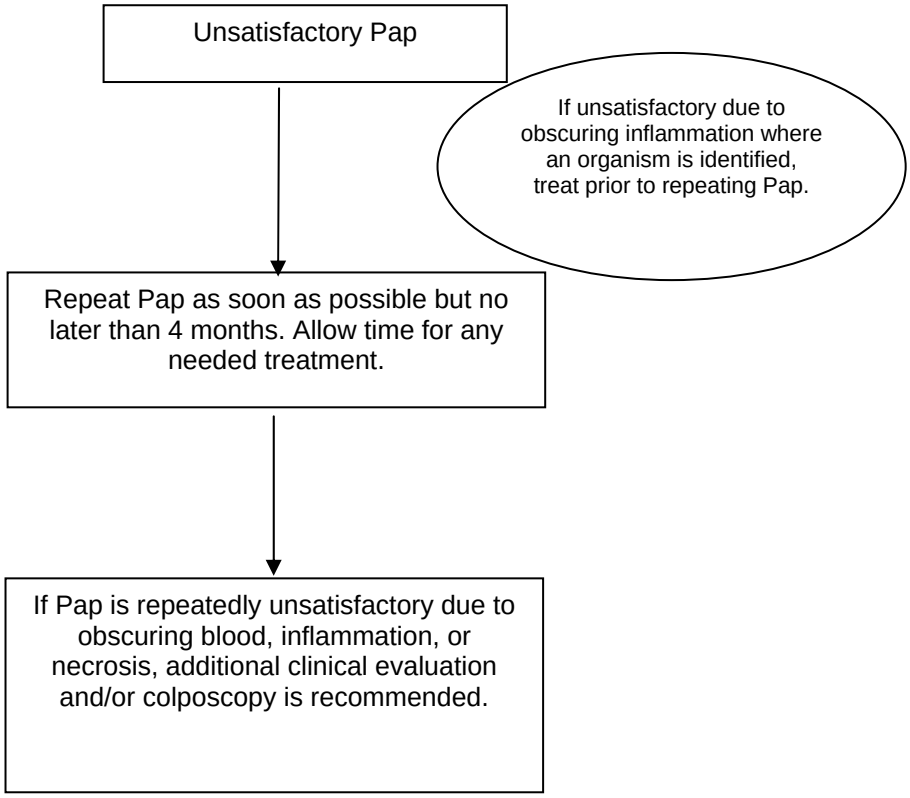
**Management Guidelines for**
**Satisfactory Pap Test**
**With No Endocervical/Transformation Zone Component (EC/TZ)**



**Management Guidelines for**
**Women with Satisfactory Pap Test**



**Management Guidelines for Women with Unsatisfactory Pap Test Results**



**Management Guidelines for**
**Women with Pap Negative for Intraepithelial Lesion**
**With Numerous Red Blood Cells, Inflammatory Cells,**
**Reactive/Inflammatory Epithelial Cells, Air-Drying**
**Or Other Factors**

1. No hx of previous squamous cell abnormality, or with history thereof, has had 3 subsequent negative Paps with at least one having EC/TZ.
2. No Pap hx of unexplained glandular cell abnormality
3. No hx of high-risk HPV.
4. No hx of immunosuppression.
6. Provider has no other clinical reason for a 6 month repeat.

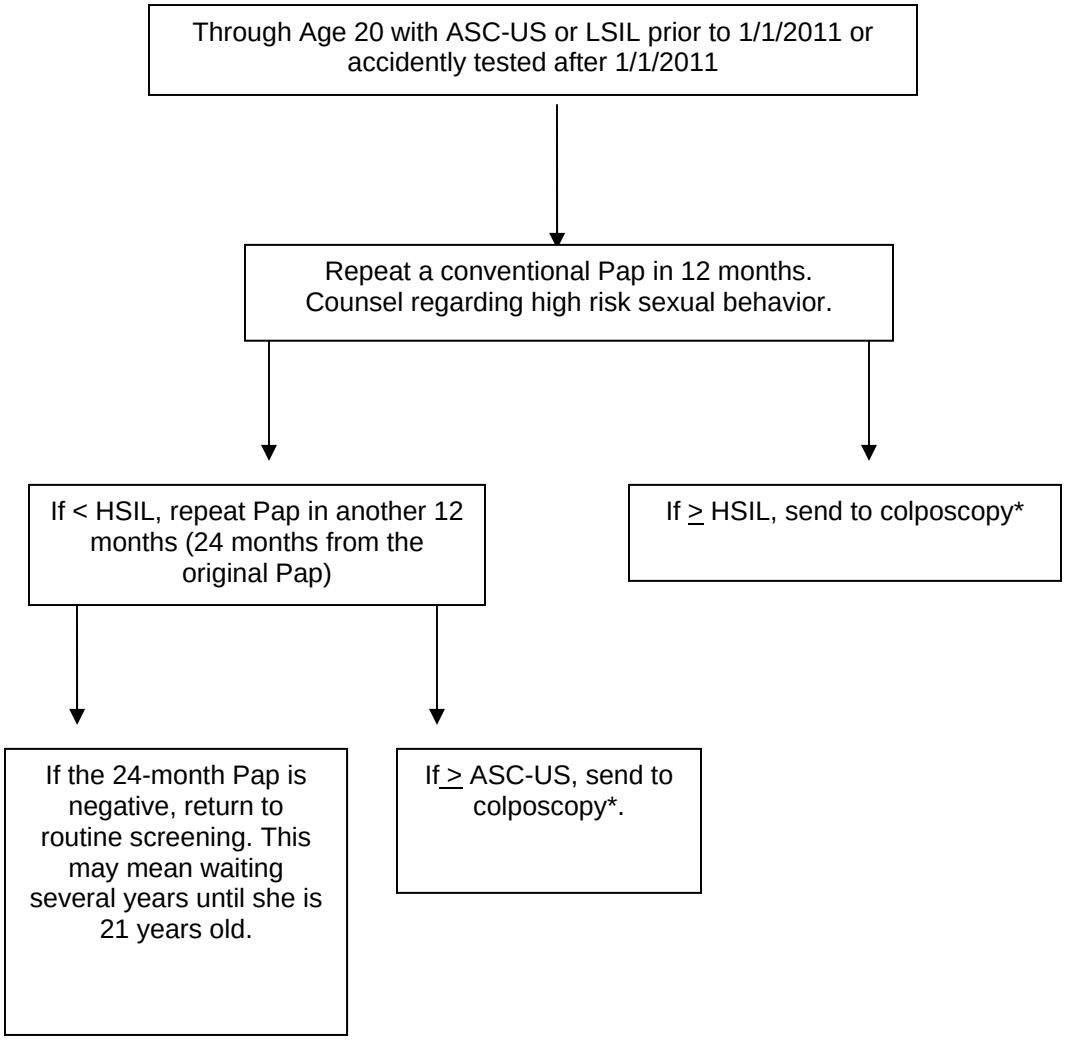
Has no history for all of the above and cervix was clearly visualized at the time of collection and the endocervical canal was sampled. Plus client returns for regular screenings and has several documented Pap tests in the chart.

Repeat Pap in 12 months all ages.

Has a history for any of the above or the provider has a clinical reason for a 6 month repeat Pap.

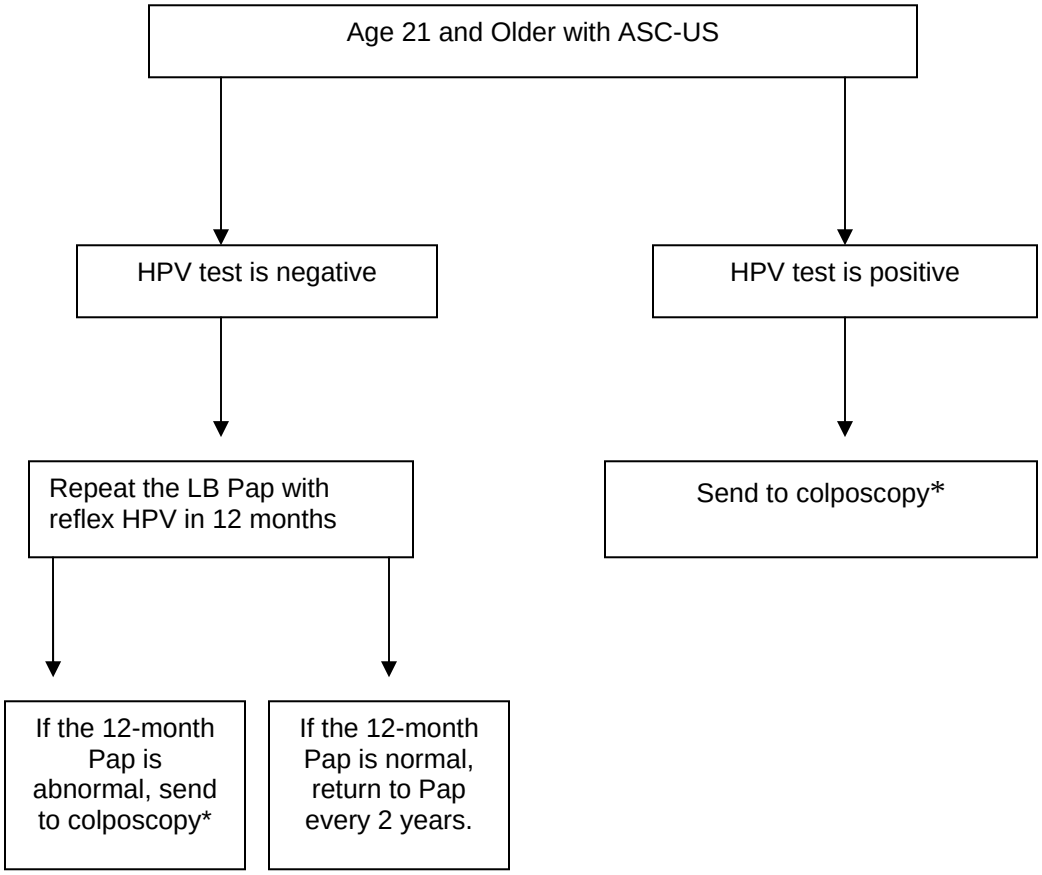
Repeat Pap in 6 months all ages.

**Management of Women Through Age 20 Years with ASC-US or LSIL**
**Who <u>Were Already in Follow-up as of January 2011 or in Situations of Accidental Non-Adherence to Guidelines as of January 2011</u>**



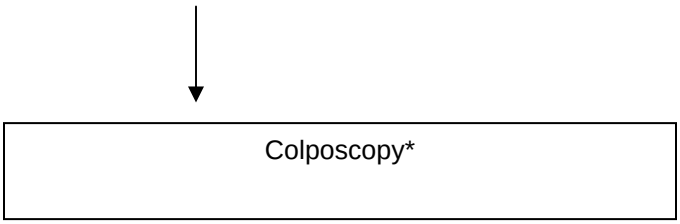

***The goal in this age group is to avoid excisional treatment. The colposcopist may elect to repeat the colposcopy and Pap every 6 months for 24 months if no CIN 2 or 3 was found on the colposcopy. After colposcopy, management is directed by the colposcopist. Discourage colposcopy providers from "see and treat" Loop Electrosurgical Excisional Procedures (LEEPs) in adolescents with HSIL**

**Management of Women Age 21 and Older with ASC-US**
**(Pap will be Liquid-based with Reflex HPV Test for ASC-US Results Only)**

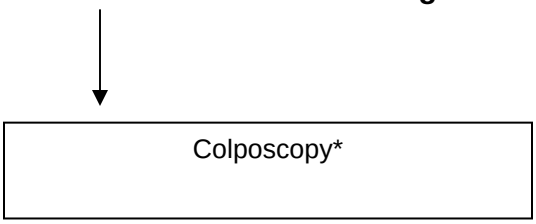



***After colposcopy, management is directed by the colposcopist**

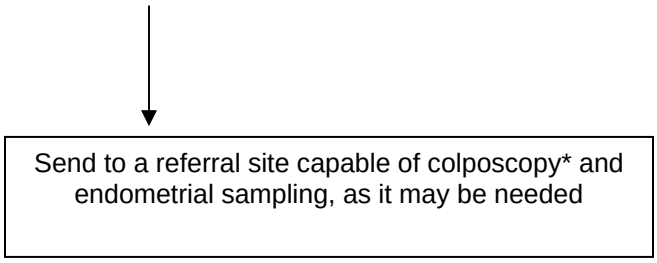
**Management of Women HSIL or ASC-H, All Ages***




**Management of Women Age 21 and Older with LSIL including Women Who are Post Menopausal**




**Management of Women with Atypical Glandular Cells, All Ages**




***After colposcopy, management is directed by the colposcopist.**
***Discourage colposcopy providers from "see and treat" Loop Electrosurgical Excisional Procedures (LEEPs) in adolescents with HSIL.**

## GUIDELINES FOR HPV DNA TESTING

### POLICY

The Tennessee Department of Health, Title X Family Planning Program promotes Pap test screening for the detection of cervical cancer or its precursors. Recent studies have shown that the conventional Pap smear test and the liquid-based Pap test are both proficient in identifying clients at risk. These studies have also shown that Human Papilloma Virus (HPV) DNA testing for high risk types of HPV does enhance Pap test follow-up since high risk HPV types are known causative agents of cervical cancer. The Tennessee Department of Health, Title X Family Planning Program offers HPV DNA testing in the situations described below. Only high risk types of HPV are significant. There is no indication for low-risk types of HPV. When HPV is referenced in this document, the reference is to high risk types only.

### TESTING FOR THE HUMAN PAPILLOMA VIRUS (HPV)

Thirteen HPV types have been identified in the pathogenesis of high-grade squamous intraepithelial lesions (HSIL) and invasive cervical cancer. These are types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68. HPV detection and identification of these high-risk types is made possible through signal amplification assay technology. This technology utilizes antibody capture and chemiluminescent signal detection. The basic steps of the assay are as follows:

1. Clinical specimens are combined with a base solution that disrupts the virus and releases the HPV DNA.
2. The HPV DNA is combined with RNA creating an RNA:DNA hybrid. (Each RNA is specific to an HPV type and multiple types are tested at once so that the presence of all high-risk types can be searched for in that particular patient's sample.)
3. These RNA:DNA hybrids are then captured onto a solid particle that is coated with universal capture antibodies specific for the RNA:DNA hybrids for HPV.
4. These captured hybrids can then be detected with multiple antibodies conjugated to alkaline phosphatase (an enzyme) resulting in a signal that can be amplified at least 3000-fold.
5. The bound alkaline phosphatase is then detected with a chemiluminescent dioxetane substrate. Alkaline phosphatase breaks down the substrate and light is produced. The light is measured on a luminometer in relative light units (RLUs), and the amount of light detected is directly proportional to the amount of HPV DNA present in the sample.

### CANDIDATES FOR HPV TESTING

HPV testing should never be done in women under the age of 21. If an HPV test is or was inadvertently collected, the results should not influence follow-up.

Women age 21 and older will receive HPV testing for the triage of ASC-US Pap. HPV testing is also used as a 12 month follow-up to colposcopy for an LSIL Pap for this same age group if deemed appropriate by the colposcopist (no CIN 2 or 3). HPV tests should not be collected in less than 12 month intervals.

### COLLECTING THE HPV SPECIMEN

In Tennessee, women age 21 and older will receive a liquid-based Pap test with reflex HPV testing for the triage of an ASC-US Pap. Thus, the HPV test is run by the laboratory using the liquid. It is unlikely that the HPV test would be collected using the cervical sampler kit. However should a kit be required, the following collection procedures would be used.

Each kit contains one cervical sampler brush with scored shaft and one transport tube with transport media. The manufacturer recommends that if a Pap test is also being collected; collect the Pap test before obtaining the specimen for the HPV test. In a setting where colposcopy is being performed, collect the HPV specimen before applying acetic acid or iodine. Remove any excess mucous from the cervical os and surrounding ectocervix with a cotton or Dacron swab. Insert the cervical sampler brush 1-1.5 centimeters into the os of the cervix until the largest outer bristles of the brush touch the ectocervix. Rotate the brush 3 full turns in a counter clockwise direction. DO NOT INSERT THE BRUSH COMPLETELY INTO THE CERVICAL CANAL. Remove the brush from the canal and insert it into the transport tube. The tube contains the necessary transport media. Avoid touching the brush to the

outside of the tube or to any other object. Snap off the shaft of the brush at the score line and cap the tube securely. (See the package instructions for a diagram of collecting the HPV specimen.) Do not use the cervical brush with pregnant women.

**ATYPICAL SQUAMOUS CELLS OF UNDETERMINED SIGNIFICANCE IN WOMEN AGE 21 AND OLDER**

In this age group, women receive a liquid-based (LB) Pap test with reflex HPV test for the triage of ASC-US. If the results are negative, then the Pap test is repeated every 2 years. If it is ASC-US, the HPV test is run reflexively by the laboratory. If the HPV test is positive the client is referred to colposcopy. If the HPV test is negative, the clients return in 12 months for another LB Pap with the reflex option. At the 12 month point, if the Pap is abnormal, the client will go to colposcopy.

**ADOLESCENTS (tested prior to January 2011 or inadvertently tested after January 2011) WITH ATYPICAL SQUAMOUS CELLS OF UNDETERMINED SIGNIFICANCE (ASC-US) or LOW GRADE SQUAMOUS INTRAEPITHELIAL LESION (LSIL)**

Atypical squamous cells of undetermined significance (ASC-US) and low grade squamous intraepithelial lesions (LSIL) are abnormalities that generally identify women who have recently been exposed to HPV. HPV is more common in adolescent women than older women. However, the risk of cervical cancer in an adolescent is virtually zero. This is because the immune system most likely will clear the HPV. Therefore, the preferred method of follow-up of an adolescent with ASC-US or LSIL is a follow-up Pap in 12 and 24 months with referral to colposcopy if the 12 month Pap is greater than or equal to HSIL or the 24 month Pap is greater than or equal to ASC-US. HPV testing is not appropriate for women through age 20. If an HPV test is inadvertently done in this age group, the results should not influence management.

**FINDINGS NOT REQUIRING HPV TESTING**

None of the following Pap test results require HPV DNA testing because they will be referred to colposcopy:

Atypical Squamous Cells Cannot Exclude High-Grade SIL (ASC-H) for all ages
Low-Grade Squamous Intraepithelial Lesion (LSIL) ages 21 years and older
High-Grade Squamous Intraepithelial Lesion (HSIL) for all ages
Atypical Glandular Cells (AGC) for all ages

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# PREGNANCY TEST GUIDELINES

## POLICY

Infant mortality reduction is a major public health focus. When a woman reports to her local health department for a pregnancy test, all staff persons must recognize that the visit is an opportunity to impact the future health of the woman, her family, and the community at large.

Pregnancy testing must be provided to all women in need of this service. Pregnancy testing is one of the most frequent reasons for an initial visit to the family planning clinic, particularly by an adolescent. It is therefore important to use this occasion as an entry point for providing education and counseling about reproductive life planning, family planning, and preconception health.

The frequency of performing controls has been determined by the State Laboratory. Clinics which perform a high volume of pregnancy tests perform weekly controls and when a new box is opened. Clinics that perform pregnancy tests less often perform controls when they need to perform a pregnancy test, but not more often than weekly.

When any woman presents to the health department requesting a pregnancy test, one should be provided on the day of request, even if prenatal or family planning clinic services are not normally available on that day. Only under extraordinary scheduling circumstances should she be denied service that day. In addition, appropriate counseling, information, and referral should be provided as indicated.

- A woman under age 30 who comes to her local health department for a pregnancy test will also be offered a test for chlamydia and gonorrhea. She will not receive a table exam. Testing will be accomplished by urine testing of the urine sample already collected for the pregnancy test. Inform the client that chlamydia is epidemic Tennessee; that it can affect her long term fertility; and that it can negatively affect the outcome of a current pregnancy should her pregnancy test be positive. The TN STD Program writes: **All women under age 30** reporting to clinic for a urine pregnancy test should be offered chlamydia and gonorrhea screening from their pregnancy test urine sample. Considering the sequelae that might occur in the mother and neonate if the infection persists, repeat testing is recommended 4 - 6 weeks after completion of therapy for all pregnant women to ensure therapeutic cure.

## PREGNANCY DIAGNOSIS

Pregnancy cannot be accurately diagnosed nor gestational age determined through laboratory testing alone. Pregnancy diagnosis consists of a history, pregnancy test, and physical examination, including pelvic examination.

For positive pregnancy tests, provide nondirective options counseling as indicated/requested. (See Options Counseling guide in the *Public Health Nursing Statewide Protocol*, “Pregnancy Test”) A major objective of Maternal and Child Health is to ensure that women, especially teenagers, receive the appropriate medical, social and educational care early in the pregnancy to minimize risks to the developing fetus. This is a valuable opportunity to get the client into prenatal care promptly. If the medical examination is not performed in conjunction with laboratory testing, the client must be counseled as to the importance of receiving a physical assessment as soon as possible, preferably within 15 days, acknowledging that scheduling in the private sector is not under the health department’s control.

Work negative pregnancy test clients, who do not want to be pregnant into the schedule that day, if possible. This is a valuable opportunity to provide sexual health education and counseling. Important topics include explaining what is considered high risk sexual behavior and safer sex practices. Other topics are reproductive life planning, family planning, and preconception care.

## COUNSELING

Face-to-face counseling must be available at the time the test results are given. Family planning programs are responsible for assuring that all staff persons who provide pregnancy options counseling including registered nurse, nurse practitioners, nurses, and counselors, have the following skills and knowledge:

- Ability to establish a relationship with a woman (and a friend/partner/parent) in order that she can explore her feelings about the pregnancy, the results of the pregnancy test, and her alternatives for decision-making.
- Ability to help the woman identify her feelings and examine the advantages and disadvantages of each of the alternatives so that she can make an informed decision.
- Ability to provide accurate information about pregnancy tests, pregnancy, prenatal care, adoption, infertility services, and contraception as appropriate. This information should include medical risks, legal requirements, available resources, cost of services, available insurance coverage or other financial support, and procedures for obtaining services.
- Ability to help the woman implement her decision by providing appropriate referrals.

Pregnant women should be offered information and counseling regarding their pregnancies. Those requesting information on options for the management of an unintended pregnancy are to be given non-directive counseling on the following alternative courses of action and referral upon request:

- Prenatal care and delivery
- Infant care, foster care, or adoption
- Pregnancy termination (Staff in family planning clinics counseling a client with a positive pregnancy test have a responsibility to provide information on all options but not to direct the client in reaching a decision. Staff persons are not permitted to make appointments for an abortion or provide transportation to abortion services.)

**INFORMATION AND REFERRALS**

Clients planning to carry their pregnancies to term should be given information about good health practices during early pregnancy, especially those which serve to protect the fetus during the first months (e.g., good nutrition, avoidance of smoking, drugs, both illicit and prescription, and exposure to x-rays). Because serious gum disease has been linked to premature birth and to low birth weight, all pregnant women need information on the importance of a dental check up. All pregnant women should be referred to a local dental provider or to a dental clinic within the health department system. Pregnant teenagers and women with risk factors for preterm birth and/or low birth weight baby, who plan to continue their pregnancy, should be referred to the health department's HUGS (Help Us Grow Successfully) program. All pregnant women who plan to carry their pregnancies to term should be referred to the WIC Program. Review all other related health department programs such as family planning and infant immunizations.

Clients planning to carry their pregnancies to term will also receive screening for presumptive eligibility for TennCare. Presumptive eligibility gives the client 45 days of immediate TennCare coverage so that she can begin her prenatal care as soon as possible. Eligible candidates will then be referred to the Department of Human Services to complete the TennCare application. Referrals to local obstetric providers should be facilitated by the health department staff. Pregnant clients under age 21 who qualify for TennCare can be referred to a TennCare dental provider as well.

Clients who are not found to be pregnant should be given information about the availability of contraceptive services. Information about fertility services may be given if indicated. The importance of folic acid prior to conception should be reviewed. The cause of the delayed menses (if present) should be investigated.
All clients should also be given specific information about the following related subjects:

- Avoiding drugs (both OTC and street), alcohol, and tobacco
- Folic acid supplementation as recommended by CDC
- Rubella
- STDs
- ECPs
- The importance of a dental check up prior to conception

**PROVIDER TASKS**

See *Public Health Nursing Statewide Protocol*, "Pregnancy Test" for nursing management and the *Laboratory Policies and Procedures Manual for Local Health Departments* for specific guidelines for performance of specific

pregnancy tests. Information on pregnancy test counseling is also detailed on/in the Family Planning Quick Reference Guide.

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CHLAMYDIA SCREENING GUIDELINES

POLICY

The Tennessee Department of Health Title X Family Planning Program policy states that gonorrhea and chlamydia screening must be performed according to the criteria defined later in this document. (See Screening Criteria). The screening criteria are established by the Tennessee STD Program.

ADDRESSING THE PROBLEM

In 1988 the CDC and the Office of Population Affairs (OPA) funded a chlamydia demonstration project (infertility prevention program) in one federal region of the nation. In 1993, Congress appropriated funds to begin a nation-wide STD-related infertility prevention program (IPP). Funding was eventually expanded to all federal regions. Through a cooperative effort between CDC and the Office of Population Affairs, the project has developed strong collaboration among Title X family planning programs, STD programs, and state public health laboratories. Significant progress has been made in reducing the incidence of chlamydia.

Region IV Infertility Prevention Project (IPP)

The Region IV Infertility Prevention Project (IPP), of which Tennessee is a member, focuses on the prevention of chlamydial infection through collaborative efforts of state Title X Family Planning Programs, STD Programs, and State Laboratories in each of the eight states in Region IV. The overall goal of the project is to assess and reduce the prevalence of chlamydial infection and associated complications through education, screening, and treatment. The project is governed by an advisory board, which is comprised of three representatives from each of the Region IV states (Family Planning Program member, STD Program member, and State Laboratory member).

The IPP requires that each state collect a specific set of data related to chlamydia and gonorrhea screening to qualify for the available federal funds. The Region IV project requires detailed reports of the prevalence of chlamydia infection as a function of gender, age, race, ethnicity, program (STD, family planning, prenatal, primary care etc.), reason for the exam, signs and symptoms, and treatment. The State's cooperative agreement with CDC requires that data be collected on all individuals who are screened. These data are collected through the State's PTBMIS computer system or through the laboratory requisition form CHLAMYDIA/GONORRHEA DETECTION (PH-3179) in Title X family planning clinics not on the PTBMIS computer system.

The purpose of the Tennessee Infertility Prevention Project has been to reduce chlamydial rates and chlamydia morbidity rates in Tennessee. Tennessee is using the Gen-Probe Aptima test for screening for chlamydia and gonorrhea using urogenital swabs or urine.

**Screening Criteria for Chlamydia and Gonorrhea**

The screening criteria for chlamydia and gonorrhea are based on risk criteria, national recommendations, and availability of funds. The Tennessee STD Program determines the screening criteria for the Family Planning Program. The screening criteria for <u>family planning</u> in Tennessee are:

For Family Planning:

- Screen at the routine initial/annual exam:
  - all clients less than age 26
  - all clients ages 26-29 who receive family planning services in a county with a chlamydia positivity rate of 3 percent or higher (*See below for these counties.)
- For clients ages 26 and over (regardless of county where family planning services are received), only screen the following:
  - a client being prepared for IUD insertion;
  - a client with documented NEW signs or symptoms;
  - a client named as a contact;
  - a client using drugs;
  - a client exchanging sex for money or drugs.

- Regardless of age, a female client who has been treated for a positive chlamydia test should be retested 3 months after treatment or whenever she next seeks medical care within the following 3-12 months regardless of whether the client believes her partner was treated.

**The sites with positivity rates of 3 percent or higher in women ages 26 through 29 are:**

| | |
|---|---|
| Northeast Region | Johnson and Unicoi |
| East Tennessee Region | Anderson, Jefferson, Campbell, Cocke, Grainger and Sevier |
| Southeast | Franklin and Marion |
| Upper Cumberland | Overton and Smith |
| Mid Cumberland | Sumner, Cheatham and Dickson |
| South Central | Giles, Lawrence and Marshall |
| West Tennessee | Chester, Crockett, Dyer, Fayette, Gibson, Hardeman, Haywood, Henry, Lake, Lauderdale, Obion, Tipton, and Weakley |
| Memphis/Shelby County | Health department clinics; Memphis Planned Parenthood |
| Nashville/Davidson County | Health department clinics, and Planned Parenthood of Middle TN |
| Knoxville/Knox County | |
| Jackson/Madison County | |

See STD Program Guidelines for screening in other programs outside of Family Planning.

For collection procedures see Laboratory Policies and Procedures Manual for Local Health Departments.

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## US Medical Eligibility Criteria for Contraceptive Use

**Policy**

The Tennessee Department of Health Title X Family Planning Program writes contraceptive guidance to the clinics using the recommendations of the American College of Obstetricians and Gynecologists (ACOG), the latest available text of Contraceptive Technology and its newsletter, Contraceptive Technology Updates, and the recommendations of the Center for Disease Control and Prevention (CDC). In 2010, the CDC published the U.S. Medical Eligibility Criteria for Contraceptive Use, 2010. This document is the guidance for contraceptive use for the Title X Family Planning Program in Tennessee. However, providers should always consider the individual clinical circumstance of each person seeking family planning services.

The CDC's rating system for the use of contraception for clients with various medical conditions is as follows:

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

I=Initiation – A condition may require a rating that reflects the initiation of the method with the condition.

C=Continuation – A condition may require a rating that reflects the continuation of the method once a condition has developed.

A rating that is not labeled initiation or continuation means that the rating given is for both initiation and continuation.

In Tennessee's Title X Family Planning Program, all conditions rated 3 or 4 will initially be considered contraindications and will not be provided by the RN at the deferred exam visit. **Conditions rated 3 could the provided by the APN or MD if there are no other reasonable choices. The APN should consult the assigned physician in these situations; there should be a plan for very close follow-up; and the client should be fully informed of the risks.** All of these factors would be documented in the chart before a method that is rated 3 for a condition is used.

Medical Conditions rated 2 could be provided the RN at a deferred exam visit by a consult with the MD or APN should be considered.

Abbreviations used in the summary table of medical eligibility criteria are as follows:

COC =Combined oral contraception
Pa = Contraceptive patch
Ri = Contraceptive ring
POP = Progestin-only pills
DMPA = Depot medroxyprogesterone
Implant = Etonogestrel single rod implant
IUD= Intrauterine device
LNG IUD = Levonorgestrel-releasing IUD
Cu IUD = Copper IUD
BMI = Body mass index
HIV = Human immunodeficiency virus
AIDS = Acquired Immunodeficiency Syndrome
NRTI = Nucleoside reverse transcriptase inhibitor
NNRTI = Non-nucleoside reverse transcriptase inhibitor
PP = Postpartum
C/S = Cesarean Section

For questions or clarifications regarding this table, please consult Appendix L in the full issue of MMWR, Vol. 59, May 28, 2010, U.S. Medical Eligibility Criteria for Contraceptive Use, 2010.

Every effort has been made to list category 2 items under, “Exercise Caution” in the discussion of each contraceptive method.

The US Medical Eligibility Criteria for Contraceptive Use is provided here in Table form.

| Condition | COC/Pa/Ri | POP | DMPA | Implant | LNG IUD | Cu IUD |
|---|---|---|---|---|---|---|
| **AGE** | | | | | | |
| Menarche to < 40 | **1** | | | | | |
| Menarche to ≥ 40 | **2** | | | | | |
| Menarche to <18 | | **1** | **2** | **1** | | |
| Age 18 to 45 | | **1** | **1** | **1** | | |
| Age > 45 | | **1** | **2** | **1** | | |
| Menarche to <20 | | | | | **2** | **2** |
| Age ≥ 20 | | | | | **1** | **1** |
| **PARITY** | | | | | | |
| Nulliparous | **1** | **1** | **1** | **1** | **2** | **2** |
| Multiparous | **1** | **1** | **1** | **1** | **1** | **1** |
| **PP BREASTFEEDING** | | | | | | |
| < 1 month postpartum | **3** | **2** | **2** | **2** | | |
| 1month to < 6 months | **2** | **1** | **1** | **1** | | |
| ≥ 6 months postpartum | **2** | **1** | **1** | **1** | | |
| **PP NOT BREASTFEEDING** | | | | | | |
| < 21 days postpartum | **3** | **1** | **1** | **1** | | |
| ≥ 21 days postpartum | **1** | **1** | **1** | **1** | | |
| | | | | | | |
| **PP vaginal and C/S delivery** | | | | | | |
| < 10 min after placenta is delivered | | | | | **2** | **1** |
| 10 min after placenta is delivered to < 4 wks | | | | | **2** | **2** |
| ≥ 4 wks | | | | | **1** | **1** |
| Puerperal sepsis | | | | | **4** | **4** |
| **POSTABORTION** | | | | | | |
| First Trimester | **1** | **1** | **1** | **1** | **1** | **1** |
| Second Trimester | **1** | **1** | **1** | **1** | **2** | **2** |
| Immediate post-septic AB | **1** | **1** | **1** | **1** | **4** | **4** |
| | | | | | | |
| **PAST ECTOPIC PREG** | **1** | **2** | **1** | **1** | **1** | **1** |
| | | | | | | |
| **HISTORY OF PELVIC SURGEY** | **1** | **1** | **1** | **1** | **1** | **1** |
| **SMOKING** | | | | | | |
| Age < 35 years any amount | **2** | **1** | **1** | **1** | **1** | **1** |
| Age ≥ 35 years & < 15 cigs/day | **3** | **1** | **1** | **1** | **1** | **1** |
| Age ≥ 35 years & ≥ 15 cigs/day | **4** | **1** | **1** | **1** | **1** | **1** |
| **OBESITY** | | | | | | |
| BMI ≥ 30 | **2** | **1** | **1** | **1** | **1** | **1** |
| Age menarche to <18 yrs & BMI ≥ 30 | **2** | **1** | **2** | **1** | **1** | **1** |
| **BARIATRIC SURGERY** | | | | | | |
| Restrictive-type | **1** | **1** | **1** | **1** | **1** | **1** |
| Malabsorbtive-type | **COC 3** / **Pa/Ri 1** | **3** | **1** | **1** | **1** | **1** |
| **CARDIOVASCULAR DISEASE (also see “other cardiac issues”)** | | | | | | |
| Multiple risk factors for arterial CVD | **3/4** | **2** | **3** | **2** | **2** | **1** |
| Hypertension adequately controlled | **3** | **1** | **2** | **1** | **1** | **1** |
| Systolic 140-159 or diastolic | **3** | **1** | **2** | **1** | **1** | **1** |

| Condition | COC/Pa/Ri | POP | DMPA | Implant | LNG IUD | Cu IUD |
|---|---|---|---|---|---|---|
| 90-99 | | | | | | |
| Systolic ≥ 160 or diastolic ≥ 100 | **4** | **2** | **3** | **2** | **2** | **1** |
| Vascular disease | **4** | **2** | **3** | **2** | **2** | **1** |
| History of hypertension in a pregnancy but normal now | **2** | **1** | **1** | **1** | **1** | **1** |
| **History of DVT/PE But not on anticoagulation therapy** | | | | | | |
| History of estrogen associated DVT/PE | **4** | **2** | **2** | **2** | **2** | **1** |
| History of pregnancy associated DVT/PE | **4** | **2** | **2** | **2** | **2** | **1** |
| Idiopathic DVT/PE | **4** | **2** | **2** | **2** | **2** | **1** |
| Known thrombophilia | **4** | **2** | **2** | **2** | **2** | **1** |
| Active cancer (excluding non-melanoma skin ca) | **4** | **2** | **2** | **2** | **2** | **1** |
| History of recurrent DVT/PE | **4** | **2** | **2** | **2** | **2** | **1** |
| History of DVT/PE but no known risk factors | **3** | **2** | **2** | **2** | **2** | **1** |
| Acute DVT/PE | **4** | **2** | **2** | **2** | **2** | **2** |
| | | | | | | |
| | | | | | | |
| **History of dvt/PE on coagulation therapy** | | | | | | |
| **DVT/PE on coagulation therapy** for 3 months & known thrombophilia, active cancer (excluding non melanoma skin cancer), or history of recurrent DVT/PE | **4** | **2** | **2** | **2** | **2** | **2** |
| **DVT/PE on coagulation therapy** for 3 months & no known risk factors as listed in cell above | **3** | **2** | **2** | **2** | **2** | **2** |
| **other DVT/PE related issues** | | | | | | |
| Family history of DVT/P in a 1st degree relative | **2** | **1** | **1** | **1** | **1** | **1** |
| Major surgery with prolonged immobilization | **4** | **2** | **2** | **2** | **2** | **1** |
| Major surgery without prolonged immobilization | **2** | **1** | **1** | **1** | **1** | **1** |
| Minor surgery without immobilization | **1** | **1** | **1** | **1** | **1** | **1** |
| Known thrombogenic mutations | **4** | **2** | **2** | **2** | **2** | **1** |
| **other vascular issues** | | | | | | |
| Varicose veins | **1** | **1** | **1** | **1** | **1** | **1** |
| Superficial thrombophlebitis | **2** | **1** | **1** | **1** | **1** | **1** |
| History of cerebrovascular accident (stroke) | **4** | **I=2 C=3** | **3** | **I=2 C=3** | **2** | **1** |
| **Other cardiac issues** | | | | | | |
| Current or history of ischemic heart disease | **4** | **I=2 C=3** | **3** | **I=2 C=3** | **I=2 C=3** | **1** |
| Known hyperlipidemias | **2/3** | **2** | **2** | **2** | **2** | **1** |
| Uncomplicated valvular heart disease | **2** | **1** | **1** | **1** | **1** | **1** |
| Pulmonary hypertension | **4** | **1** | **1** | **1** | **1** | **1** |
| Risk of atrial fibrillation | **4** | **1** | **1** | **1** | **1** | **1** |
| History of subacute bacterial endocarditis | **4** | **1** | **1** | **1** | **1** | **1** |
| Peripartum cardiomyopathy with normal or mildly impaired | **4** | **1** | **1** | **1** | **2** | **2** |

| Condition | COC/Pa/Ri | | POP | | DMPA | | Implant | | LNG IUD | | Cu IUD | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| cardiac function < 6 months | | | | | | | | | | | | |
| Peripartum cardiomyopathy with normal or mildly impaired cardiac function ≥ 6 months | **3** | | **1** | | **1** | | **1** | | **2** | | **2** | |
| Peripartum cardiomyopathy with moderate or severely impaired cardiac function | **4** | | **2** | | **2** | | **2** | | **2** | | **2** | |
| **rheumatic diseases** | | | | | | | | | | | | |
| Systemic lupus (SLE) with positive or unknown antiphospholipid antibodies | **4** | | **3** | | **3** | | **3** | | **3** | | **1** | |
| SLE with severe thrombocytopenia | **2** | | **2** | | **I=3** | **C=2** | **2** | | **2** | | **I=3** | **C=2** |
| SLE with immunosuppressive therapy | **2** | | **2** | | **2** | | **2** | | **2** | | | |
| SLE without any of the above | **2** | | **2** | | **2** | | **2** | | **2** | | **1** | |
| Rheumatoid arthritis with immunosuppressive therapy | **2** | | **1** | | **2/3** | | **1** | | **I=2** | **C=1** | **I=2** | **C=1** |
| Rheumatoid arthritis not on immunosuppressants | **2** | | **1** | | **2** | | **1** | | **1** | | **1** | |
| **Neurologic Conditions** | | | | | | | | | | | | |
| Mild or severe nonmigrainous headache | **I=1** | **C=2** | **1** | | **1** | | **1** | | **1** | | **1** | |
| Migraine without aura age < 35 years | **I=2** | **C=3** | **I=1** | **C=2** | **2** | | **2** | | **2** | | **1** | |
| Migraine without aura age ≥ 35 years | **I=3** | **C=4** | **I=1** | **C=2** | **2** | | **2** | | **2** | | **1** | |
| Migraine with aura at any age | **I=4** | **C=4** | **I=2** | **C=3** | **I=2** | **C=3** | **I=2** | **C=3** | **I=2** | **C=3** | **1** | |
| Epilepsy | **1** | | **1** | | **1** | | **1** | | **1** | | **1** | |
| **Depression** | | | | | | | | | | | | |
| All depressive disorders | **1** | | **1** | | **1** | | **1** | | **1** | | **1** | |
| **reproductive tract disease & disorders** | | | | | | | | | | | | |
| Irregular vaginal bleeding pattern without heavy bleeding | **1** | | **2** | | **2** | | **2** | | **1** | | **1** | |
| Heavy or prolonged vaginal bleeding irregular & regular | **1** | | **2** | | **2** | | **2** | | **I=1** | **C=2** | **2** | |
| Unevaluated, unexplained, suspicious vaginal bleeding | **2** | | **2** | | **3** | | **3** | | **I=4** | **C=2** | **I=4** | **C=2** |
| Endometriosis | **1** | | **1** | | **1** | | **1** | | **1** | | **2** | |
| Benign ovarian tumors including cysts | **1** | | **1** | | **1** | | **1** | | **1** | | **1** | |
| Sever dysmenorrhea | **1** | | **1** | | **1** | | **1** | | **1** | | **2** | |
| Gestational trophoblastic disease decreasing BHCG | **1** | | **1** | | **1** | | **1** | | **3** | | **3** | |
| Gestational trophoblastic disease persistently elevated BHCG or malignant disease | **1** | | **1** | | **1** | | **1** | | **4** | | **4** | |
| Cervical exotropia | **1** | | **1** | | **1** | | **1** | | **1** | | **1** | |
| Undiagnosed breast mass | **2** | | **2** | | **2** | | **2** | | **2** | | **1** | |
| Benign breast mass | **1** | | **1** | | **1** | | **1** | | **1** | | **1** | |
| Family history of breast cancer | **1** | | **1** | | **1** | | **1** | | **1** | | | |
| Current breast cancer | **4** | | **4** | | **4** | | **4** | | **4** | | **1** | |
| Past breast cancer and no evidence of current breast cancer for 5 years | **3** | | **3** | | **3** | | **3** | | **3** | | **1** | |
| Cervical intraepithelial neoplasia | **2** | | **1** | | **2** | | **2** | | **2** | | **1** | |
| Cervical cancer awaiting treatment | **2** | | **1** | | **2** | | **2** | | **I=4** | **C=2** | **I=4** | **C=2** |
| Endometrial hyperplasia | **1** | | **1** | | **1** | | **1** | | **1** | | **1** | |
| Endometrial Cancer | **1** | | **1** | | **1** | | **1** | | **I=4** | **C=2** | **I=4** | **C=2** |
| Ovarian cancer | **1** | | **1** | | **1** | | **1** | | **1** | | **1** | |
| Uterine fibroids | **1** | | **1** | | **1** | | **1** | | **2** | | **2** | |

| Condition | COC/Pa/Ri | POP | DMPA | Implant | LNG IUD | | Cu IUD | |
|---|---|---|---|---|---|---|---|---|
| Distorted uterine cavity | | | | | **4** | | **4** | |
| Cervical stenosis or laceration or other abnormality that does not distort the uterine cavity | | | | | **2** | | **2** | |
| Past PID with no current risk factors with subsequent pregnancy | **1** | **1** | **1** | **1** | **1** | | **1** | |
| Past PID with no current risk factors without subsequent pregnancy | **1** | **1** | **1** | **1** | **2** | | **2** | |
| Current PID, | **1** | **1** | **1** | **1** | **I=4** | **C=2** | **I=4** | **C=2** |
| Current purulent cervicitis or chlamydial or gonorrhea infection | **1** | **1** | **1** | **1** | **I=4** | **C=2** | **I=4** | **C=2** |
| Other STDs excluding HIV and hepatitis | **1** | **1** | **1** | **1** | **2** | | **2** | |
| Vaginitis including trichomonas and bacterial vaginosis | **1** | **1** | **1** | **1** | **2** | | **2** | |
| Risk factors for STDs | **1** | **1** | **1** | **1** | **I=2/3** | **C=2** | **I=2/3** | **C=2** |
| High risk for HIV | **1** | **1** | **1** | **1** | **2** | | **2** | |
| HIV Infection | **1** | **1** | **1** | **1** | **2** | | **2** | |
| AIDS clinically well on ARV therapy | Check drug interactions with these methods | | | | **2** | | **2** | |
| **infections** | | | | | | | | |
| Uncomplicated Schistosomiasis | **1** | **1** | **1** | **1** | **1** | | **1** | |
| Complicated schistosomiasis with fibrosis of the liver | **1** | **1** | **1** | **1** | **1** | | **1** | |
| Non-pelvic tuberculosis | **1** | **1** | **1** | **1** | **1** | | **1** | |
| Pelvic tuberculosis | **1** | **1** | **1** | **1** | **I=4** | **C=3** | **I=4** | **C=3** |
| Malaria | **1** | **1** | **1** | **1** | **1** | | **1** | |
| **Endocrine disease** | | | | | | | | |
| History of gestational diabetes | **1** | **1** | **1** | **1** | **1** | | **1** | |
| Nonvascular noninsulin dependent diabetes | **2** | **2** | **2** | **2** | **2** | | **1** | |
| Nonvascular insulin dependent diabetes | **2** | **2** | **2** | **2** | **2** | | **1** | |
| Nephropathy, retinopathy, neuropathy with diabetes | **3/4** | **2** | **3** | **2** | **2** | | **1** | |
| Other vascular disease or diabetes of ≥ 20 years | **3/4** | **2** | **3** | **2** | **2** | | **1** | |
| Thyroid simple goiter | **1** | **1** | **1** | **1** | **1** | | **1** | |
| Hyperthyroid | **1** | **1** | **1** | **1** | **1** | | **1** | |
| hypothyroid | **1** | **1** | **1** | **1** | **1** | | **1** | |
| **gastrointestinal conditions** | | | | | | | | |
| Inflammatory bowel diseases, ulcerative colitis, Crohn Disease | **2/3** | **2** | **2** | **1** | **1** | | **1** | |
| Symptomatic gallbladder disease treated by cholecystectomy | **2** | **2** | **2** | **2** | **2** | | **1** | |
| Symptomatic gallbladder disease medically treated | **3** | **2** | **2** | **2** | **2** | | **1** | |
| Current, symptomatic gallbladder disease | **3** | **2** | **2** | **2** | **2** | | **1** | |
| Asymptomatic gallbladder disease | **2** | **2** | **2** | **2** | **2** | | **1** | |
| History of pregnancy-related cholestasis | **2** | **1** | **1** | **1** | **1** | | **1** | |
| History of Past COC-related cholestasis | **3** | **2** | **2** | **2** | **2** | | **1** | |
| Acute or flare – viral hepatitis | **I=3/4** **C=2** | **1** | **1** | **1** | **1** | | **1** | |
| Viral hepatitis carrier | **1** | **1** | **1** | **1** | **1** | | **1** | |

| Condition | COC/Pa/Ri | POP | DMPA | Implant | LNG IUD | | Cu IUD | |
|---|---|---|---|---|---|---|---|---|
| Chronic viral hepatitis | **1** | **1** | **1** | **1** | **1** | | **1** | |
| Mild compensated cirrhosis of the liver | **1** | **1** | **1** | **1** | **1** | | **1** | |
| Sever decompensated cirrhosis of the liver | **4** | **3** | **3** | **3** | **3** | | **1** | |
| Liver tumors focal nodular hyperplasia | **2** | **2** | **2** | **2** | **2** | | **1** | |
| Liver tumors hepatocellular adenoma | **4** | | | | | | | |
| Malignant hepatoma | **3** | **3** | **3** | **3** | **3** | | **1** | |
| **anemias** | | | | | | | | |
| Thalassemia | **1** | **1** | **1** | **1** | **1** | | **2** | |
| Sickle cell disease | **2** | **1** | **1** | **1** | **1** | | **2** | |
| Iron-deficiency anemia | **1** | **1** | **1** | **1** | **1** | | **2** | |
| **solid organ transplantation** | | | | | | | | |
| Complicated: acute or chronic graft failure; rejection, cardiac allograft vasculopathy | **4** | **2** | **2** | **2** | **I=3** | **C=2** | **I=3** | **C=2** |
| Uncomplicated | **2** | **2** | **2** | **2** | **2** | | **2** | |
| **drug interactions** | | | | | | | | |
| Antiretroviral therapy-NRTI's | **1** | **1** | **1** | **1** | **I=2/3** | **C=2** | **I=2/3** | **C=2** |
| Antiretroviral therapy-NNRTI's | **2** | **2** | **1** | **2** | **I=2/3** | **C=2** | **I=2/3** | **C=2** |
| Antiretroviral therapy-Ritonavir-boosted protease inhibitors | **3** | **3** | **1** | **2** | **I=2/3** | **C=2** | **I=2/3** | **C=2** |
| Anticonvulsants: phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine | **3** | **3** | **1** | **2** | **1** | | **1** | |
| Anticonvulsant: lamotrigine | **3** | **1** | **1** | **1** | **1** | | **1** | |
| Broad spectrum antibiotics | **1** | **1** | **1** | **1** | **1** | | **1** | |
| Antifungals | **1** | **1** | **1** | **1** | **1** | | **1** | |
| Antiparasitics | **1** | **1** | **1** | **1** | **1** | | **1** | |
| Rifampicin or rifabutin | **3** | **3** | **1** | **2** | **1** | | **1** | |

## Reference


1. U.S. Medical Eligibility Criteria for Contraceptive Use, 2010, MMWR, Volume 59, May 28, 2010, www.cdc.gov/mmwr

## ABSTINENCE GUIDELINES

### POLICY

The Tennessee Department of Health Family Planning Program policy states that abstinence is an option for women of reproductive age who are at risk for unintended pregnancy. The Title X guidelines, *Program Guidelines for Project Grants for Family Planning Services, January 2001*, state that it is important not to assume that adolescents are sexually active simply because they have come for family planning services. Teenagers may be in clinic seeking assistance in making decisions concerning their sexuality and contraception. Abstinence is a valid and responsible option and should be discussed.

Interventions that are effective in encouraging teenagers to postpone sexual intercourse are those that help young people develop the interpersonal skills they need to resist premature sexual involvement. Effective interventions include a strong abstinence message, as well as information about contraception, safer sex, STDs and HIV, decision making, resisting coercion to have sex, and family involvement. Abstinence should be presented as a 3-part plan:

1. A goal statement. For example, I will be abstinent until_____.
2. These are the techniques I will use to remain abstinent until I reach my goal (list techniques such as having friends who are also abstinent, or no alcohol on a date etc.)
3. Upon reaching my goal or if I find myself at risk of becoming sexually active, and if I am not ready to be a parent, I will continue to be or return to being abstinent or seek contraception by going to _____.

### EDUCATIONAL APPROACHES

HEALTH CONCERNS: These arguments revolve around the dangers of diseases such as AIDS and herpes as well as the life-changing consequences of pregnancy.

VALUES EDUCATION: Adolescent development specialists propose that two of the primary tasks of adolescence are (a) establishing independence and (b) defining one's value system. Given these two characteristics, educators cannot and should not be "value-free" in their teaching. Family planning staff can strongly support values in their programs such as respect for oneself and others, honesty in relationships, and the destructiveness of sexual coercion. However, attempts to impose one’s specific religious or personal biases on clients are not appropriate.

DECISION-MAKING: Discussing with teens the pros and cons of teenage sexual activity tends to validate their feelings that the pressures to have sex exist and are very real. Helping adolescents develop decision-making skills gives them the power to see situations in a new light.

REFUSAL SKILLS: Family planning staff must counsel teens on how to resist coercive maneuvers to engage in sexual activities.

FAMILY COMMUNICATION: Parents may need support in order to learn how to communicate their value system to their children. Human sexuality is one part of that value system that needs to be shared if parents are to influence the decisions their young people make regarding sex.

COMPREHENSIVE SEXUALITY EDUCATION: Sexuality is a life-long process. Persons need to hear accurate information and have opportunities to discuss their feelings about sexuality as they grow. Staff involvement in community education efforts outside the clinic establishes credibility which translates into enhanced community respect for family planning programs.

### PROVIDER TASKS

- Encourage teens to make healthy decisions for themselves.
- Support those teens that have chosen abstinence by helping them establish their personal abstinence plan.
- Give straight facts about the health concerns of teen pregnancy and STDs.
- Strengthen communication between parents and their children.
- Support comprehensive sexuality education that involves parents and community leaders.
- Offer quality counseling and medical services to those teens who call for help.

## REFERENCES


1. U.S. Department of Health and Human Services, Office of Public Health and Science, Office of Population Affairs, Office of Family Planning, *Program Guidelines for Project Grants For Family Planning Services*, January, 2001.

2. Advocates for Youth, *Science and Success: Sex Education and Other Programs That Work to Prevent Teen Pregnancy, HIV & Sexually Transmitted Infections*, 2003.

3. Douglas Kirby, Ph.D., *Emerging Answers: Research Findings on Programs to Reduce Teen Pregnancy*, 2001.

4. Douglas Kirby, Ph.D., *Do Abstinence-Only Programs Delay the Initiation of Sex Among Young People and Reduce Teen Pregnancy?* National Campaign to Prevent Teen Pregnancy, Washington, DC, 2002

5. *The Case for a Cautious Generation*, National Campaign to Prevent Teen Pregnancy, Washington, DC, 2003.

*Teaching Abstinence as a Part of Comprehensive Sex Education: What Is Abstinence?*, Lesson Plan adapted from *Life Planning Education*, a comprehensive sex education curriculum, Advocates for Youth, Washington, DC: in press (2004).

# COMBINED ORAL CONTRACEPTIVE (COCs) GUIDELINES

## POLICY

The Tennessee Department of Health Family Planning Program policy states that combined oral contraceptives (COCs) must be available for reproductive age women who are at risk for unintended pregnancy. COCs are available to clients after they have been fully counseled on usage and assessed to be medically appropriate. Method specific consent forms are provided to document informed consent and client counseling. See the Appendix for a copy of the consent form, teaching tool, and client instruction sheet in English and Spanish.

## DEFINITION

The Combined Oral Contraceptive (COC) pill is a tablet containing an estrogen and a progestin that when taken as directed can prevent pregnancy. COCs are only moderately effective at preventing pregnancy. COCs are subject to human error which decreases effectiveness. Typically, COCs are only 92% effective in preventing pregnancy.

## MECHANISM OF ACTION

COCs prevent pregnancy primarily by suppressing ovulation through the combined actions of estrogen and progestin.

ESTROGENIC EFFECTS: Estrogen is included in COCs primarily for cycle control, but it may also boost the contraceptive effect.

PROGESTATIONAL EFFECTS: Progestins provide most of the contraceptive effect found in COCs. Progestins inhibit ovulation by suppression of luteinizing hormone (LH) and the LH surge. Cervical mucus is thickened in the presence of progestin, hampering the transport of sperm. Capacitation, the activation of enzymes that permit the sperm to penetrate the ovum, is also inhibited. Ovum transport may be slowed. Finally, implantation may be hampered by production of a decidualized endometrial bed with exhausted and atrophied glands.

## EFFICACY

If combined COCs are used perfectly (when pills are taken at the same time every day as directed and other instructions regarding concomitant drug use or diarrhea or vomiting are followed), only about 1 in 1,000 women is expected to become pregnant within the first year. Failure rates during typical use are determined by the extent and type of imperfect use. Among COC users in the United States, about 8 percent become pregnant during the first year of typical use. Certain medications may make the COCs less effective. These include rifampin, barbiturates, phenylbutazone, phenytoin, carbamazepine, griseofulvin, felbamate, oxcarbazepine, topiramate; St. John's Wort may also reduce the effectiveness of contraceptive steroids. Also, decreased plasma concentrations of acetaminophen and increased clearance of temazepam, salicylic acid, morphine, and clofibirc acid have been noted when administered with oral contraceptives. **The package insert for all combined hormonal methods of contraception lists broad spectrum antibiotics such as ampicillin or tetracycline as decreasing the effectiveness of combined hormonal contraceptives. It is now solidly confirmed by experts that broad spectrum antibiotics do not decrease effectiveness but FDA requirements regarding changes in package inserts makes it unlikely the insert will be changed.** Finally, contraceptive effectiveness may be reduced when combined hormonal contraceptives such as COCs are co-administered with anti-HIV protease inhibitors. Health care providers should refer to the label of the individual anti-HIV protease inhibitor for further drug interaction information.

## INDICATIONS

- Sexually active women of reproductive age and adolescents who want to avoid pregnancy
- Couples using birth control for spacing
- Non-lactating postpartum women or well-established breastfeeding women
- Need for short- or long-term reversible birth control
- Women with endometriosis who are not ready to get pregnant

- Need for postcoital birth control
- Acne
- Heavy, painful, or irregular menstrual periods
- Recurrent ovarian cysts
- Family history of ovarian cancer
- Women experiencing anxiety due to irregular periods

**BENEFITS**

- Safe and highly effective
- An option throughout the reproductive years
- Reversible
- Beneficial menstrual cycle effects
- PID protection
- Prevention of ovarian and endometrial cancer
- Decreased risk for benign breast disease
- Ectopic pregnancy prevention
- Acne improvement
- Enhanced sexual enjoyment
- Used in the treatment of disorders such as endometriosis
- Can be used as emergency hormonal contraception (See Emergency Contraceptive Pills [ECPs] Guidelines in this manual)

**DISADVANTAGES**

- Requires daily attention
- No protection against STDs including HIV

**SIDE EFFECTS**

- Break through bleeding and/or spotting
- Nausea and vomiting
- Headaches
- Depression
- Decreased libido
- Breast tenderness
- Changes in contact lens prescription
- Slight weight gain
- Increase in normal vaginal secretions

**MAJOR ADVERSE EVENTS (RARE)**

- Thrombophlebitis, pulmonary emboli, and other cardiovascular disease
- Glucose intolerance
- Gallbladder disease
- Hepatocellular adenomas

Please see the table for **US Medical Eligibility Criteria for Contraceptive Use** provided in that section of this guidance and in the 2010-2012 edition of Managing Contraception for Your Pocket. Categories 3 (risks usually outweigh benefits) and category 4 (risks outweigh benefits) will be considered contraindications. However if there are no better options and physician consult and agreement has been obtained and the client fully understands the risks versus benefits, then category 3 conditions for the method could be used.

**MAJOR PROBLEMS:** These are **NOT NORMAL** and should be reported to the clinic or hospital at once.

- Speech or vision changes

- Muscle weakness or numbness
- Sudden severe pain or soreness in leg
- Severe headache, blackouts, or dizziness
- Skin turns yellow (jaundice)
- Heavy bleeding between periods
- Severe depression

**PROVIDER TASKS**

The physical exam may be deferred for as many as three to six months at the client's request, or for client or clinic convenience. The reason for the deferral must be documented in the chart. A thorough medical history would be collected and reviewed by the nurse, nurse-practitioner, or physician and only clients who are without level 3 or 4 conditions (see US Medical Eligibility Criteria for Contraceptive Use) would begin COCs without an exam. Instruct the patient in how to obtain emergency contraception should she have unprotected intercourse.

Visit Schedule: All clients placed on oral contraceptives for the first time should receive a 3 or 4 month supply of COCs and return three months after initiating their COCs. At this visit clients may be given a 9 or 10 month supply of COCs to carry them to their annual exam (thirteen cycles altogether) based on history, physical exam, and compliance history.

Compliant, non-high risk, continuing COC clients, including adolescents, can be given a twelve-month supply of COCs (thirteen cycles) at one visit. Providers may use their judgment about clients who are new to the health department, but are already taking COCs and experiencing no problems. These clients can also be given a twelve-month supply of COCs (thirteen cycles). For clients who have medical problems that require periodic monitoring, the schedule of visits should be individualized. For noncompliant or potentially noncompliant COC users, the schedule of visits should be individualized.

Other Provider tasks:

- Provide individualized counseling in a setting that assures confidentiality.
- Include her partner if she so desire.
- Assist the woman in making a contraceptive decision that is uniquely tailored to her needs based on personal preference, lifestyle, convenience, and future pregnancy plans.
- Provide information on efficacy, mechanism of action, risks, benefits, side effects, contraindications, and cautions of each method at the women's level of understanding. This can be provided in writing.
- **Encourage all women who smoke tobacco to stop, regardless of contraceptive method.** However, for women who are light smokers (< 15 cigarettes daily and are age 34 or younger), the advantages of effective combined hormonal contraception generally out weigh the disadvantages.
- Share information on the health risks associated with unintended pregnancy (written material can be used).
- Encourage a dialogue.
- Address any specific fears or misconceptions.
- Respect the client's decision.
- Balance the risks and benefits of pill use for each individual.
- Be aware of issues surrounding the use of hormonal contraception with coexisting medical conditions such as diabetes, hypertension, migraine headaches, and cardiovascular disease.
- Always obtain informed consent.
- Provide client with pill instructions including how to begin pills, importance of daily regime, what to do about missed pills etc., (see Client Instructions found in the Appendix).
- Explain side effects and danger signs.
- Provide follow-up as indicated.

**NURSING MANAGEMENT**

See Public Health Nursing Statewide Protocols, "Combined Pills, Continuing Contraceptor" for nursing management

## CLIENT INSTRUCTIONS

See the Appendix for Client Instruction sheet and Consent Form with the Teaching Tool.

## APPENDIX

1. Consent for Combined Oral Contraceptive Pills (PH-3370)
2. Teaching Tool – Combined Oral Contraceptive Pills (This is found on the reverse side of the consent form, and a tear-off copy is given to the client.)
3. Autorizacion de Uso de la Pildora Anticonceptiva (PH-3397)
4. Meterial Educativo - Pildora Anticonceptiva (This is found on the reverse side of the consent form, and a tear-off copy is given to the client.)
5. Combined Oral Contraceptives (COCs), Client Instructions

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# DIAPHRAGM GUIDELINES

## POLICY

The Tennessee Department of Health Family Planning Program policy states that the diaphragm with spermicidal jelly or cream must be available for reproductive age women who are at risk for unintended pregnancy. Diaphragms are available to clients after they have been fully counseled on usage and assessed as medically appropriate. Informed consent is required of any woman who receives a diaphragm from the family planning clinic. See the Appendix for a copy of the consent form, teaching tool, and client instruction sheet in English and Spanish.

## DEFINITION

The diaphragm is a bowl-shaped silicone cup with a flexible rim which is inserted into the vagina before intercourse so that the posterior rim of the diaphragm rests in the posterior fornix of the vagina and the anterior rim of the diaphragm fits comfortable behind the pubic bone. The diaphragm forms a cup that covers the cervix. Spermicidal cream or jelly is placed within the cup before insertion.

## MECHANISM OF ACTION

The diaphragm provides effective contraceptive protection by acting as a barrier to sperm and as a device to hold a spermicide against the cervix. Diaphragms are available in sizes from 65 mm to 80 mm (diameter) and are available in one style, the all-flex arcing spring.

The diaphragm can be placed into the vagina up to six hours ahead of intercourse keeping in mind that the spermicide will lose its effectiveness after six hours. If a longer interval has elapsed since the diaphragm and spermicide were placed in the vagina, insertion of additional, fresh spermicide with an applicator (without removing the diaphragm) is recommended. (Again, the effectiveness of the spermicide is limited to six hours.) Whenever intercourse is repeated, additional spermicide must be inserted into the vagina. After the last act of intercourse, the diaphragm is left in place for six hours. Wearing it for longer than twenty-four hours is not recommended because of the possible risk of toxic shock syndrome.

## EFFICACY

The percentage of women experiencing an unintended pregnancy within the first year of diaphragm use is 16 percent for typical use and 6 percent for perfect use.

## INDICATIONS

The diaphragm is indicated for the prevention of pregnancy in women who desire a hormone-free contraceptive method.

## BENEFITS

- No hormonal effects.
- Partner involvement not required.
- Available for occasional use
- Relatively low cost. (If the diaphragm is used regularly, replacement is recommended every 12-18 months, depending on the condition of the diaphragm.)

## DISADVANTAGES

- Requires a certain comfort level with touching one’s genitalia.
- Must be in place prior to genital sexual contact.
- Requires professional fitting.
- Requires brief formal training and practice to learn to place and remove correctly.

## SIDE EFFECTS

- Possible allergic reactions to latex or spermicide.
- Pain, pressure, or vaginal trauma during diaphragm use.
- Partner discomfort during diaphragm use.
- Foul odor or vaginal discharge.
- Urogenital tract infections.

**CONTRAINDICATIONS**

The following conditions may preclude satisfactory use or make vaginal barrier methods inadvisable:

- Allergy to spermicide, latex, or polyurethane.
- Abnormalities in vaginal anatomy that interfere with satisfactory fit or stable placement of a diaphragm.
- Inability to learn correct insertion technique.
- Repeated urinary tract infections that persist despite efforts to refit the diaphragm.
- History of toxic shock syndrome.

**EXERCISE CAUTION** if a diaphragm is used in the following situations and monitor carefully:

- Previous pregnancy while using a diaphragm.
- Personal style or sexual patterns that make consistent use difficult.
- Method failure (pregnancy) would be devastating.

**MAJOR PROBLEMS:** The following are **DANGER SIGNALS** of **TOXIC SHOCK SYNDROME**; these are **NOT NORMAL** and should be reported to the clinic as soon as possible:

- Sudden high fever
- Vomiting, diarrhea
- Sore throat, aching muscles and joints
- Dizziness, fainting, weakness
- Sunburn-like rash
- Pain or burning with urination (sign of a bladder infection)

**PROVIDER TASKS**

- Ensure that the client is able to insert and remove her device correctly.
- Check placement and reaffirm the correct size after the client herself has inserted her device.
- Stress importance of consistent, correct use.
- Stress the importance of using a spermicide with the diaphragm.
- Stress the importance of waiting at least six hours after intercourse before removing the device.
- Remind each user to watch for toxic shock syndrome danger signs.
- Discuss the possibility of using two methods.
- Confirm that the user is aware of ECPs and knows how to obtain them.
- Clients selecting diaphragms for the first time should be scheduled for medical revisit to check fit and to answer questions and reinforce counseling on proper use of the method.

DIAPHRAGM FITTING: See latest edition of Contraceptive Technology for fitting instructions. Refit at each annual exam and refit after weight gain or loss of 10 pounds or more, after abortion, and after a full term pregnancy.

**NURSING MANAGEMENT**

See *Public Health Nursing Statewide Protocol*, “Diaphragm, Continuing Contraceptor”, for nursing management.

CLEANING FITTING RINGS: Ortho-McNeil reports three methods for cleaning diaphragm fitting sets. (See appendix). However, experts disagree on the effectiveness of the various methods. Bounds and Hoffman in the British Journal of Family Planning, 1995, note that until single use devices are available, heat decontamination by autoclave or boiling water (five-minute rapid boil) remain the only safe method. Ortho-McNeil cites the Bounds and

Hoffman reference, but goes on to describe chemical disinfecting as acceptable. Contraceptive Technology, 19th edition, 2007, lists autoclave and chemical disinfection as well. The Tennessee Department of Health believes that autoclave sterilization is the only safe option for assuring sterilization of the fitting devices, and has so stated in the Bureau's Infection Control Manual.

## CLIENT INSTRUCTION

A Client Instruction Sheet is available in the Appendix of this manual, as is the Teaching Tool found on the back of the Diaphragm consent form.

## APPENDIX

1. Diaphragm Consent Form – English PH 3373
2. Diaphragm Consent Form – Spanish PH 3401
3. Diaphragm, Client Instructions in English and Spanish (This document may be copied and given to the client.)
4. Diaphragm Cleaning Methods (Choose the autoclave option.)

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## EMERGENCY CONTRACEPTIVE PILLS (ECPs) GUIDELINES

### POLICY

The Tennessee Department of Health Family Planning Program policy states that emergency contraceptive pills (ECPs) must be available for women of reproductive age. A physical exam, pregnancy test, or a Pap smear will not be a requirement for receiving ECPs. The federal government has directed Title X grantees, which includes the Tennessee Department of Health, to "consider the availability of emergency contraception the same as any other method which has been established as safe and effective". Emergency contraception is an integral component of the comprehensive family planning program. Counseling and informed consent are required for any woman who receives ECPs from the family planning program. (See the Appendix for consent forms and client instruction sheet in English and Spanish.)

All family planning clients in every region/metro/agency should be advised of the availability of emergency contraception and of the accessibility of the service in all regions/metros/agencies. Each region/metro/agency must have a plan for making emergency contraception available and accessible. The plan must include:

- How the clinics will assure that a client has access to emergency contraception.
- How the clinics will educate the client regarding access to emergency contraception after hours and on weekends.
- How the clinic will accept walk-ins for emergency contraception.
- How all office staff (especially those answering the telephone) will know that ECPs are provided, know how to handle the calls in a professional, unbiased manner, and know the procedures to follow.
- How the clinic will assure that local protocols address the need to routinely discuss emergency contraception with clients.

### DEFINITION

Emergency contraception is a method of preventing pregnancy after sexual intercourse. ECPs consist of a higher than usual dose of the same hormones found in birth control pills. There are 3 different types of ECPs. 1. Combined ECPs consist of two elevated doses of COCs taken 12 hours apart. 2. Products for Progestin-only ECPs vary. Some products consist of two elevated doses of progestin-only pills taken 12 hours apart. Others consist of one dose. The sum total of progestin in the two-tablet product is the same as the dosage found in the one dose product. The APN or MD may decide which dosing regimen to use. 3. The latest ECP product is an anti-prostaglandin taken in a single dose up to 5 days after sexual intercourse.

In 2008, Tennessee's Pregnancy Risk Assessment Monitoring Survey (PRAMS) revealed that 49.6% of births that year in Tennessee were unintended. Unintended pregnancy is a major public health problem that affects individuals and society in many ways. Approximately half of all unintended pregnancies end in abortion. For unintended pregnancies carried to term, the mother is at greater risk of depression, physical abuse, and not achieving her educational, financial, and career goals. Her relationship is at three times the risk of dissolution. The child of an unintended pregnancy is at greater risk of being born at low birth weight, dying in the first year of life, not receiving resources necessary for healthy development, and being abused or neglected.

### MECHANISM OF ACTION

When given before ovulation, emergency contraception disrupts normal follicular development and maturation, resulting in anovulation or disrupted ovulation. Thus, when taken after ovulation has occurred or after fertilization may have taken place, pregnancy will occur. Pregnancy occurs because ECPs cannot disrupt the endometrium or other post-ovulatory events when taken after the LH surge begins. These observations suggest that emergency contraception failure, (i.e. pregnancy), most likely occurs if ovulation and fertilization have already taken place at the time of treatment. In summary:

- ECPs inhibit or disrupt ovulation
- Levonorgestrel ECPs thicken cervical mucous which can block sperm from the uterus
- ECPs cannot disrupt an established (implanted in the uterus) pregnancy or any other postovulatory events

Brands of birth control pills and dedicated products currently approved by the FDA for use as ECPs are included on the following chart. This chart may be copied for use as a desktop reference.

**ECP Regimens**
**For pregnancy prevention within 72 hours of unprotected sexual intercourse**

| Brand | Pills per Dose Take 2 doses 12 hours apart | Ethinyl Estradiol per dose (mcg) | Norgestrel or Levonorgestrel (per dose) (mg)[a] |
|---|---|---|---|
| Alesse | 5 pink pills | 100 | 0.5 |
| Aviane | 5 orange pills | 100 | 0.5 |
| Cryselle | 4 white pills | 120 | 0.6 |
| Enpresse | 4 orange pills | 120 | 0.5 |
| Jolessa | 4 pink pills | 120 | 0.6 |
| Lessina | 5 pink pills | 100 | 0.5 |
| Levlen | 4 light-orange pills | 120 | 0.6 |
| Levlite | 5 pink pills | 100 | 0.5 |
| Levora | 4 white pills | 120 | 0.6 |
| Lo Ovral | 4 white pills | 120 | 0.6 |
| Low Ogestrel | 4 white pills | 120 | 0.6 |
| Lutera | 5 white pills | 100 | 0.5 |
| Nordette | 4 light orange pills | 120 | 0.6 |
| Ogestrel | 2 white pills | 100 | 0.5 |
| Ovral | 2 white pills | 100 | 0.5 |
| Portia | 4 pink pills | 120 | 0.6 |
| Quasense | 4 white pills | 120 | 0.6 |
| Seasonale | 4 pink pills | 120 | 0.6 |
| Seasonique | 4 light blue-green pills | 120 | 0.6 |
| Trilevlen | 4 yellow pills | 120 | 0.5 |
| Trivora | 4 pink pills | 120 | 0.5 |
| | | | |
| Dedicated Emergency Contraception products | | | |
| Next Choice | 2 peach pills | 0 | Levonorgestrel 0.75mg each tablet |
| Plan B One-step | 1 pill and only 1 dose | 0 | Levonorgestrel 1.5 mg |
| Ella | 1 pill, 1 dose, up to **120 hours after unprotected intercourse** | 0 | Ulipristal acetate 30 mg |

[a]The progestin in Cryselle, Lo Ovral, Low Ogestrel, Ogestrel and Ovral is norgestrel which contains two isomers, only one of which is bioactive, the amount of norgestrel in each tablet is twice the amount of levonorgestrel.

## EFFICACY

Risk of pregnancy varies during a woman's cycle, with the highest risk occurring in the 6 days leading up to and including ovulation. Typically, if 100 women had unprotected sex once during the second or third week of their cycle, 8 would become pregnant. If the same 100 women use combined ECPs within 72 hours of unprotected sex, only 2 would become pregnant. This is a 75 percent reduction in risk. Similarly, if the same 100 women used progestin-only ECPs within 72 hours of unprotected sex, only 1 would become pregnant – an 89 percent reduction in risk of pregnancy. The risk of pregnancy applies to a single use of ECP treatment and therefore cannot be directly compared to annual failure rates of regular contraceptive methods.

A study by the World Health Organization (WHO) found that even within the initial 72 hour window, effectiveness declined significantly with increasing delay between unprotected coitus and the initiation of ECPs. Treatment delay of the first dose by 12 hours raised the odds of pregnancy by almost 50 percent, regardless of the ECP used (combined COCs or progestin-only). Thus, the WHO study suggests that ECPs should be taken as soon after unprotected intercourse as is practical.

All sexually active women of reproductive age should be informed about the option of ECPs and provided with a mechanism to receive care as needed. It is appropriate to provide ECPs in advance of need so that the client has easy access should she need the product.

## INDICATION

ECPs are indicated for the prevention of pregnancy after unprotected sexual intercourse. Currently there are 3 dedicated ECP products approved by the FDA. These include:

1. Plan B OneStep® – A one dose levonorgestrel-only product (1.5 mg) that is FDA approved for use up to 72 hours after unprotected sexual intercourse.
2. Next Choice® – A two dose levonorgestrel-only product (0.75 mg each tablet) that is FDA approved for use up to 72 hours after unprotected sexual intercourse.
3. Ella® – A one dose progesterone agonist/antagonist (ulipristal acetate 30 mg) that is FDA approved for use up to 120 hours after unprotected sexual intercourse.

Experts note that that taking 2 tablets of Next Choice® at the same time is as effective as one tablet followed by the second tablet 12 hours later. Experts also note that both of the levonorgestrel-only ECP products have efficacy up to 120 hours after unprotected intercourse. But these expert opinions are off-label. It is generally accepted within the Bureau of Health Services that off-label use of drugs will be limited to APNs and MDs. RNs must obtain an APN or MD order before providing ECPs off-label.

## BENEFITS

Emergency contraceptives are the only method a couple can use to prevent pregnancy after unprotected coitus has occurred or after a method failure. ECPs are an essential part of treatment in the care of sexual assault victims. Situations in which emergency contraception may be appropriate include but are not limited to:

- No contraceptives used
- Method failure
- Rape
- Exposure to possible teratogen when not protected by an effective contraceptive method

## DISADVANTAGES

- Next menses may be early
- Changes in menstrual flow with next menses
- Does not prevent STDs including HIV

## SIDE EFFECTS

- Nausea and/or vomiting
- Breast tenderness

- Irregular bleeding
- Headaches
- Drowsiness if an antiemetic is prescribed

**CONTRAINDICATIONS**

- A known established pregnancy (will not harm fetus but will not prevent pregnancy)
- Undiagnosed abnormal vaginal bleeding
- Allergy or sensitivity to the product

**CAUTIONS**

According to the American College of Obstetricians and Gynecologists, there have been no reports of major cardiovascular or neurological side effects associated with estrogen-containing ECPs. Nevertheless, it may be preferable to choose a progestin-only ECP for clients who are having (currently, at that time) a severe headache or migraine headache or who have a history of the following:

- Heart attack
- Stroke
- Blood clot in the brain, leg, lung, or eye
- Thrombophlebitis

**PROVIDER TASKS**

Current review of professional literature reveals that pregnancy testing, Pap smear, and physical examination are not required. Assessments needed for the safe provision of ECPs include a personal medical history of deep vein thrombosis or pulmonary embolism. In these cases, only provide a progestin-only EC method.

Failure to provide access to ECPs to medically suitable clients who have had unprotected intercourse and do not wish to get pregnant may open providers to malpractice liability. Emergency contraception is the only treatment available to prevent an unintended pregnancy after unprotected intercourse. A California court ruled that a hospital could be held liable for failing to provide a rape victim with information about and access to emergency contraception. The court reached this decision even though the hospital had a religious affiliation and state law exempted health care facilities with religious affiliations from liability for refusing to perform abortions or refusing to permit the performance of abortions in their facilities. The court concluded that this immunity did not apply to the provision of emergency contraception, which is a "pregnancy prevention" treatment, rather than an abortion.

Nausea occurs in 30 to 50 percent of women taking combined ECPs. For women using progestin-only ECPs, nausea is much less common, occurring only 23 percent of the time. Routine use of anti-nausea medication one hour prior to each ECP dose may help reduce nausea and vomiting. At the least, ECP providers should instruct the client concerning the availability of over the counter (OTC) anti-nausea medications. Regions/metros/agencies may opt to give prescriptive anti-nausea medications. Vomiting occurs in 15 to 25 percent of women taking combined ECPs. For the progestin-only ECP, vomiting occurs in some 6 percent of women. There is no research to indicate whether it is necessary to repeat the dose. There is a variance of opinion regarding advisability of repeating ECP after emesis. ACOG states "there is no evidence on which to base a recommendation for repeating the dose if emesis occurs." *Contraceptive Technology* states that some practitioners give a replacement dose whereas other practitioners conclude that a replacement dose is not necessary. The World Health Organization advises to repeat the dose if vomiting occurs within 2 hours. Albert Yuzpe, MD, advises to repeat the dose if vomiting occurs within one hour.

The effectiveness of combined oral contraceptives is reduced for women who concurrently use anticonvulsants or the antibiotics, rifampicin and griseofulvin. Combined oral contraceptive use also can affect the potency of some medications such as anticoagulants and antidepressants. It is not known whether similar drug interactions are associated with one-time, short-term ECP use Clients using other therapeutic drugs who elect to use ECPs should be encouraged to inform their regular health care provider.

In planning for emergency contraceptive services, it is important to keep in mind the short time frame for treatment and to eliminate as many barriers to access as possible. Providing ECP information, instructions, and an advance

prescription (that can be filled immediately or later if needed) during annual check-ups or other visits is the most convenient option for both clients and providers. In 2002, the Medical Services Evaluation Committee (MSEC) of Tennessee approved the policy of providing ECPs in advance of need. Regions/Metros/agencies now have the option of providing ECPs at the routine annual or initial visit so that the client will have the product itself on hand should she need it. Robert Hatcher, MD, states that, "It is extremely important, if prescribing ECPs (as contrasted with providing, which is definitely preferable), to know that the pharmacy to which you are sending your patient has the specific pill you are prescribing". This option helps educate clients about emergency contraception, eliminates the need for an unscheduled office visit, and helps to ensure that ECPs are taken as soon as possible after unprotected sex. It is also cost-effective. Providing advance information and a prescription is particularly appropriate for clients using barrier methods or natural family planning.

Experience has shown that very few women request ECPs repeatedly. Given the potential to prevent unplanned unintended pregnancy and lack of serious health risks, ECPs can be provided as frequently as requested. If a client is concerned regarding risk of pregnancy, the option of ECP should be available. Counseling about benefits of consistent use of a regular contraceptive method is important for all clients, but particularly for one who requests ECPs repeatedly. Exploration of reasons of method failure and how it can be prevented in the future is appropriate. Providers should be aware that not all clients are interested in contraceptive counseling at the time of ECP treatment. A follow-up appointment should be scheduled for a more convenient time. Counseling about regular contraceptives is recommended, but should not be a prerequisite for providing ECPs.

Provide the toll-free Emergency Contraception Hotline number: 1-888-NOT-2-LATE. The Emergency Contraception Website can be found at: www.not-2-late.com. Regions/metros/agencies who wish to join the directory of providers listed on the Emergency Contraception Hotline or Emergency Contraception Website may call the hotline number.

**ECPs following rape and sexual abuse**

If the victim is underage, refer to *Health Services Administration (HSA) Policy Manual section 8.8* for direction regarding child abuse reporting. All citizens of Tennessee, including health care professionals, are required to report if they SUSPECT child abuse including child sexual abuse. The Department of Children's Services (DCS) has established a central intake number: 1-877-237-0004 for reporting SUSPECTED child abuse or child sexual abuse. Tennessee citizens are required to report if they SUSPECT (child abuse or child sexual abuse), and it is the responsibility of DCS to decide whether or not the reported suspicion qualifies for investigation under Tennessee's child abuse/child sexual abuse laws. DCS also has a website: at www.tennessee.gov/youth/childsafety where the process for reporting SUSPECTED child abuse or child sexual abuse is described. The Child Protective Services section of the website provides the important reporting information. All nurses need to know the DCS central intake number for reporting SUSPECTED child abuse or child sexual abuse. Clinics are discouraged from defining what is or is not child abuse or child sexual abuse. Each individual citizen reports if they SUSPECT based on the situation as they observe it. DCS will decide if it qualifies for investigation under the law.

**If the rape/sexual abuse occurred up to 120 hours ago (a very acceptable off-label use in this traumatic and difficult situation):**

- Offer ECPs
- Refer to an Emergency Room (ER) or physician who is equipped to do evidence-based work-up of rape
- If client refuses referral to ER/MD, assist client in referral to an acceptable resource (police, mental health consultation, safe housing, etc.); include written information on resources
- Assure client of safety and confidentiality
- Provide support.

**More than 72 hours before client presents in clinic requesting ECPs:**

- Recent studies have found that emergency contraception works as effectively up to 120 hours after unprotected intercourse as it does using the traditional 72-hour cut off; offer ECPs to rape victims UP TO 120 HOURS AFTER THE ASSAULT
- Assist with referrals to police and mental health consultants if the client so desires
- Take accurate history; use quotes from client
- Record any witnesses to abuse/injuries

- Document physical findings. If client is going to involve law enforcement, exam client only as directed by law enforcement as there are legal requirements for the collection of evidence in cases of sexual assault. A referral to an emergency room with trained sexual assault examiners may be required.
- Assess for emotional, as well as physical injuries
- Assure client of confidentiality and safety
- Counsel regarding the cycle of violence
- Instruct in emergency numbers, shelters, mental health consultation, and area resources
- Offer referral to physician
- Offer pregnancy test and STD workup
- Instruct in advisability of repeating serology test and pregnancy test 3 to 4 weeks after the assault; repeat the HIV test in 3 to 6 months
- Offer contraceptive methods, if not currently supplied

**NURSING MANAGEMENT**

See Public Health Nursing Statewide Protocol, "Emergency Contraceptive Pills".

**CLIENT INSTRUCTIONS**

See OPA Title X Guidelines, January 2001, sections 8.1 and 8.2 for counseling guidelines. See Teaching Tool on the reverse side of the Consent for Emergency Contraceptive Pills (ECPs) for client instructions.

## APPENDIX

1. Emergency Contraceptive Pills, Client Instructions (This document may be copied and given to the client.)
2. Consent Form for Emergency Contraception PH 3375 English
3. Consent Form for Emergency Contraception PH 3400 Spanish
4. Teaching Tool for Emergency Contraception (on back of Consent Forms)

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# FERTILITY AWARENESS-BASED METHODS

## POLICY

The Tennessee Department of Health Family Planning Program policy states that fertility awareness-based methods must be available as a viable contraception option that should be discussed with women of reproductive age who are at risk for unintended pregnancy. These methods can also be used to promote conception.

## DEFINITION

Fertility awareness helps couples avoid or achieve pregnancy by abstaining from sex, using a barrier method, or by having sex during the woman's identified fertile period. Persons who abstain from sex during the identified fertile days are said to practice natural family planning. Persons who use barrier methods during fertile days practice fertility awareness-combined methods. There are five different types of fertility awareness-based methods. Couples may elect to use more than one of these at a time. The methods are:

- Ovulation Method
- Symptothermal Method
- Calendar Rhythm Method
- Standard Days Method
- Simple Observation Method

**MECHANISM OF ACTION** (See the latest edition of Contraceptive Technology for complete details)

Ovulation Method

This ovulation method relies on assessment of the cervical mucus by look, touch, and by the feeling of wetness at the vulva. Highly fertile secretions are abundant, clear, stretchy, and slippery with a vulvar sensation of wetness. Ovulation occurs within one day before, during or after the last day of abundant, clear stretchy slippery secretions and vulvar wetness. Secretions are checked daily after menstrual bleeding has stopped both before and after urination. Check the secretions on tissue paper wiping front to back. Some counselors recommend no sex the day and night after sexual intercourse on preovulatory days in order to avoid confusion with the secretions of intercourse. Check secretions the following day. The fertile period begins when cervical secretions are first observed until 4 days past the last day of clear, stretchy slippery secretions.

Symptothermal Method

The symptothermal method is a method that combines observation of cervical mucous with basal body temperature (BBT). Basal body temperature is the temperature of the body at rest. It is lower in the first part of the menstrual cycle and rises to a higher level around the time of ovulation. It remains higher until the time of the next menses. The client takes her temperature before rising each morning with a special BBT thermometer. She records the reading on a special chart. When her temperature has risen at least 0.4 degrees and remained there for at least 3 days, the client has ovulated and entered her postovulatory (infertile) days. The client relies on the cervical mucus testing to define the beginning of her fertile days and the BBT to determine the end of the fertile period.

Calendar Rhythm Method

The calendar rhythm method requires that a woman keep a record of the length of 6-12 menstrual cycles (from the beginning of one menses to the beginning of the next menses). In this time period (6-12 months) note how many days there are in the longest cycle and how many days there are in the shortest menstrual cycle. Subtract 11 from the longest cycle to find the last fertile day and 18 from the shortest to find the first fertile day.

Standard Days Method (CycleBeads®)

The standard days method is only for women whose menstrual cycles are 26 to 32 days long. To simplify this method, the client may use a specially designed, color-coded string of beads, brand name CycleBeads®. The menstrual cycle begins on day one of her menstrual period. The woman counts each day up to day 7. She can safely have intercourse on days 1 through 7. On days 8-19, she must consider herself fertile. From day 20 until the next menses begins, the woman can once again consider herself infertile. The process then repeats.

Simple Observation Method (Two Day Method)

The two day method is based simply on the presence or absence of cervical secretions on the tissue after wiping. The woman asks herself two questions: 1. Did I have secretions yesterday? 2. Do I have secretions today? If she has had any type of secretions today or yesterday she should consider herself fertile. Another way to express this is that until she can say, “I do not have secretions today and I did not have secretions yesterday, she is fertile.

**EFFICACY**

Effective use of fertility-awareness-based methods requires that couples understand how to identify fertile days and then adapt their sexual behavior to accommodate their family planning intentions. Unintended pregnancies among women practicing these methods are primarily user-related. A sizable but unknown portion of the failures is attributable to improper teaching and poor use of the method.

Ovulation Method

Three percent of perfect users of this method will experience pregnancy in the first year. But typically, 22% of users of this method become pregnant in the first year.

Symptothermal Method

Two to three percent of perfect users of this method will experience pregnancy in the first year. But typically, 13% to 20% of users of this method become pregnant in the first year.

Calendar Rhythm Method

Five percent of perfect users of this method will experience pregnancy in the first year. But the probability is 13%. There are no well-designed studies with estimates for this method.

Standard Days Method

Five percent of perfect users of this method will experience pregnancy in the first year. The probability of pregnancy with typical use is 12%.

Simple Observation Method

There is no efficacy data on this method. Some studies have suggested that it is as effective as other FAB methods when used correctly.

**INDICATIONS**

- To conceive
- To prevent pregnancy

**BENEFITS**

- No interference with the woman’s normal physiology
- Requires no drugs or devices
- No known physical side effects
- Both partners share the responsibility for family planning
- May improve communication about sexuality
- Enables a couple to take control of their fertility
- Women can monitor and observe changes in sexual health
- Morally and culturally acceptable when normal contraception is unacceptable
- Cost-effective once properly taught; couples do not require medical supervision

**DISADVANTAGES**

- Learning to recognize and chart fertility symptoms takes time.
- Initial teaching from an experienced teacher is required.
- Some women find charting difficult.
- Even though method failure is relatively low, there is a higher user failure rate particularly during the learning phase.
- Fear of unplanned pregnancy is a concern.
- Both partners require a high degree of motivation and commitment. Modifications to sexual behavior are needed to ensure abstinence or barrier method during the fertile phase.
- Decreased sexual spontaneity.
- There may be difficulty using fertility awareness-based methods at times of stress, after childbirth, illness, during lactation, recent menarche, recent discontinuation of a hormonal method, and during the perimenopause.

**CAUTION**

Certain situations may make fertility awareness methods more difficult to use:

- Irregular intervals between menses
- History of irregular temperature charts
- Recent discontinuation of hormonal contraceptive methods
- Recent menarche
- Approaching menopause and perimenopause
- Discomfort with lack of sexual spontaneity during fertile days
- Inability to keep careful records
- Persistent reproductive tract infections

**PROVIDER TASKS**

Broadly speaking, the provider's task is to teach the FAB method clearly and correctly such that the client can use the method effectively. This may require several follow-up visits to assure that the client is comfortable with the method and using it correctly. Visits should be individualized to the needs of the client.

**CLIENT COUNSELING**

Providers counseling couples should communicate the importance that FAB methods are cooperative ventures. Neither of the partners has to bear the health burden or do it alone. The basis of this method is the mutual agreement to pay close attention and abstain or use barrier methods during times of fertility in order to prevent pregnancy. Due to the irregular bleeding patterns of women who are perimenopausal, close attention should be paid to any spotting or bleeding. Abstain or protect from pregnancy for four days past any spotting because it could be ovulatory bleeding rather than menses.
Many women experience other physiological changes that correlate with ovulation. Awareness of these changes is instrumental in helping the woman utilize FAB methods more effectively. Following are changes which may be observed:

- Changes in the position, shape of the os, and consistency of the cervix
- Breast changes
- Ovulatory pain (mittelschmerz)

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## OTHER RESOURCES

U.S. Department of Health and Human Services, Office of Public Health and Science, Office of Population Affairs, Office of Family Planning, *Program Guidelines for Project Grants for Family Planning Services, January 2001*.

Tennessee Department of Health, Bureau of Health Services, Office of Nursing, Public Health Nursing Statewide Protocol.

# INTRAUTERINE DEVICE (IUD)

## POLICY

The Tennessee Department of Health Family Planning Program policy states that IUDs must be available for women of reproductive age who are at risk for unintended pregnancy. It is available to them after they have been fully counseled on usage and assessed as medically appropriate. Two IUDs are on the market in the United States. These are the ParaGard® T 380A, manufactured by Duramed Pharmaceuticals, Inc. (a subsidiary of Barr Pharmaceuticals, Inc.) and Mirena® Intrauterine System, a levonorgestrel-releasing IUD, by Bayer HealthCare Pharmaceuticals, Inc.

The method-specific informed consent is required of any woman who is about to have an IUD inserted. When the manufacturer provides a consent form, it is required as well.

Each region must have a plan for the insertion and removal of an IUD regardless of whether the IUD was inserted in the health department or elsewhere. For insertion of or medical referral for the insertion of IUDs, providers must practice within their scope of practice, be appropriately trained in IUD insertion and removal prior to performing the procedure, and have a protocol that includes resources for insertion techniques as well as client education and counseling.

## DEFINITION

The ParaGard® T 380A is a copper-bearing IUD placed into and removed from the uterus by a health care professional. Its polyethylene body is wound with copper wire and carries a copper collar on each of its transverse arms. The dimensions of the ParaGard® T 380A are 36 mm in the vertical direction and 32 mm in the horizontal direction. The ParaGard® T 380A is equipped with a monofilament polyethylene thread, which is tied through the bulb, resulting in two threads at the tip to aid in the removal of the IUD. The ParaGard® T 380A contains barium sulfate to render it radiopaque. It is approved for use up to ten years. The IUD is a convenient, highly effective form of contraception that does not interfere with sexual spontaneity and requires no daily attention.

The Mirena® Intrauterine System is a levonorgestrel-releasing IUD (LNG IUD). It is a T-shaped polyethylene device containing 52 mg of levonorgestrel. The device is placed into and removed from the uterus by a health care professional. Initially it releases 20 micrograms of levonorgestrel into the uterus. By the 5$^{th}$ year it is releasing 14mcgs. The T-Shaped body of the device is 32 mm in both the horizontal and vertical directions. It is radiopaque. There are two threads extending from the device into the vagina to aid in the removal of the LNG IUD. The device is effective for 5 years. It is convenient, highly effective, does not interfere with sexual spontaneity, and requires no daily attention.

## MECHANISM OF ACTION

Copper-bearing and Levonorgestrel-releasing IUDs

Available data indicate that the contraceptive effectiveness of the ParaGard® T 380A is enhanced by the continuous release of copper ions into the uterine cavity. The exact mechanism by which metallic copper enhances the contraceptive effect of an IUD has not been conclusively demonstrated. Clinical studies with copper-bearing IUDs suggest that fertilization is prevented either due to an altered number or lack of viability of spermatozoa. The local mechanism by which continuously released levonorgestrel enhances contraceptive effectiveness of the Mirena IUS® has also not been conclusively demonstrated. It is now believed that IUDs work primarily by preventing fertilization. Tubal flushing studies done in women using intrauterine contraception find no fertilized, normally dividing eggs. Also, studies examining sensitive assays for pregnancy in IUD users do not reveal positive pregnancy tests. And, since IUD users have fewer ectopic pregnancies than the general population, inhibition of fertilization is implied.

## EFFICACY

IUD characteristics, such as size, shape, and presence of copper or progestin, low expulsion rate, and user characteristics, such as age and parity, contribute to differences in effectiveness for different IUDs. The failure rate of IUDs also depends on a number of administrative, client, and medical variables, including ease of insertion,

clinician experience, client detection of IUD expulsion (partial and complete expulsions), and the user's access to medical services. Failure rates tend to be lower if the IUD has the following characteristics:

- Medicated with copper, silver, or a progestin.
- Large surface area, especially for non-medicated IUD.
- Inserted all the way to the top of the fundus of the uterus.

Copper-bearing IUDs

The first-year failure rate in typical users is 0.8 percent for the ParaGard® T 380A. Perfect use failure is 0.6 percent.

Levonorgestrel-releasing IUDs

Both the perfect and typical use failure rates in the first year are 0.2 percent for Mirena®.

**INDICATIONS**

Candidates for the IUD may include women who have medical contraindications to estrogen-progestin contraceptives, want a longer-acting method, want a reversible method, are in a monogamous relationship, or are lactating or postpartum. The appropriate candidate may have one or more of these characteristics:

ParaGard® T 380A

- Has contraindications to hormonal methods (would only receive Paragard®)
- Prefers a method that does not require action daily or at the time of intercourse
- No high risk behaviors for pelvic inflammatory disease
- Has successfully used an IUD in the past
- Wants longer term contraception (up to 10 years)
- Has no recent history of (in the last 3 months) or current suspicion of pelvic inflammatory disease
- Paragard® can by used by nulliparous women who have an adequate intrauterine cavity,, that is, a minimum of 6 centimeters as determined by sounding the uterus prior to insertion. (Nulliparity is a WHO category 2) Nulliparous women can have more cramping and are more likely to expel the device than multiparous women.
- Has current negative gonorrhea and chlamydia screening test results

Mirena®

- Has at least one child
- Prefers a method that does not require action daily or at the time of intercourse
- Has successfully used an IUD in the past
- Wants longer term contraception but neither she nor her partner want to be sterilized at the present time
- Has no history of PID or has had an intrauterine pregnancy since having had PID

**BENEFITS**

- The IUD is less expensive per year and easier to use than any other method.
- Women who have contraindications to hormonal methods can use the copper-bearing IUD
- The levonorgestrel-releasing IUD decreases menstrual blood loss and the incidence and intensity of dysmenorrhea
- Does not interfere with breastfeeding
- Does not interfere with sexual spontaneity
- 78% of Paragard® users continue the use of their method to one year compared to 71% of Pill users
- Very effective, long term (10 years for Paragard® and 5 years for Mirena®) method of birth control

**DISADVANTAGES**

Screening women for IUD use is important. Mirena™ labeling identifies nulliparous women as a group that should not receive an IUD. Managing Contraception For Your Pocket, (current edition), states that nulliparous women at low risk for STDs may also be candidates. This same text also suggests that a paracervical block can be used at the time of insertion. The Paragard® package insert no longer lists nulliparity as a contraindication. However, the uterus must sound to a minimum of 6 centimeters and the woman should be at low risk for sexually transmitted infection.

Pelvic Inflammatory Disease (PID): The greatest risk of pelvic inflammatory disease (PID) associated with the use of the IUD occurs from the time of insertion through 20 days post-insertion. Strict asepsis at the time of insertion and leaving the IUD in place for its life span can reduce the chance of developing PID. Women who have more than one sexual partner or whose partner has other sexual partners are at higher risk for acquiring sexually transmitted diseases and PID regardless of their IUD status. Screen all potential IUD users for chlamydia and gonorrhea prior to insertion of the IUD. IUD users with a high risk STD lifestyle also risk complications related to their IUD use.

Expulsion: Between 2-10 percent of IUD users spontaneously expel their IUD within the first year. Risk factors for expulsion include nulliparity, heavy menstrual bleeding, and severe dysmenorrhea before IUD insertion.

Pregnancy Complications: There are very few pregnancies with IUDs. But up to one-half of these pregnancies will be ectopic (outside the uterus). One-half of intrauterine pregnancies occurring with an IUD in place end in spontaneous abortion. If the IUD is removed early in an intrauterine pregnancy, the spontaneous loss will be approximately 25 percent. Severe pelvic infections resulting in death are more likely to occur if the IUD is left in place in a pregnant woman.

**SIDE EFFECTS**

Menstrual Problems: Increased dysmenorrhea may accompany copper-bearing IUD use. From 10-15 percent of copper-bearing IUD users will have their IUD removed because of symptoms associated with bleeding or spotting. However, the average copper-bearing IUD client has an increase in blood loss that is usually minor and of little consequence. Clients with levonorgestrel IUDs have less cramping and bleeding and may become amenorrheic.

Problems with Insertion: Some women experience a severe vasovagal response at the time of insertion. There also can be pain at the time of insertion or removal of the IUD. The risk of uterine perforation at the time of insertion by an experienced provider is 1:1000.

Other: Headache, acne, and breast tenderness can be experienced in the first few months after a levonorgestrel-releasing IUD is inserted. Occasionally, the IUD strings irritate the partner during intercourse.

Please see the table for **US Medical Eligibility Criteria for Contraceptive Use** provided in that section of this guidance and in the 2010-2012 edition of Managing Contraception for Your Pocket. Categories 3 (risks usually outweigh benefits) and category 4 (risks outweigh benefits) will be considered contraindications. However if there are no better options and physician consult and agreement has been obtained and the client fully understands the risks versus benefits, then category 3 conditions for the method could be used.

**WARNING SIGNS**

- Abdominal or pelvic pain
- Prolonged or heavy bleeding/discharge/odor
- Painful sexual intercourse
- Fever or chills
- Any signs of pregnancy
- Exposure to gonorrhea/chlamydia/any STD
- Cannot feel string or can feel plastic
- Missed period or abnormal spotting or bleeding
- Flu-like illness

**PROVIDER TASKS**

Before insertion, obtain a medical and social history. Review the patient package insert with the client and give it to her to read (available on line at www.paragard.com listed on the home-page top right or www.mirena-usa.com under Patient Information at the bottom of the USA page. Advise her to take the patient package insert with her to the IUD insertion visit. Document in the chart that the patient package insert was reviewed and given to the client.

The physical examination should include a pelvic exam, Pap smear, gonorrhea/chlamydia test and any other appropriate tests for STDs, as indicated. Assess and discuss the factors relating to safety and effectiveness.

An IUD can be inserted any time during the menstrual cycle as long as the woman is not pregnant. If there is any question of pregnancy, perform a pregnancy test or delay insertion until the next menstrual flow. If the IUD is inserted one or two days after childbirth, there is a greater risk of expulsion as the uterus contracts.

IUDs can be inserted immediately following the delivery of the placenta, however this is rarely performed in the United States.

Appropriate times for insertion in the clinic setting include:

- Postpartum or after spontaneous or elective second trimester abortion - Insert after complete involution of the uterus (generally 6 weeks but not before the second month postpartum or second month after second trimester abortion). Rule out infection.
- Immediately after elective or spontaneous first trimester abortion if infection can be ruled out.
- Any time in her menstrual cycle if a woman has been consistently and reliably using a method of birth control OR if she has not had intercourse since her last menses, OR if she has a negative pregnancy test. (Expulsion rates are higher when inserted during menses. Removal requests are lowest when insertion is midcycle).
- Within six days of unprotected coitus, if the woman desires a postcoital emergency contraceptive device.

Insertion and Removal Technique: See Duramed Pharmaceuticals, Inc. package information for ParaGard® T 380A, for preparation, insertion, and removal technique (www.paragard.com). See Bayer HealthCare Prescribing Information for Mirena® Intrauterine System for insertion and removal information or www.mirena-usa.com. For all devices, follow manufacturer instructions. Providers must have appropriate training. Managing Contraception, (current edition) or the latest edition of Contraceptive Technology are also resources for insertion and removal information.

Possible Indications for removal of IUD.

- If the client becomes dissatisfied with the IUD or desires a pregnancy
- If the client's relationship ceases to be mutually monogamous (This is the preferred lifestyle for both IUDs per package insert. The presence of the IUD will not increase the likelihood of an STD; but the lifestyle does).
- If the client or partner becomes HIV positive or
- If the client acquires a sexually transmitted disease (STDs may not require removal of device during antibiotic therapy –the benefit of leaving the device in place during treatment generally outweighs the risk of removing the device)
- If the client reaches the end of the tenth year of use for the Paragard or fifth year for Mirena
- If the client experiences medical problems
- Menorrhagia and/or metrorrhagia-producing anemia
- Pelvic infection (possible indication – may be able to treat with device in place)
- Actinomyces-like organism on Pap smear (possible indication only if symptomatic pelvic infection is also present – see Contraceptive Technology, latest edition)
- Intractable pelvic pain
- Dyspareunia
- Pregnancy
- Endometrial or cervical malignancy
- Uterine or cervical perforation
- Increase in length of the threads extending from the cervix or any other indication of partial expulsion

## NURSING MANGEMENT

See *PHN Statewide Protocol* for nursing management.

## CLIENT COUNSELING

- Foremost, allow the client to participate in choosing her method.
- The client must be an informed user. Clients need to receive and understand the patient package insert and the teaching tool on the back of the method specific consent form. It is imperative that every effort is made to assure that the client understands the contents of the patient package insert (packaged with the device or located on the websites listed above) and the teaching tool. Document in the chart that the patient package insert was reviewed with and given to the client.
- Make all presentations, counseling, and educational materials compatible with the language, culture and education of the client.
- Set aside a time for counseling as a routine part of the clinic visit. During the initial visit, a woman needs counseling to help her select a method, then additional counseling prior to and after the IUD insertion given that is her selected method.
- Be aware of any local myths and misconceptions about IUDs. Address these misconceptions sensitively but directly.
- Use the Teaching Tool (on the back of the consent form) as an outline of information to be presented to the client.
- Ask the client to repeat important information.
- Give each IUD user an identification card with the name and picture of the IUD. The card may note the dates of insertion and recommended removal.
- If a client is not accustomed to following a calendar, inform her about the recommended dates for checkups and IUD removal.
- Sample IUDs should be available so that women can handle and examine them.
- Provide flip charts, posters, and handouts describing key information about IUDs (and other available contraceptive methods).

## OTHER CLIENT INSTRUCTIONS

- Some women experience pain or nausea immediately after IUD insertion. The client should be instructed that she might want to come to the clinic with a partner or friend in case she needs someone to assist her home.
- Advise the client not to try to remove the IUD herself. She should not allow her partner to pull on the strings.
- If the client has mild cramping, over-the-counter pain medications may be recommended or a prescription written.

<u>IUD Strings</u>: After insertion, give cut strings to client to feel and to keep. She should learn how to feel the strings that protrude 2 inches or so into her vagina. Explain that if she cannot feel the strings or if she can feel the plastic, her IUD may not protect her against pregnancy. Use another method until she can return to the clinic to have her IUD checked. An IUD can be expelled without knowing it. She should check for the strings frequently during the first months she has the device, then after each period and any time she has abnormal cramping while menstruating. Advise the client to always wash her hands before and after checking the strings. Follow-up with an appointment in 6 weeks; at that time be sure the client can feel the IUD strings.

<u>Signs of Infection</u>: If at any time she has fever, pelvic pain or tenderness, severe cramping, foul odor, or unusual vaginal bleeding, she should contact her clinician immediately because she may have an infection. Infections can be serious and, if untreated, can lead to hysterectomy or even death. Inform the client where she can go to be treated for an infection, giving her the phone numbers and contacts for treatment during and after business hours. Women in long term, faithful, mutually monogamous relationships have a decreased risk of serious infections.

<u>Menstruation:</u> If the client misses a menstrual period, advise her to contact her health care provider. The most commonly reported nuisance side effects of the copper IUD are increased menstrual flow, menstrual cramping and spotting, and increased mucous discharge. Heavier menstrual bleeding may be serious if she is anemic. However, a

small increase in the menstrual flow is normal with the copper IUD, especially during the first two to three periods. Clients with LNG IUDs may have initial break through bleeding and spotting as seen with other progestin-only methods. There is however a decrease in overall menstrual flow and cramping. Amenorrhea develops in 20-50% of LNG IUD users.

Teach the client the IUD Warning Signs:

P Period late (pregnancy), abnormal spotting or bleeding (ectopic pregnancy)
A Abdominal pain, pain with intercourse
I Infection exposure (any STD), abnormal discharge
N Not feeling well, fever, chills
S String missing, shorter or longer

Also see the Teaching Tool found on the back of the consent form.

## Appendix

1. Consent for Intrauterine Device (IUD) (PH-3374)
2. Teaching Tool - Intrauterine Device (Back of Consent Form)
3. Autorizacion de Uso del Dispositivo Intrauterino (DUI) (PH-3403)
4. Meterial Educativo - Dispositivo Intrauterino (DUI) (Back of Consent Form)

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# NON-PRESCRIPTIVE CONTRACEPTIVE METHODS

## MALE CONDOM, FEMALE CONDOM, CONTRACEPTIVE SPONGE AND VAGINAL SPERMICIDES (FOAM, CREAM, FILM, JELLY, and VAGINAL SUPPOSITORIES)

### POLICY

The Tennessee Department of Health Family Planning Program policy states that non-prescriptive contraceptive methods must be available for reproductive age women who are at risk for unintended pregnancy. Non-prescriptive methods are available to clients after they have been fully counseled on usage and assessed as medically appropriate. These guidelines discuss the non-prescriptive methods: male condoms, female condoms, contraceptive sponge, and vaginal spermicides (foam, cream, film, jelly, and suppositories). Consent forms are provided to document client counseling and to document informed consent for non-prescriptive methods.

**Public health staff should counsel users of non-prescriptive methods regarding the efficacy of the method in preventing pregnancy. PRAMS 2008 revealed that 49% of Tennessee women reported that their recent pregnancy was unintended. Half of these women used contraception at the time of conception with their method of contraception being male condoms**.

Regions and agencies have the option to schedule physical exams and Pap smears every other year on clients using non-prescriptive methods of family planning. If there are medical problems, follow-up with an appropriate provider would be needed.

### DEFINITIONS

MALE CONDOM: The condom is a sheath worn over the penis during sex, preventing sperm from entering the vagina. There are two types of condoms: those made from latex and those made from processed animal tissue. Condoms may be colored, textured, lubricated, or non-lubricated. Some lubricated condoms also contain spermicide. Condoms lubricated with a spermicide do not prevent pregnancy better than condoms with a plain lubricant. Spermicides used to lubricate condoms can be irritating to the vaginal walls and cervix creating entry sites for the human immunodeficiency virus (HIV).Some condoms have a nipple-shaped end to contain the semen. Condoms are used only once and are available without a prescription in a variety of retail stores.

FEMALE CONDOM: The female condom is a thin polyurethane sheath that contains two flexible polyurethane rings. One ring lies inside the vagina near the cervix, at the closed end of the sheath, and serves as an insertion mechanism and internal anchor. The other ring forms the external, open edge of the device and remains outside the vagina after insertion. The external portion of the device thus covers part of the perineum and provides protection to the labia and the base of the penis during intercourse. The sheath is prelubricated on the inside with a silicone-based lubricant. It is intended for one-time use. It does not contain a spermicide. Female condoms are available in drug stores without a prescription. Reality® is the brand name of the female condom currently sold in the United States. Other brands are available in other countries.

CONTRACEPTIVE SPONGE: The contraceptive sponge is a small round single use polyurethane device containing 1 gram of Nonoxynol 9. Approximately 125 mg of the Nonoxynol 9 is released over the 24 hour wear period. The contraceptive sponge is moistened thoroughly with tap water prior to insertion. It is left in place 6 hours after the last act of intercourse making the maximum wear time 30 hours. Leaving the contraceptive sponge in longer than 30 hours is not recommended due to the risk of toxic shock syndrome. The Today® sponge is the brand name of the contraceptive sponge currently available in the United States.

VAGINAL SPERMICIDES: Vaginal spermicides act in two ways to prevent pregnancy. First they are detergents that disrupt sperm motility. Second they act as a barrier to keep sperm from entering the cervix. Nonoxynol-9 is the active chemical agent in most spermicidal products available in the United States. Spermicides can be irritating to the vaginal walls and cervix creating entry sites for the human immunodeficiency virus (HIV).

### MECHANISM OF ACTION

MALE CONDOM: Placed over the erect penis, a condom acts as a mechanical barrier, preventing direct contact with semen. It may also prevent contact with lesions and infectious secretions. Most U.S. condoms available today are made of latex while a small proportion are made of processed collagenous tissue from the intestinal cecum of lambs ("skin" or "natural membrane" condoms). Male condoms are also made of polyurethane ("plastic" condoms). Latex, polyurethane, and membrane condoms prevent pregnancy by blocking the passage of sperm through their surfaces. Membrane condoms are **not** recommended for protection against sexually transmitted diseases. The surface of membrane condoms contain small pores that have been shown in laboratory tests to permit the passage of viruses including hepatitis B virus, herpes simplex virus, and HIV.

FEMALE CONDOM: The female condom provides a physical barrier that lines the inner contours of the vagina and partially shields the perineum preventing contact with the penis. Semen is trapped within the condom and then discarded. Female condoms are made of polyurethane.

CONTRACEPTIVE SPONGE: The contraceptive sponge provides a spermicide and a physical barrier to cover the cervix. The sponge itself also absorbs sperm. Prior to insertion, the sponge must be thoroughly moistened with clean tap water.

VAGINAL SPERMICIDES: Spermicidal preparations consist of two components:

- Base or carrier (foam, cream, jelly, film, or suppository)
- Spermicidal chemical that disrupts sperm motility

**EFFICACY**

MALE CONDOM: Condoms can be very effective at preventing unintended pregnancy when used consistently and correctly. Method failure of the condom is relatively uncommon. The estimate of the failure rate for the first year of use among perfect users of condoms is about 2 percent. The typical use failure rate is 15 percent.

FEMALE CONDOM: Condoms can be very effective at preventing unintended pregnancy when used consistently and correctly. Method failure of the condom is relatively uncommon. The estimate of the failure rate for the first year of use among perfect users of female condoms is about 5 percent. The typical use failure rate is 21 percent.

CONTRACEPTIVE SPONGE: According to Contraceptive Technology Reports, efficacy of the sponge may vary for nulliparous women versus parous women. The estimate of the failure rate for the first year of use among nulliparous perfect users of the contraceptive sponge is 9% and for parous perfect users is 20%. The typical use failure rate for nulliparous women is 16% and for parous women is 32%.

VAGINAL SPERMICIDES: Consistent use is the most important factor in minimizing failure with spermicides. For perfect users the failure rate is 18%. For typical users the failure rate is 29%.

**INDICATIONS**

Nonprescriptive methods of contraception are indicated for the prevention of unintended pregnancy. Male condoms are also indicated for STD risk reduction.

**BENEFITS**

MALE CONDOM:

- Available over-the-counter
- Inexpensive
- Male participation
- Portable
- Helps prevent transmission of STDs and HIV

FEMALE CONDOM:

- Available over-the-counter

- No latex
- Portable
- Insertion can occur hours prior to intercourse
- Does not require partner involvement
- No systemic side effects
- Helps prevent transmission of STDs and HIV

CONTRACEPTIVE SPONGE

- Available over-the-counter
- No latex
- Portable
- Not messy
- Partner involvement not required
- Lasts for 24 hours
- No systemic side effects

VAGINAL SPERMICIDES:

- Available over-the-counter
- Inexpensive and easy to use
- Partner involvement not required
- Provides lubrication
- Available for immediate use
- Can augment other methods of contraception

**DISADVANTAGES**

MALE CONDOM:

- Reduced sensitivity
- Interrupts foreplay
- Male involvement required
- Embarrassment
- Breakage, slippage, and/or retention of condom in vagina
- Requires prompt withdrawal after ejaculation
- When high contraception efficacy is required, better to use with another method

FEMALE CONDOM:

- Cumbersome, outer ring
- Noisy
- Requires education and experience for successful use
- History of toxic shock syndrome
- Concomitant use of spermicides may cause skin irritation

CONTRACEPTIVE SPONGE

- Contraindicated if allergic or sensitive to Nonoxynol 9 or polyurethane or the preservative metabisulfite. (Consult if the client or her partner is allergic to sulfa drugs).
- Toxic Shock Syndrome may be a risk factor especially if worn during menses or beyond the 30 hour limit.
- Contraindicated for use during menses, immediately following childbirth, miscarriage or abortion or by women who have had toxic shock syndrome in the past.

VAGINAL SPERMICIDES:

- Allergy or sensitivity to the spermicidal agent or to ingredients in the base may cause irritation
- Requires correct insertion technique
- May not be as effective with abnormal vaginal anatomy (such as vaginal septum, prolapse, double cervix)
- Foams can be messy
- Films and suppositories require 15 minutes for activation prior to penetration
- Spermicides can be irritating to the vaginal walls and cervix creating entry sites for the human immunodeficiency virus (HIV)

**CONTRAINDICATIONS**

Nonprescriptive methods of contraception are contraindicated in persons allergic to spermicides, latex, or polyurethane. The Today® sponge is contraindicated for use during menses, immediately following childbirth, miscarriage or abortion or by women who have had toxic shock syndrome in the past. The Today® sponge may also be contraindicated in women allergic to sulfa drugs (see above and consult physician).

**CAUTION**

Nonprescriptive methods of contraception containing the spermicide nonoxynol-9 can increase the risk of HIV transmission.

**PROVIDER TASKS**

CONDOMS (MALE AND FEMALE)

- Encourage clients to share fears and problems associated with condom use
- Provide enough condoms so that the client will not have to visit the clinic frequently
- Convey the message that condoms have to be used with every act of intercourse

CONTRACEPTIVE SPONGE

- Provide instructions about proper use
- Teach the signs of toxic shock syndrome

VAGINAL SPERMICIDES

- Reinforce instructions about proper use
- Remind women who have abnormalities of vaginal anatomy such as septate vagina or severe prolapse, which may interfere with proper spermicide placement, that spermicide use may not be effective for them
- Warn women that spermicides may enhance the transmission of HIV

**CLIENT INSTRUCTIONS**

See Client Instruction Sheet for Condoms and Spermicide found in the Appendix.

**NURSING MANAGEMENT**

See *PHN Statewide Protocol* Condoms and Spermicidal Agents.

## APPENDIX

1. Consent for Family Planning Services for Non-Prescriptive Methods (PH-3371)
2. Autorizacion de Uso de Metodos de Control de la Natalidad Que No Requiren Receta Medica (condon, espuma, jalea, pelicula ["film"], cremas, capsulas vaginales, control de la natalidad natural y otros) (PH-3399)

3. Male Condoms, Client Instructions
4. Female Condoms and Vaginal Spermicides, Client Instructions

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## OTHER RESOURCES

Tennessee Department of Health, Office of Nursing, *Public Health Nurse Statewide Protocol*.

# THE CONTRACEPTIVE PATCH

## POLICY

It is the Tennessee Department of Health Family Planning Program policy that the clinics may provide the contraceptive patch to reproductive age women who are at risk for unintended pregnancy. Provision of the Patch is dependent upon available funds. Therefore, provide the contraceptive patch to woman for whom there is no other acceptable option.

Women particularly well-suited for this method are women with a history of noncompliance with the proper use of oral contraceptives and an aversion or contraindication to injectable contraception. The contraceptive patch is available to clients after they have been fully counseled on usage and are deemed medically appropriate. It is dispensed in accordance with established Family Planning guidelines and the public health nurse protocol. A consent form is available to document informed consent and client counseling.

## DEFINITION

In November 2001, the U.S. Food and Drug Administration approved a contraceptive patch marketed by Ortho-McNeil under the trade name of Ortho Evra for the prevention of unintended pregnancy. Ortho Evra® is a type of hormonal birth control similar to oral contraceptives in that it contains an estrogen and a progestin, but it is administered via a skin patch. The contraceptive patch is worn for 3 weeks followed by a patch-free week during which time menstruation occurs. Initially, the patch can be applied on the day the next period begins or on the first Sunday after the period begins. (If the period begins on a Sunday, start that day). The day the first patch is applied becomes and is called the “patch change day”. The patch is applied to clean, dry, healthy, lotion-free, and powder-free skin. Clients avoid touching the patches sticky surface by removing half of the protective liner, applying the sticky side to the chosen site and then removing the other side of the protective liner. The client presses down firmly on the patch with the palm of her hand for 10 seconds making sure the edges stick well. The patch is applied to the buttocks, abdomen, upper outer arm, or upper torso (never on the breasts). To avoid irritation each new patch is applied to a different site. The patch is worn for 7 days, then at any time on the “patch change day”, the old patch is removed and a new patch is applied.

## MECHANISM OF ACTION

Ortho Evra® is a combination transdermal contraceptive patch with a contact surface area of 20 $cm^2$. It contains 6mg norelgestromin and 0.75mg ethinyl estradiol. Systemic exposures and steady state concentration of Ortho Evra® are higher, while peak concentrations are lower, than those produced by an oral contraceptive containing norgestimate 250 mcg / ethinyl estradiol 35 mcg. Women using the Ortho Evra® are exposed to approximately 60% more ethinyl estradiol over the menstrual month compared with women using an oral contraceptive containing 35 mcg of ethinyl estradiol. In contrast, daily peak concentrations for ethinyl estradiol are approximately 25% lower in women using Ortho Evra®. Some experts (Contraceptive Technology Update January 2006) advise that providers might want to think of the contraceptive patch, Ortho Evra®, as similar to a COC containing 50 mcg of ethinyl estradiol.

The patch prevents pregnancy by preventing ovulation and by thickening the cervical mucus which inhibits sperm transport.

## EFFICACY

Ortho Evra® is a highly effective method of birth control when the client adheres to the recommended dosage schedule. As with COCs, the typical use failure rate of the Patch is 8%. Certain medications can make the patch less effective. These include rifampin, barbiturates, phenylbutazone, phenytoin, carbamazepine, felbamate, oxcarbazepine, and topiramate. Griseofulvin is now considered a category 1 antifungal. St. John’s Wort may also reduce the effectiveness of contraceptive steroids (CT). Also, decreased plasma concentrations of acetaminophen and increased clearance of temazepam, salicylic acid, morphine, and clofibirc acid have been noted when administered with combined hormonal contraceptives. Finally, contraceptive effectiveness may be reduced when combined hormonal contraceptives such as the Patch are co-administered with anti-HIV protease inhibitors. Health care providers should refer to the label of the individual anti-HIV protease inhibitor for further drug interaction information. The package insert for all combined hormonal methods of contraception lists broad spectrum antibiotics

such as ampicillin or tetracycline as decreasing the effectiveness of combined hormonal contraceptives. Other experts report that broad spectrum antibiotics do not decrease effectiveness. Efficacy is also decreased when used by women weighing ≥ 198 pounds.

**INDICATIONS**

Ortho Evra is indicated for women of reproductive age who are seeking to avoid an unintended pregnancy.

**BENEFITS**

- Regular periods with less cramping/bleeding
- Reduced risk of ovarian and uterine cancer
- Fewer benign breast lumps and ovarian cysts
- Safe and effective method of birth control
- Less acne
- Does not require daily attention

**DISADVANTAGES**

- May cause skin irritation at placement site
- Delivers estrogen, over the menstrual month, at levels similar to a 50mcg (ethinyl estradiol) birth control pill
- Will not protect against HIV/AIDS or other sexually transmitted diseases
- Early on there can be menstrual irregularities including no bleeding, irregular bleeding, and spotting
- May not be as effective for women weighing 198 pounds or more
- Patches must be applied correctly and changed on the appropriate day or effectiveness can be decreased

**SIDE EFFECTS**

Some women may experience the following:

- Spotting between periods
- Mood changes
- Breast tenderness
- Changes in contact lens prescription
- Headaches
- Irritation at the application site
- Menstrual cramps/abdominal pain
- Nausea and vomiting

Please see the table for **US Medical Eligibility Criteria for Contraceptive Use** provided in that section of this guidance and in the 2010-2012 edition of Managing Contraception for Your Pocket. Categories 3 (risks usually outweigh benefits) and category 4 (risks outweigh benefits) will be considered contraindications. However if there are no better options and physician consult and agreement has been obtained and the client fully understands the risks versus benefits, then category 3 conditions for the method could be used.

**WARNING SIGNS**

These are NOT NORMAL and should be reported to the clinic or hospital at once:

- Severe chest pain and shortness of breath (possible clot in lung or heart attack)
- Severe abdominal pain (possible rupture of a liver tumor, gall bladder disease, or ectopic pregnancy)
- Speech or vision changes (possible stroke)
- Skin turns yellow (possible liver problems)
- Muscle weakness or numbness (possible stroke)
- Heavy bleeding between periods (possible infection)
- Sudden severe pain or soreness in leg (possible clot in leg)

- Severe depression
- Severe headaches, blackouts, dizziness (possible stroke)
- Breast lump (possible breast cancer)
- Signs of pregnancy

**PROVIDER TASKS**

- Provide individualized counseling in a setting that assures confidentiality.
- Include her partner if she so desire.
- Assist the woman in making a contraceptive decision that is uniquely tailored to her needs based on personal preference, lifestyle, convenience, and future pregnancy plans.
- Provide information on efficacy, mechanism of action, risks, benefits, side effects, contraindications, and cautions of each method at the women's level of understanding. This can be provided in writing.
- Encourage all women who smoke tobacco to stop, regardless of contraceptive method. However, for women who are light smokers (< 15 cigarettes daily and are age 34 or younger), the advantages of effective combined hormonal contraception generally out weigh the disadvantages.
- Share information on the health risks associated with unintended pregnancy (written material can be used).
- Encourage a dialogue.
- Address any specific fears or misconceptions.
- Respect the client's decision.

The provider may elect to defer the physical exam for as many as three to six months at the client's request, or for client or clinic convenience. The reason for the deferral must be documented in the chart. A thorough medical history would be collected and only clients who are without contraindications or cautions would begin the contraceptive patch without an exam.

Instruct the patient in how to obtain emergency contraception should she have unprotected intercourse.

**CLIENT INSTRUCTIONS**

See Teaching Tool for the Contraceptive Patch found on the back of the consent form and the Patch Client Instruction Sheet. These can be found in the Appendix.

**NURSING MANAGEMENT**

See the Public Health Nurse Statewide Protocol for the contraceptive patch.

**APPENDIX**

1. Consent for the Contraceptive Patch PH No. 3761
2. Consent in Spanish PH No. 3761S
3. Client Instruction Sheet for the Contraceptive Patch

**REFERENCES**


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# GUIDELINES FOR A PROGESTIN-ONLY IMPLANT CONTRACEPTIVE

## POLICY

The Tennessee Department of Health Family Planning Program policy states that progestin-only implants should be available for clients after they have been fully counseled and assessed as medically appropriate. Informed consent is required of any woman who receives a progestin-only implant contraceptive. **Progestin-only implants can be inserted only by providers who have received the manufacturer-sponsored insertion training.** See the Appendix for a copy of the consent form and teaching tool in English and Spanish.

## DEFINITION

Progestin-only implant contraceptives are methods of contraception that contain a chemical similar to (but not the same as) the naturally-occurring hormone progesterone. In August of 2006, the FDA approved Implanon®, a contraceptive implant containing the progestin, etonogestrel. Implanon® is a single rod 4 cm in length and 2mm in diameter (about the size of a matchstick). It contains 68 mg of etonogestrel surrounded by an ethylene vinylacetate (EVA) copolymer skin. It does not contain silicone or latex. It is placed in the upper, inner aspect of the non-dominant arm. It releases 60-70 mcg per day in week 5-6 and decreases to approximately 35-45 mcg/day at the end of the first year. The second year it releases 30-40 mcg and then approximately 25 to 30 mcg by the end of the third year.

## MECHANISM OF ACTION

Like other progestin-only methods, progestin-only implants prevent pregnancy by preventing ovulation, by thickening cervical mucus, and by altering the endometrium.

## EFFICACY

Progestin-only implant contraception is a highly effective contraceptive method. The probability of pregnancy among perfect and typical users is 0.05%. Clients use a back-up method of contraception for the first seven days after the implant is placed.

To ensure that the client is not pregnant at the time of the insertion, it is essential that the implant be placed as follows:

- For women with no preceding method of contraception, insert during the first five days of a normal menstrual period.
- For women who are using combined hormonal contraceptives (Pill, Patch or Ring), insert during the 7 hormone-free days
- For women using progestin-only pills, insert any day of the month
- For women with an implant, insert on the day the implant is removed
- For women with a progestin-bearing IUD, insert on the day the IUD is removed
- For women with a copper-bearing IUD, insert on the day the IUD is removed
- For women using progestin-only injections, insert on the day the next injection would be due
- For women who have undergone a first trimester abortion or miscarriage, insert immediately or up to 5 days postpartum
- For women who have had a second trimester abortion or a full-term delivery and are not exclusively breastfeeding, insert on days 21-28 postpartum
- For women who are exclusively breastfeeding, insert after milk supply is well established and not before 28 days postpartum (package insert). Insertion less than 1 month postpartum is CDC MEC Guidelines category (2). One to six months postpartum is a category 1.
- For women who are more than 28 days postpartum, rule out pregnancy and client must use a non-hormonal method of birth control during the first seven days after the insertion.

## INDICATIONS

Progestin-only implant contraceptives are indicated for the prevention of pregnancy in women who seek a long acting contraceptive (up to 3 years for Implanon®) that is reversible.

**BENEFITS**

- All progestin-only contraceptives including progestin-only implants, may be appropriate where estrogen is contraindicated.
- May be used by breastfeeding women after the milk supply is well established
- Older women (perimenopausal) may benefit from the fewer thromboembolic risks
- Highly effective long acting method.
- Reversible with rapid return of fertility (as early as one week)
- Minimal weight gain of approximately 2-4 lbs

**DISADVANTAGES**

- Does not prevent STDs including HIV.
- Requires a minor surgical procedure to insert and remove. There is a risk of infection at the time of insertion and removal.
- Must be placed subdermally or removal may be difficult to impossible requiring an operating room procedure.
- Removals can be difficult if implant becomes encapsulated in fibrous tissue.
- Failure to remove Implanon® after 3 years may lead to infertility, ectopic pregnancy, or drug-related adverse event. (After removal of old implant, a new implant may be inserted)
- Highly irregular menstrual bleeding, break through bleeding, and spotting. This is the most common reason given for discontinuing progestin-only implant contraceptives.
- Induces mild insulin resistance that could be significant for diabetics or others with impaired glucose tolerance.
- Weight gain of 2-4 lbs by the end of the second year of use.
- Increased risk of ovarian cysts that generally resolve on their own rarely requiring surgery.
- Since some progestins may elevate LDL levels, women with known hyperlipidemias should be monitored carefully.
- May aggravate depression in a woman with a history of depression
- May affect the prescription of contact wearers.
- May be less effective in women taking long term medications that are inducers of hepatic enzymes.
- May be less effective in women whose weight is more than 130% of ideal body weight.

**SIDE EFFECTS**

- Menstrual cycle disturbance: Women using the implant, Implanon®, will have irregular and unpredictable menstrual bleeding. Ten percent of women using the product have it removed because of this disturbance. Women can have more bleeding, less bleeding, or no bleeding. The time between periods may vary and in between periods, women may have spotting. Women who cannot accept menstrual changes are not good candidates for this method.
- Weight gain: Progestin-only implants are associated with weight gain on average of 2-4 lbs by the end of the second year of use (Implanon® data).
- Mood swings
- Headache
- Acne
- Depression
-

Please see the table for **US Medical Eligibility Criteria for Contraceptive Use** provided in that section of this guidance and in the 2010-2012 edition of Managing Contraception for Your Pocket. Categories 3 (risks usually outweigh benefits) and category 4 (risks outweigh benefits) will be considered contraindications. However if there are no better options and physician consult and agreement has been obtained and the client fully understands the risks versus benefits, then category 3 conditions for the method could be used.

**MAJOR PROBLEMS:** These are **NOT NORMAL** and should be reported to the clinic or hospital at once.

- Heavy vaginal bleeding
- Severe painful headaches, vomiting, dizziness or fainting, numbness in arm or leg (possible stroke)
- Blurred, double, or loss of vision (clot in eye)
- Coughing up blood, chest pain, shortness of breath (possible clot in lung)
- Severe crushing chest pain (possible heart attack),
- Severe abdominal pain (possible ectopic pregnancy, ovarian cyst, gallbladder disease, or liver problems)
- Severe and persistent leg pain (possible clot in leg)
- Jaundice
- Breast lump
- Sadness, tiredness, lack of energy, weakness, difficulty sleeping (possible severe depression)
- Pregnancy symptoms
- Allergic reaction (rare)
- Severe depression
- Pain, pus, or bleeding at insertion site

**PROVIDER TASKS**

Clients will be returned in two weeks to have the placement site examined. The implant(s) should be easily palpable just below the skin. Clients should also return as needed for problems and for their annual exam. Other referral indicators include:

- Any signs/symptoms of pregnancy
- Blood pressure 140/90 or greater, resting on three separate visits, or a diastolic measurement of 110 or more on a single visit
- Urinalysis positive for glucose or 2+ or greater for protein
- Side effects or complication of method
- Any severe lower abdominal pain
- Any of the warning signs

Other provider tasks include:

- Provide individualized counseling in a setting that assures confidentiality.
- Include her partner if she so desire.
- Assist the woman in making a contraceptive decision that is uniquely tailored to her needs based on personal preference, lifestyle, convenience, and future pregnancy plans.
- Assure that the client understands and accepts that her MENSTRUAL BLEEDING WILL BE DISRUPTED.
- Provide information on efficacy, mechanism of action, risks, benefits, side effects, contraindications, and cautions of each method at the women's level of understanding. This can be provided in writing.
- Encourage all women who smoke tobacco to stop, regardless of contraceptive method. However, for women who are light smokers (< 15 cigarettes daily and are age 34 or younger), the advantages of effective hormonal contraception generally out weigh the disadvantages.
- Share information on the health risks associated with unintended pregnancy (written material can be used).
- Encourage a dialogue.
- Address any specific fears or misconceptions.
- Respect the client's decision.
- The package insert for Implanon® requires a physical exam including gynecologic exam prior to insertion of the implant.
- Provide the client with the patient labeling information included with the implant.
- Always obtain informed consent prior to insertion.
- Instruct the patient in how to obtain emergency contraception should she have unprotected intercourse prior to insertion of the implant.

**NURSING MANAGEMENT**

See *Public Health Nursing Statewide Protocol*, "Progestin-only Implant(s), Continuing Contraceptor," for nursing management. Also see the Teaching Tool on the reverse side of the Consent for Progestin-only Implant(s) and the client instruction sheet found in the appendix of this manual (not yet available).

## CLIENT INSTRUCTIONS

See Teaching Tool on the back of the progestin-only implant consent form (not yet available).
See Client Instruction Sheet for Progestin-only Implants (not yet available).

## APPENDIX

1. Consent form for progestin-only Implant – English PH 3949
2. Consent form for progestin-only Implant – Spanish PH 3949S
3. Teaching Tool for progestin-only Implant (on back of English and Spanish Consent Forms)
4. Client Instruction Sheet for Progestin-only Implant(s) (English and Spanish)

## REFERENCES


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6. Centers for Disease Control and Prevention. *U.S.*, *Medical Eligibility Criteria for Contraceptive Use*, Early Release 2010; Volume 59, May 28, 2010

# PROGESTIN-ONLY INJECTABLE CONTRACEPTION

## POLICY

The Tennessee Department of Health Family Planning Program policy states that progestin-only injectable contraception must be available for clients after they have been fully counseled and assessed as medically appropriate. Informed consent is required of any woman who receives progestin-only injectable contraception. See the Appendix for a copy of the consent form and teaching tool in English and Spanish.

## DEFINITION

Progestin-only injectable contraceptives are injectable methods of contraception that contain a chemical similar to (but not the same as) the naturally-occurring hormone progesterone. There are preparations for intramuscular (IM) administration and subcutaneous (subq) administration.

## MECHANISM OF ACTION

When administered every 3 months, progestin-only injectable contraception acts by inhibiting the secretion of gonadotropins, thus preventing follicular maturation and inhibiting ovulation. It also thickens and decreases the amount of cervical mucus. Finally, progestin-only injectable contraception creates a thin, atrophic endometrial lining.

The package insert for progestin-only injectables recommends that the maximum interval for repeating IM progestin-only injectable contraception is 13 weeks or 91 days. If the time interval is greater than 13 weeks or 91 days, assessments must be made to assure that the client is not pregnant. The goal should be to send no woman away without her reinjection if it is at all possible. Clients who receive a late reinjection will need to use a back-up method of contraception for 7 days. Always include the client in the decision making process for late reinjection. It is strongly recommended that the algorithm for late re-injection found in “Managing Contraception for Your Pocket” be used in these instances.

The shortest interval for repeat IM injections is a regional decision, but could be as early as 10-11 weeks, for example, to accommodate travel plans. However, some third party health insurance payors have restrictions regarding early re-injections. Therefore, your clients who have third party payors, need to find out what their health insurance plan requires by asking at their pharmacy. All of this should be kept in mind when scheduling return appointments.

According to the package insert, the maximum interval for repeating subcutaneous progestin-only injectable contraception is 14 weeks or 98 days. If the time interval is greater than 14 weeks or 98 days, assessments must be made to assure that the client is not pregnant. The goal should be to send no woman away without her reinjection if it is at all possible. Clients who receive a late reinjection will need to use a back-up method of contraception for 7 days. Always include the client in the decision making process for late reinjection. It is strongly recommended that the algorithm for late re-injection found in “Managing Contraception for Your Pocket” be used in these instances.

The package insert for subq injections recommends that the minimum re-injection be 12 weeks. However, the shortest interval for repeat injections is a regional decision, and could be as early as 10-11 weeks, for example, to accommodate travel plans. However, some third party health insurance payors have restrictions regarding early re-injections. Therefore, your clients who have third party payors, need to find out what their health insurance plan requires by asking at their pharmacy. All of this should be kept in mind when scheduling return appointments.

## EFFICACY

Progestin-only injectable contraception is an aqueous suspension of microcrystals. After IM injection or subcutaneous injection, an initial peak blood level of the drug can be measured. The low solubility of the microcrystals at the injection site results in prolonged circulating levels of the active progestin for 3-4 months following the injection.

Progestin-only injectable contraception is a highly effective contraceptive method. The probability of pregnancy among perfect users is 0.3% and among typical users is 3%.

Assure that the client is not pregnant at the time of the first injection. The package insert recommends first injections be given:

- During the first five days of a normal menstrual period.
- Within the first five days postpartum, if the client is not breastfeeding.
- As soon as the milk supply is well-established if the client is exclusively breastfeeding but never before the 6th postpartum week.

Contraceptive Technology Update November 2007 and September 2008 describes the "DMPA now" strategy. The DMPA now strategy provides the initial injection the day of the office visit as long as the urine pregnancy test is negative that day. For DMPA Now, follow the same algorithm found in Managing Contraception for Your Pocket used for late reinjection. Always include the client in this decision-making process. After a consult with and approval from the MD or APN, PHNs could provide "DMPA now". Document the consult and order in the chart. Obtain the appropriate co-signature.

If the client does not return for reinjection for several months, but still remains within the one year limitation of the prescription, then the injections can be resumed when pregnancy has been ruled out.

**INDICATIONS**

Progestin-only injectable contraception is indicated for the prevention of pregnancy in:

- Breastfeeding women: Begin progestin-only injectable contraception as soon as the milk supply is well-established. The package insert recommends not before 6 weeks postpartum. Beginning progestin-only injections less than 1 month postpartum is categorized as a (2)-benefits outweigh risks- in the CDC MEC Guidelines and a category (1) for 1 month to 6 months postpartum. Progestin-only injectable contraception does not have adverse effects on lactation. Although progestins can be transferred through breast milk, the dose consumed by the infant is small.
- Older women: Progestin-only injectable contraception is desirable because of safety and low failure rates. There is decreased risk of thrombolic complications as compared with estrogen/progestin combinations methods. Nevertheless, Progestin-only injectable contraception is a category 3 method as regards hypertension $\geq$ 160/100, vascular disease, stroke, and current or history of ischemic heart disease.
- Young women: Progestin-only injectable contraception has a low failure rate.

**BENEFITS**

- Progestin-only contraceptives may be appropriate where estrogen is contraindicated.
- Progestin-only methods may be considered for women who have hypertension, coronary artery disease, systemic lupus erythematosus, risk factors for thromboembolism, and age greater than 35 who smoke. According to the American College of Obstetricians and Gynecologists [ACOG] Technical Bulletin, June 2006, such use is indicated regardless of package labeling contraindications. Amenorrhea will develop over time which can mean decreased anemia.
- Less cramping and bleeding over time. (Less bleeding can lead to decreased anemia.)
- Decreased risk of endometrial cancer and ectopic pregnancy.
- Highly effective method that provides 13 weeks of protection per injection.
- This method is reversible, though there can be a delay in the return to fertility.

Amenorrhea: During the first year of progestin-only injectable contraception use, 30-50 percent of women are amenorrheic. By the end of the second year, 70 percent are amenorrheic, and by the end of the fifth year, 80 percent.
Culturally acceptable: In some cultures, receiving medications by injection is considered desirable. In some cultures, a woman may wish to use a contraceptive without the knowledge of her partner or family.
No drug interactions: There is no interaction between progestin-only injectable contraception and antibiotics or enzyme-inducing drugs. The only drug that decreases the effectiveness of progestin-only injectable contraception is aminoglutethimide (Cytadren) which is usually used to suppress adrenal function in selected cases of Cushing's syndrome. Progestin-only injectable contraception is given parenterally; therefore, effectiveness is not dependent on normal gastrointestinal function.

Fewer seizures: Progestin-only injectable contraception has been found to decrease the frequency of seizures. Improvement in seizure control is probably due to the sedative properties of progestins.
Improved sickle cell disease: Clients with a history of sickle cell disease may actually improve while taking Progestin-only injectable contraception.

**DISADVANTAGES**

- Some clients object strongly to any type of injection.
- Does not prevent STDs including HIV.
- Can be a delay in the return to fertility of up to 18 months.
- Irregular bleeding during the first several months.
- Requires multiple clinic visits per year
- **Decrease in bone density (See bone density comments below).**

**SIDE EFFECTS**

- Menstrual cycle disturbance: Some women using progestin-only injectable contraception experience an increased number of days of heavy bleeding. For many women, amenorrhea becomes more common over time. During the first year of use, progestin-only injectable contraception often increases the number of days the user has very light spotting or breakthrough bleeding. The longer a woman is on progestin-only injectable contraception, the greater the likelihood of amenorrhea.
- Weight gain: Progestin-only injectable contraception is associated with weight gain on average 3.5 to 5.4 lbs in the first year. By the end of the second year the total weight gain averages7 to 8 lbs; by the end of the fifth year, the total weight gain was 11.2 lbs or 5 lbs more than users of non-hormonal methods of contraception.
- Breast tenderness: Breast tenderness has been noted in some women using progestin-only injectable contraception. Occasionally breast tenderness is very painful. Always rule out pregnancy as the cause.
- Bone density decrease: Clients using progestin-only injectable contraception experience the effects of low estrogen which includes a decrease in bone density. This decrease is similar to decreases seen in women during lactation. Studies have demonstrated that bone mineral density is regained when DMPA is discontinued. Women age 21 and older regain bone density by 30 months post discontinuation of DMPA. Adolescent women have rapid regain of their bone density after discontinuation of DMPA. Menopausal women who used DMPA during the reproductive years have no lower bone density than menopausal women who never used DMPA. In all three age groups, it is not known whether a history of DMPA use will equal an increase in fracture risk. However Committee Opinion released by ACOG in 2008 do not recommend limitations to DMPA use based on current bone density research. All women should be educated about the importance of adequate calcium, vitamin D, and magnesium and the benefits of regular weight-bearing exercise in order to enhance bone health. Clients need to know that smoking and regular heavy alcohol consumption can also negatively affect bone density. Clients, who are concerned about decreases in bone density, should choose another method of contraception or use progestin-only injectable contraception no longer than 2 years. (See Provider Tasks for further instruction.)
- Delay in the return to fertility: While it is possible to become pregnant immediately after discontinuing progestin-only injectable contraception, it is more likely that the client will experience a delay in her return to fertility of up to 18 months.
- No immediate discontinuation: Weight gain, depression, breast tenderness, and menstrual irregularities may continue until the progestin-only injectable contraception is cleared from a woman's body, about 6-8 months after her last injection.
- Lipid changes: High-density lipoprotein cholesterol levels decrease in women using progestin-only injectable contraception.
- Headaches, depressed mood and pain at the injection site

Please see the table for **US Medical Eligibility Criteria for Contraceptive Use** provided in that section of this guidance and in the 2010-2012 edition of Managing Contraception for Your Pocket. Categories 3 (risks usually outweigh benefits) and category 4 (risks outweigh benefits) will be considered contraindications. However if there are no better options and physician consult and agreement has been obtained and the client fully understands the risks versus benefits, then category 3 conditions for the method could be used.

**MAJOR PROBLEMS:** These are **NOT NORMAL** and should be reported to the clinic or hospital at once.

- Heavy vaginal bleeding
- Severe or repeated painful headaches
- Blurred, double, or loss of vision
- Severe chest, stomach, or leg pain
- Pregnancy symptoms
- Allergic reaction (rare)
- Severe depression
- Pain, pus, or bleeding at injection site

**PROVIDER TASKS**

- Provide individualized counseling in a setting that assures confidentiality.
- Include her partner if she so desire.
- Be especially attuned to risk factors for osteoporosis including metabolic bone disease, chronic alcohol and/or tobacco use, anorexia nervosa, chronic use of anticonvulsants or corticosteroids, or strong family history of osteoporosis.
- Assist the woman in making a contraceptive decision that is uniquely tailored to her needs based on personal preference, lifestyle, convenience, and future pregnancy plans.
- Provide information on efficacy, mechanism of action, risks, benefits, side effects, contraindications, and cautions of each method at the women's level of understanding. This can be provided in writing.
- Provide information regarding the decrease in bone density. Bone density decreases during progestin-only injectable contraception use are similar to those seen during lactation. Calcium, vitamin D, and magnesium supplementation is recommended as is regular weight bearing exercise, but this does not guarantee protection from decreased bone density during progestin-only injectable contraception use. Manufacturers of DMPA suggest that, unless there is no better contraceptive choice for the client, use be limited to two years.
- Smoking and heavy alcohol consumption also negatively impact bone density.
- Encourage all women who smoke tobacco to stop, regardless of contraceptive method. However, for women who are light smokers (< 15 cigarettes daily and are age 34 or younger), the advantages of effective hormonal contraception generally out weigh the disadvantages.
- Share information on the health risks associated with unintended pregnancy (written material can be used).
- Instruct the patient in how to obtain emergency contraception should be late for re-injection and have unprotected intercourse
- Encourage a dialogue.
- Address any specific fears or misconceptions.
- Respect the client's decision.

The provider may elect to defer the physical exam for as many as three to six months at the client's request, or for client or clinic convenience. The reason for the deferral must be documented in the chart. A thorough medical history would be collected and only clients who are without contraindications or cautions would begin progestin-only injectable contraception without an exam.

**NURSING MANAGEMENT**

See *Public Health Nursing Statewide Protocol*, "Progestin-only injectable contraception, Continuing Contraceptor," for nursing management. Also see the Teaching Tool on the reverse side of the Consent for Progestin-only injectable contraception form for client instruction.

**CLIENT INSTRUCTIONS**

See Teaching Tool on the back of the progestin-only injectable contraception consent form.

**APPENDIX**

1. Consent form for progestin-only injectable contraception – English PH 3372
2. Consent form for progestin-only injectable contraception – Spanish PH 3398
3. Teaching Tool for progestin-only injectable contraception (on back of English and Spanish Consent Forms)

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# PROGESTIN-ONLY ORAL CONTRACEPTIVE PILLS

## POLICY

The Tennessee Department of Health Family Planning Program policy states that oral contraceptives (OCs) must be available for reproductive age women who are at risk for unintended pregnancy. OCs are available to clients after they have been fully counseled on usage and assessed as medically appropriate. These guidelines address progestin-only pills (POPs). Consent forms are provided to document informed consent and client counseling.

## DEFINITION

The progestin-only pill (POPs) is an oral contraceptive pill that contains only progestin. It is taken daily. There are no hormone-free days.

## MECHANISM OF ACTION

POPs may prevent pregnancy via several mechanisms: inhibition of ovulation, thickening and decreasing the amount of cervical mucus (making it more difficult for sperm to penetrate), creation of a thin, atrophic endometrium, and premature luteolysis of the corpus luteum.

## EFFICACY

The effectiveness of progestin-only pills (POPs) is highest if ovulation is consistently inhibited. Effectiveness is greatest when the “normal” cyclic bleeding pattern is most disturbed. If ovulation is not suppressed, menstrual bleeding remains cyclical.

POPs are generally less effective than combined oral contraceptives (COCs). In order to work properly, progestin-only pills require obsessive regularity in pill-taking. If taken perfectly, only 0.3% of women using this method become pregnant. With typical use however, 8% of women using this method become pregnant. POPs do not alter the quantity of breast milk, so they represent an effective form of contraception for lactating women.

## INDICATIONS

- Breastfeeding women (after 6 weeks postpartum)
- Healthy women who are nonsmokers, who have no cardiovascular disease, who experience no side effects, and who want to use pills may continue POPs until they are 50
- Women who cannot take estrogen
- Women of childbearing age seeking a reversible method of contraception

## BENEFITS

- No estrogen
- Reversible
- Used during lactation after milk supply established
- Possible amenorrhea
- May decrease risk of endometrial cancer
- Lighter periods with less cramping

## DISADVANTAGES

- Progestin-only pills require obsessive regularity in pill-taking in order to be effective.
- Irregular menses/break through bleeding and spotting

## SIDE EFFECTS

- Frequent and irregular menstrual bleeding
- Headache

- Breast tenderness
- Nausea

Please see the table for **US Medical Eligibility Criteria for Contraceptive Use** provided in that section of this guidance and in the 2010-2012 edition of Managing Contraception for Your Pocket. Categories 3 (risks usually outweigh benefits) and category 4 (risks outweigh benefits) will be considered contraindications. However if there are no better options and physician consult and agreement has been obtained and the client fully understands the risks versus benefits, then category 3 conditions for the method could be used.

**WARNING SIGNS**

- Severe low abdominal pain
- Severe headache
- Numbness in arm or leg
- Severe chest pain
- Signs of pregnancy

**PROVIDER TASKS**

- Provide individualized counseling in a setting that assures confidentiality.
- Include her partner if she so desire.
- Assist the woman in making a contraceptive decision that is uniquely tailored to her needs based on personal preference, lifestyle, convenience, and future pregnancy plans.
- Provide information on efficacy, mechanism of action, risks, benefits, side effects, contraindications, and cautions of each method at the women's level of understanding. This can be provided in writing.
- **Encourage all women who smoke tobacco to stop, regardless of contraceptive method.** However, for women who are light smokers (< 15 cigarettes daily and are age 34 or younger), the advantages of effective combined hormonal contraception generally out weigh the disadvantages.
- Share information on the health risks associated with unintended pregnancy (written material can be used).
- Encourage a dialogue.
- Address any specific fears or misconceptions.
- Respect the client's decision.

The provider may elect to defer the physical exam for as many as three to six months at the client's request, or for client or clinic convenience. The reason for the deferral must be documented in the chart. A thorough medical history would be collected and only clients who are without contraindications or cautions would begin the progestin-only pills without an exam.

Instruct the patient in how to obtain emergency contraception should she have unprotected intercourse.

Visit Schedule: All clients placed on progestin–only oral contraceptives for the first time should receive a 3 or 4 month supply of POPs and return three months after initiating their POPs. At this visit clients may be given a 9 or 10 month supply of POPs to carry them to their annual exam (thirteen cycles altogether) based on history, physical exam, and compliance history. Providers may use their judgment about "new" clients who are new to the health department, but are already taking POPs and experiencing no problems. These clients can be given a twelve-month supply of POPs (thirteen cycles) at one visit. For clients who have medical problems that require periodic monitoring, the schedule of visits should be individualized. For noncompliant or potentially noncompliant POP users, the schedule of visits should be individualized.

**NURSING MANAGEMENT**

See *Public Health Nursing Statewide Protocol*, "Progestin-Only Pills" for nursing management.

**CLIENT INSTRUCTIONS**

See Appendix for Teaching Tool – Progestin-Only Pills found on the back of the consent form, and Progestin-Only Pills, Client Instruction Sheet.

## APPENDIX

1. Consent for Progestin-Only Pills PH 3707
2. Teaching Tool – Progestin-Only Pills (This is found on the reverse side of the consent form, and a tear-off copy is given to the client.)
3. Consent for Progestin-Only Pills (with Teaching Tool on reverse side of the consent form, in Spanish) PH 3707S
4. Progestin-Only Pills, Client Instructions

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# THE VAGINAL CONTRACEPTIVE RING GUIDELINES

## POLICY

The Tennessee Department of Health Family Planning Program policy states that the vaginal contraceptive ring may be available for reproductive age women who are at risk for unintended pregnancy. Availability of the vaginal contraceptive ring is dependent upon funding Use this method when there is no other acceptable option. Women particularly well suited for this method are women with a history of noncompliance with the proper use of oral contraceptives and an aversion or contraindication to injectable contraception. The vaginal contraceptive ring is available to clients after they have been fully counseled on usage and are deemed medically appropriate. A consent form is available to document informed consent and client counseling.

## DEFINITION

In October 2001, the U.S. Food and Drug Administration approved the first vaginal contraceptive ring to be sold in the USA. Today it is marketed by Merck Pharmaceuticals under the trade name of NuvaRing®. NuvaRing® is approved for the prevention of unintended pregnancy. NuvaRing® is a type of hormonal birth control similar to oral contraceptives in that it contains an estrogen and a progestin, but it is administered via a vaginal ring. This vaginal contraceptive ring is worn for 3 weeks followed by a ring-free week during which time a withdrawal bleed occurs.

The ring is placed in the vagina during the first five days of the menstrual cycle whether or not the client is still menstruating. During this first cycle, a back-up method must be used for the first seven days. If the client is switching to the ring from oral contraceptives, she can begin the ring anytime during the seven hormone-free days or on the day she would have begun a new pack of pills. In this case, no back-up contraception is needed. If the client is switching from an IUD, she can insert the ring on the day the IUD is removed. She must use a back-up method of contraception for seven days. Women should insert the vaginal contraceptive ring as follows if they have been using a progestin-only method:

- Any day of the month when switching from a progestin-only pill; do not skip any days between the last pill and the first day of the ring. Use a back-up method for seven days.
- On the same day as a contraceptive implant is removed. Use a back-up method for seven days.
- On the same day as the removal of a progestin–containing IUD. Use a back-up method for seven days.
- On the day when the next contraceptive injection would be due. Use a back-up method for seven days.

After childbirth or second trimester abortion, the ring can be initiated four weeks postpartum. The client will need a back-up method for the first seven days of ring use. The ring may be initiated within the first five days after a miscarriage or first trimester abortion. No back-up will be needed during the first seven days of ring use.

For storage in the client's home, the vaginal contraceptive ring can be stored at room temperature (that is, from 59-86 degrees Fahrenheit). Avoid storing in direct sunlight. The ring comes in a foil pouch. After opening, the pouch should be saved. When the ring is removed from the vagina three weeks later, place the used ring in this pouch for disposal.

To insert the vaginal ring, hold it between the thumb and index finger and press the opposite sides together. Gently push the folded ring into the vagina. The exact position of the ring is not important for it to work. Some women may be aware of the ring in the vagina but most are not. There can be discomfort if the ring is not inserted far enough to the back. Clients need to be reassured that the ring cannot be pushed too far to the back and be lost. The male partner may or may not feel the presence of the ring.

Remove the ring three weeks after insertion on the same day of the week as it was inserted, at about the same time. For example, if the ring is inserted on a Sunday at about 10:00 PM, the ring should be removed on the Sunday three weeks later at about 10:00 PM. Remove the ring by hooking the index finger under the forward rim or by holding the rim between the index and middle finger and pulling it out. Place the used ring in the saved foil pouch and dispose of it in a waste receptacle out of reach of children and pets. Do not flush down the toilet.

The vaginal contraceptive ring may not be appropriate for women with conditions that make the vagina more susceptible to vaginal irritation or ulceration. Conditions such as vaginal stenosis, cervical prolapse, rectoceles, and cystoceles can also preclude the use of the ring. The ring can be accidentally expelled during sexual intercourse or

when straining with a bowel movement especially with constipation. If the ring has been removed or expelled during the three-week use period, it should be rinsed with cool to lukewarm (not hot) water and re-inserted as soon as possible, at the latest within three hours of removal or expulsion. It the ring is lost, a new ring should be inserted and the regimen continued without alteration. If the ring has been out of the vagina for more than three hours, contraceptive effectiveness may be reduced and an additional method of contraception must be used until the ring has been used continuously for seven days. A diaphragm is NOT recommended as a back-up method for the vaginal contraceptive ring because the ring may interfere with the proper placement of the diaphragm.

If the vaginal contraceptive ring has been left in the vagina for an extra 1-7 days (that is, up to an extra week), remove it and insert a new ring after taking the one week break for menstruation. If the ring is left in place for more than 7 extra days (that is, for more than an extra week), the client may not be protected from pregnancy. A pregnancy test should be done. If the test is negative, insert a new ring and use a back-up method until the ring has been in place for seven days in a row. No one week break for menstruation would be taken.

All clients need information regarding the use of emergency contraception (ECPs) for unprotected intercourse. Whenever possible, provide ECPs in advance of need.

Always check for pregnancy if:

- There is a missed period and the ring was out of the vagina for more than three hours during the three weeks of ring use.
- There is a missed period and the client waited longer than one week to insert a new ring.
- Despite following all instructions, the client has missed two periods in a row.
- The ring was left in place longer than four weeks.

**MECHANISM OF ACTION**

NuvaRing® is a non-biodegradable, flexible, transparent, opaque combination hormonal contraceptive vaginal ring. It contains two active components, a progestin, etonogestrel and an estrogen, ethinyl estradiol. When placed in the vagina, NuvaRing® releases on average 0.120 mg/day of etonogestrel and 15 mcg/day of ethinyl estradiol over the three week period. The primary effect of the product is inhibition of ovulation. Other alterations include changes in the cervical mucus and the endometrium.

**EFFICACY**

The failure rate for the vaginal contraceptive ring with perfect use is 0.3% and with typical use is 8%. Like oral contraceptives, it is highly effective when used according to package instructions. In two large clinical trials of 13 cycles of use, pregnancy rates were between one and two per 100 women-years of use. Certain medications may make the vaginal contraceptive ring less effective. These include rifampin, barbiturates, phenylbutazone, phenytoin, carbamazepine, griseofulvin, felbamate, oxcarbazepine, topiramate; St. John's Wort may also reduce the effectiveness of contraceptive steroids. Also, decreased plasma concentrations of acetaminophen and increased clearance of temazepam, salicylic acid, morphine, and clofibirc acid have been noted when administered with oral contraceptives. It is possible that the vaginal contraceptive ring may also have this effect. The package insert for all combined hormonal methods of contraception lists broad spectrum antibiotics such as ampicillin or tetracycline as decreasing the effectiveness of combined hormonal contraceptives. Other experts report that broad spectrum antibiotics do not decrease effectiveness. Finally, contraceptive effectiveness may be reduced when hormonal contraceptives are co-administered with anti-HIV protease inhibitors. Health care providers should refer to the label of the individual anti-HIV protease inhibitor for further drug interaction information.

**INDICATIONS**

The vaginal contraceptive ring is indicated for women of reproductive age who are seeking to avoid an unintended pregnancy.

**BENEFITS**

The benefits of the vaginal contraceptive ring are the same as those found with other combined hormonal contraceptives with the added advantage of not requiring daily attention.

- Regular periods with less cramping/bleeding
- Reduced risk of ovarian and uterine cancer
- Fewer benign breast lumps and ovarian cysts
- Safe and effective method of birth control without the need for daily attention
- Less acne
- Only 15 mcg of ethinyl estradiol per day
- Placed in the vagina once a month

**DISADVANTAGES**

- Will not protect against HIV/AIDS or other sexually transmitted diseases.
- The ring must be inserted and changed on the appropriate day or effectiveness can be decreased.

**SIDE EFFECTS**

- Spotting between periods
- Mood changes
- Breast tenderness
- Changes in contact lens prescription
- Foreign body sensations in vagina and/or ring expulsion
- Headaches
- Heavier vaginal discharge, vaginitis, vaginal discomfort
- Slight weight gain
- Nausea
- Partner-related complaints due to foreign body sensation
- Any of the side effects listed under combined oral contraceptives (COCs) could potentially be experienced with this method

Please see the table for **US Medical Eligibility Criteria for Contraceptive Use** provided in that section of this guidance and in the 2010-2012 edition of Managing Contraception for Your Pocket. Categories 3 (risks usually outweigh benefits) and category 4 (risks outweigh benefits) will be considered contraindications. However if there are no better options and physician consult and agreement has been obtained and the client fully understands the risks versus benefits, then category 3 conditions for the method could be used.

**WARNING SIGNS**

These are NOT NORMAL and should be reported to the clinic or hospital at once:

- Severe chest pain and shortness of breath (possible clot in lung or heart attack)
- Severe abdominal pain (possible rupture of a liver tumor, gallbladder disease, or ectopic pregnancy)
- Speech or vision changes (possible stroke)
- Skin turns yellow (possible liver problems)
- Muscle weakness or numbness (possible stroke)
- Heavy bleeding between periods (possible infection)
- Sudden severe pain or soreness in leg (possible clot in leg)
- Severe depression
- Severe headaches, blackouts, dizziness (possible stroke)
- Breast lump (possible breast cancer)
- Signs of pregnancy

**PROVIDER TASKS**

- Provide individualized counseling in a setting that assures confidentiality.
- Include her partner if she so desire.

- Assist the woman in making a contraceptive decision that is uniquely tailored to her needs based on personal preference, lifestyle, convenience, and future pregnancy plans.
- Provide information on efficacy, mechanism of action, risks, benefits, side effects, contraindications, and cautions of each method at the women's level of understanding. This can be provided in writing.
- **Encourage all women who smoke tobacco to stop, regardless of contraceptive method**. However, for women who are light smokers (< 15 cigarettes daily and are age 34 or younger), the advantages of effective combined hormonal contraception generally out weigh the disadvantages.
- Share information on the health risks associated with unintended pregnancy (written material can be used).
- Encourage a dialogue.
- Address any specific fears or misconceptions.
- Respect the client's decision.

The provider may elect to defer the physical exam for as many as three to six months at the client's request, or for client or clinic convenience. The reason for the deferral must be documented in the chart. A thorough medical history would be collected and only clients who are without contraindications or cautions would begin the vaginal contraceptive ring without an exam.

**CLIENT INSTRUCTIONS**

See the Appendix for Teaching Tool for the Vaginal Contraception Ring found on the back of the consent form and the Client Instruction Sheet for the Vaginal Contraceptive Ring.

**NURSING MANAGEMENT**

See the *Public Health Nurse Statewide Protocol* for the Vaginal Contraceptive Ring.

**APPENDIX**

1. Consent Form for Vaginal Contraceptive Ring PH 3780 English
2. Consent Form for the Vaginal Contraceptive Ring PH3780S Spanish
3. Teaching Tool found on the back of the consent form
4. Client Instruction Sheet for the Vaginal Contraceptive Ring

**REFERENCES**


1. American Health Consultants, *Contraceptive Technology Update*, Organon Launches NuvaRing, First Combined Contraceptive Vaginal Ring, Volume 22, Number 12, December 2001, p. 137-139.
2. American Health Consultants, *Contraceptive Technology Update*, New Contraceptives: Get Ready to Add Patch, Vaginal Ring, Volume 23, Number 5, May 2002, p. 54-57.
3. American Health Consultants, *Contraceptive Technology Update*, Volume 23, Number 7, July 2002.
4. American Health Consultants, *Contraceptive Technology Reports*, A Supplement to Contraceptive Technology Update, the Vaginal Contraceptive Ring - Efficacy, Caution, and Instructions, BB#507, February 2002.
5. Hatcher, R. A., Nelson, A. L., Zieman, M., et. al., *A Pocket Guide to Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2010-2012.
6. The Contraceptive Report, Volume 12, Numbers 3 and 5, June and October 2001.
7. Centers for Disease Control and Prevention. *U.S.*, *Medical Eligibility Criteria for Contraceptive Use*, Early Release 2010; Volume 59, May 28, 2010.
8. NuvaRing Package Insert, Organon, Inc., October 2001.

# STERILIZATION GUIDELINES

## General Information

Sterilization is the surgical interruption or closure of pathways for sperm or ova. This prevents fertilization. The method should be considered a permanent method of contraception. Although some surgical procedures to reverse both vasectomies and tubal ligations have been successful, none are guaranteed. Sterilization is the most popular method of contraception in the United States and worldwide. Sterilization provides highly effective, permanent means of birth control for both sexes. Female sterilization (tubal ligation or tubal closure) and male sterilization (vasectomy) are available through Tennessee's Title X Family Planning Clinics by referral.

### STERILIZATION POLICY

Family Planning Program Guidelines section 8.4, "Fertility Regulation", state:

"The counseling and consent process MUST assure that the client's decision to undergo sterilization is completely voluntary and made with full knowledge of the permanence, risks, and benefits associated with female and male sterilization procedures. Federal sterilization regulations, which address informed consent requirements, MUST be complied with when a sterilization procedure is performed or arranged for by the project (see Attachment C).

Tennessee's Title X Family Planning Program sterilization guidelines are governed by the federal Title X Sterilization Regulations, which specifically limit those persons on whom a sterilization can be performed and outline the procedures which must be followed. The following is a summary of the regulations.

### FEDERAL STERILIZATION REQUIREMENTS – Summary of Main Provisions

1. Minimum Age: All persons must be at least 21 years of age at the time the consent is obtained and capable of consenting to the sterilization himself or herself.

2. Mental Competence/ Institutionalized Individuals: Sterilizations cannot be performed (or arranged for) on any mentally incompetent individual or any institutionalized individual.

3. Waiting Period: The consent form must be signed at least 30 days prior to the procedure but no more than 180 days. The day on which the consent is signed and the day of the procedure itself cannot be counted as part of the required 30 days. This is to allow the client an opportunity to reconsider his/her decision.

4. Informed Consent: The individual has voluntarily given his or her informed consent in accordance with the outlined federal procedures. Informed consent may not be obtained while the individual is in labor or childbirth or under the influence of alcohol or other substances that affect the individual's state of awareness.

### OTHER PROVISIONS

1. The client's decision at any time not to be sterilized will not result in the withdrawal or withholding of any benefits provided by federal or state programs or projects.

2. Under <u>no circumstances</u> can a hysterectomy be performed using Title X dollars.

### REQUIRED SELECTION CRITERIA

Due to limited funding available for sterilization procedures, each region and agency should have a system in place for the selection of clients from among those requesting sterilization. **Title X program services, including sterilizations, are available for both U.S. citizens and non-U.S. citizens.**

Family planning clients or their partners on the clinic waiting list and family planning clients requesting sterilization but not yet on a list **have priority** for male or female sterilization.

**OTHER SELECTION CRITERIA MAY INCLUDE:**

1. Sites providing no-scalpel vasectomy may accept any clients requesting the service. Charges for services are based on the sliding fee scale. These sites may also elect to bill insurance or TennCare.
2. Poverty level clients.
3. No clients with TennCare or insurance should generally be considered for use of the sterilization dollars. An appropriate referral for these clients should be made. However, exceptions could include the client with a high co-pay or deductible; providers should evaluate each client individually.
4. Clients with method(s) failure.
5. Clients with medical contraindications to the use of temporary forms of contraception.
6. Clients over 35 years of age
7. Clients with 4 or more pregnancies.
8. Clients with other high risk factors.
9. Priority should be given to those who will have an outpatient procedure so that more clients can be served.

**POSSIBLE CONTRAINDICATIONS FOR VOLUNTARY STERILIZATION**

1. The client has physical, mental, or emotional conditions that could be improved by other treatment.
2. The client or couple feels they are not yet ready to assume the responsibility of parenthood.
3. The client counts on reversing the operation in case of change of circumstances such as remarriage or death of children.

**STERILIZATION CONSENT FORM**

Federal regulations require an informed consent with a properly completed written consent form for each client requesting a sterilization procedure — both male and female. This section clearly outlines the procedures to be taken in obtaining informed consent.

Consent forms are available in English and Spanish. The OMB Clearance Number must be on the form if it is to be used on any family planning client. All forms for procedures paid by or arranged by the Family Planning Program, whether locally or by the central office, **must have the mandatory OMB Clearance Number on the form** as follows:

1. Form Approved
2. OMB No. 0937-0166
3. Expiration Date

Each clinic must ensure that the client is provided the necessary information to arrive at an informed decision. Such information should include but not be limited to:

1. Advantages or benefits of sterilization.
2. An explanation of the procedures to be followed.
3. Information concerning risks involved (complications and failures) and discomforts.
4. Review of the alternative, temporary contraceptive methods available.
5. The procedure is considered irreversible.
6. Information concerning the relative merits of male versus female sterilization in any specific situation.
7. Information and instructions concerning the need for follow-up, particularly for males.
8. Information relating to the fact that sterilization does not interfere with sexual function or pleasure.
9. Client may change his/her mind about having the surgery with no penalty or loss of available services.
10. The surgery will not be performed for at least 30 days after signing the sterilization consent form. After 180 days the consent form is out of date, and the program will not be responsible for surgical costs.
11. Give the client an opportunity to ask any questions.

**GENERAL INSTRUCTIONS**

1. No consent form is valid unless all blanks are completed; the only exceptions being the interpreter's statement and optional designation of race and ethnicity. No bills will be accepted if there are blanks other than these exceptions on the form.

2. No consent form is valid if there has not been at least 30 days between the date the consent was signed by the client and the date of the procedure. The only exceptions are the cases when the client had emergency abdominal surgery or premature delivery; the circumstances must be described on the consent form.

3. No consent form is valid if more than 180 days has lapsed from the date the consent was taken.

4. It is critical that the referring physician's name or group or hospital or facility be listed on the consent form at the time the consent is taken (located on the left side, mid-page). Failure to fill in the blanks before the client signs the form may result in the sterilization being refused for payment.

5. Do not use abbreviations on the consent form - i.e., BTL or NSV.

6. The consent form is a three-part labeled form; however, at least four copies are needed. One extra copy will have to be made. Completed copies of the form should be distributed as follows:

   a. Copy to the client.
   b. Copy in the client's medical record in the office of the provider performing the procedure (physician or facility).
   c. Original copy in the client's medical record at the referring agency/health department. NOTE: The physician or facility performing the procedure may elect to keep the original copy; if so, place a copy in the client's medical record at the referring site.
   d. Copy to attach to the billing form (PH-1512, Authorization for Service).

7. Each regional/agency office should have on hand adequate quantities of client education/information sterilization booklets for men and for women. Both versions are available in English and in Spanish. An original of each booklet should be maintained so that copies can be made at those times when the booklets are not available from the federal government. Forms for Consent for Sterilization are available from the Office of Population Affairs Clearinghouse. Fax or email only: 866-592-3299 (fax) or clearinghouse@dhhsopa.net .

8. Handling payment of bills and required reporting of sterilizations to the federal government are the responsibility of the regional and agency family planning administrators.

## REFERENCES

1. U.S. Department of Health and Human Services, Office of Population Affairs, Office for Family Planning, Program Guidelines for Project Grants for Family Planning Services, Attachment C, January 2001.

# APPENDIX

## Family Planning Forms List

**Note:**

- All of the PH numbered forms are available from Central Stores.
- Pap smear requisition forms are ordered from the individual laboratory.
- Consent for Sterilization forms are available from the Office of Population Affairs Clearinghouse. Fax or email only: 866- 592-3299 (fax) or clearinghouse@dhhsopa.net.
- Other Clearinghouse Publications: 866-640-7827.
- Copies of the Method Consent forms in English and Spanish and Client Instruction Sheets follow this list of forms.

| FORMS # | NAME |
|---|---|
| | |
| PH – 1501 | Laboratory Findings, Tests, and Contraceptives/Drugs Dispensed |
| PH – 1522 | Family Planning Initial History |
| PH – 1522S | Planificacion Familiar Histroia Inicial |
| PH – 1523 | Family Planning Physical Examination |
| PH – 3133 | AIDS Risk Assessment |
| PH – 3522 | Por Favor Complete Este Cuestionario Antes De Su Visita |
| PH – 3370 | Consent for Combined Oral Contraceptives |
| PH - 3397 | Consentimiento Para Las Pildoras Anticonceptivas Orales (PAOs) |
| PH – 3372 | Consent For Progestin-only injectable contraception |
| PH – 3372S | Consentimiento Para Anticonceptivo Inyectable de Progestina Sola |
| PH – 3373 | Consent For Diaphragm |
| PH - 3401 | Consentimiento Para El Diafragma |
| PH – 3375 | Consent For Emergency Contraceptive Pills (ECPs) |
| PH – 3400 | Consentimiento de Emergencia Para Pastillas Anticonceptivas (ECPs) |
| PH - 3374 | Consent for Copper Intrauterine Device |
| PH - 3403 | Consentimiento Para El Dispositivo Intrauterino (DIU) Con Cobre |
| PH - 3795 | Consent for Levonorgestrel Releasing Intrauterine Device |
| PH – 3795S | Consentimiento Para El Dispositivo Intrauterino Que Emite |
| PH – 3371 | Consent for Family Planning Services For Non-prescriptive Methods |
| PH - 3399 | Consentimiento Para Servicios De Planicacion Familiar De Metodos Sin Receta |
| PH - 3761 | Consent for the Contraceptive Patch |
| PH – 3761S | Consentimiento Para El Parche Anticonceptivo |
| PH - 3707 | Consent for Progestin-Only Oral Contraceptive Pills (POPs) |
| PH – 3707S | Consentimiento Para Las Píldoras Anticonceptivas Orales Progestina-Solamente (PPSs) |
| PH -3780 | Consent for the Vaginal Contraceptive Ring |
| PH – 3780S | Consentimiento Para El Anillo Vaginal Anticonceptivo |
| PH - 3949 | Consent for Progestin-only Implant |
| PH - 3949S | Consentimiento Para Implantes De Solo-Progestina |

## Family Planning Brochures

All DH brochures can be ordered from Central Stores

| Brochure number | |
|---|---|
| DH 0115 | HPV Get the Facts |
| DH 0115S | Spanish version: HPV Get the Facts |
| DH 0118 | Family Planning is More Than You Think |
| DH 0118s | Spanish Version: Family Planning is More Than You Think |
| Approved to print English & Spanish* | TN Title X Family Planning Brochure: Welcome to Your County Health Department |

*Contact your local Title X family planning administrator for a pdf copy to print at your location. (Customize to include the name of your county, metro, or agency)

# CONSENT FORMS

Tennessee Department of Health
Family Planning Program
**CONSENT FOR COMBINED ORAL CONTRACEPTIVE PILLS (COCs)**

**IMPORTANT:** *Make sure that you understand all information before signing.*

All procedures necessary for me to receive family planning services have been explained to me I have been given information about all methods of birth control, including abstinence, and the risks and benefits of each. I understand that no method is 100% effective against pregnancy and that undesirable side effects may occur. I recognize that it is important to follow instructions given to me and to return for checkups on schedule.

I understand all the information provided. I consent to be a patient in the family planning program, to receive all that is required in a family planning examination, and any treatment that is deemed necessary. I have voluntarily chosen combined oral contraceptives (**COCs**) as my method of birth control. I have been given the chance to ask questions about **COCs** and about this consent form. I accept the risks of this method and understand there may be other risks that the clinic is not aware of. Instructions for the use of this birth control method have been given to me in writing and orally. I have been given a copy of this consent form to refer to as needed. I may call the clinic during office hours if I have questions.

I understand that **COCs** will not prevent me from getting a sexually transmitted disease (STD), including the AIDS virus. I have been advised to practice "safer sex" by also using condoms, especially if I have sex with more than one partner, or if I or my partner has possibly been exposed to an STD. Although the use of this second method does not insure that I or my partner will not get an STD, it may reduce the risk.

I was assured that all information that I give to anyone in this clinic is confidential and will not be given or sent to anyone, unless I give written permission, except as necessary to provide services at the clinic or as required by law. By my signature below, I indicate that I have read **both sides** of this form and that I understand its contents.

In case of an emergency or severe problem, I can call the clinic at _____ or the emergency room at_____.

| Date | Patient Signature | Witness Signature |
|---|---|---|
| | | |

Reviewed:

| Date | Patient Signature | Witness Signature |
|---|---|---|
| | | |
| | | |

# TEACHING TOOL-COMBINED ORAL CONTRACEPTIVE PILLS

**EXPLANATION: Combined Oral Contraceptives** (COCs) prevent the ovary from releasing an egg each month. Mucus in the cervix gets thicker and helps keep sperm out of the uterus. With perfect use only 0.1% of women on COCs will become pregnant. Typically, about 8% of women using COCs become pregnant. COCs can be started on the day you are in clinic as long as you are not pregnant (Quick Start Method), or the first day of your next period or on Sunday after your period begins. Take one pill daily at the same time each day. Your protection from pregnancy begins after you have taken pills for 7 days. Birth control pills do not protect you from sexually transmitted diseases (STDs). Use a condom to help prevent STDs. Some medications will make your pills work less effectively. These include anti-seizure drugs such as barbiturates, phenytoin sodium, carbamazepine, felbamate, oxcarbazepine, and topiramate; the TB medication rifampin; and the antifungal griseofulvin, phenylbutazone, a non-steroidal anti-inflammatory, and St. John's Wort, an herbal preparation, may also decrease the effectiveness of COCs as can some anti-HIV medications. Laboratory tests can be affected by COCs. Make sure you receive written instructions on what to do if you miss one or more pills. Emergency contraception is available if you have had unprotected sex. You can stop your COCs at any time. You should not take COCs if you are hypersensitive to any component of the product. No woman using a hormonal method of contraception should smoke cigarettes.

## BENEFITS

- Regular periods with less cramping/bleeding
- Reduced risk of ovarian and uterine cancer
- Fewer benign breast lumps and ovarian cysts
- Safe and effective method of birth control
- Less acne
- Reduces excessive body/facial hair

## CONTRAINDICATIONS

- Controlled hypertension under treatment, or BP ≥140/90 on 3 visits or BP 160+/100+ on one visit
- Current history of low or high risk factors for deep vein thrombosis, pulmonary embolism, or other thromboembolic vascular disease or known thrombogenic mutation
- Major surgery with prolonged immobilization
- History of or current ischemic heart disease/heart attack, complicated heart valve disease, cardiomyopathy, angina or stroke or multiple CV risk factors
- Migraine with focal neurologic symptoms, any age
- Migraines with no focal neurologic symptoms age≥ 35, or that start with the use of COCs any age
- Known hyperlipidemia (Routine screening not required)
- Positive Antiphospholipid Antibodies as may be seen with
- Complicated solid organ transplantation
- Pregnancy; breastfeeding and less than 1 month after delivery; or < 3wks after delivery if not breastfeeding
- Cigarette smokers age 35 or older
- History of or current gallbladder disease or past history with the use of COCs and no cholecystectomy
- All types of liver disease; liver problems during a pregnancy or while using birth control pills
- Current or past history of breast cancer
- Diabetes > 20 years, or end organ damage, or with any other accompanying vascular disease
- Unexplained vaginal bleeding
- Extensive IBD with VTE risk factors
- Certain HIV drugs, anticonvulsants, and rifampicin

## SIDE EFFECTS

- Spotting between periods
- Mood changes
- Breast tenderness
- Changes in contact lens prescription
- Headaches
- Heavier vaginal discharge
- Slight weight gain
- Nausea

**MAJOR PROBLEMS:** These are **NOT NORMAL** and should be reported to the clinic or hospital at once.

- Speech or vision changes
- Muscle weakness or numbness
- Sudden severe pain or soreness in leg
- Severe headaches, blackouts, dizziness
- Skin turns yellow (jaundice)
- Heavy bleeding between periods
- Severe depression

Departamento de Salud de Tennessee
Programa de planificación familiar

# CONSENTIMIENTO PARA PÍLDORAS ANTICONCEPTIVAS ORALES COMBINADAS (AOC)

**IMPORTANTE:** *Asegúrese de entender toda la información antes de firmar.*

Se me explicaron todos los procedimientos necesarios para poder recibir servicios de planificación familiar. Recibí información sobre todos los métodos anticonceptivos, incluida la abstinencia, y los riesgos y las ventajas de cada uno. Entiendo que ningún método es 100% eficaz para evitar el embarazo, y que puede haber efectos secundarios. Reconozco que es importante seguir las instrucciones que recibí y volver a las revisiones en las fechas programadas.

Entiendo toda la información que recibí. Estoy de acuerdo en participar como paciente en el programa de planificación familiar, recibir todo tratamiento y lo necesario en un examen de planificación familiar. He optado voluntariamente por los anticonceptivos orales combinados (**AOC**) como método anticonceptivo para mí. Tuve oportunidad de hacer preguntas acerca de los **AOC** y de este formulario de consentimiento. Acepto los riesgos de este método, y entiendo que puede haber otros riesgos que la clínica desconoce. Recibí verbalmente y por escrito las instrucciones para el uso de este método anticonceptivo. Se me entregó una copia de este formulario de consentimiento como referencia según sea necesario. Si tengo preguntas, puedo llamar a la clínica durante horas hábiles.

Entiendo que los **AOC** no evitan que contraiga una enfermedad de transmisión sexual (ETS), ni el virus del SIDA. Se me aconsejó la práctica de 'relaciones sexuales seguras' mediante el uso de preservativos, especialmente si tengo más de una pareja sexual, o si es posible que mi pareja haya estado expuesta a una ETS. Aun cuando el uso de este segundo método no garantiza que mi pareja o yo contraigamos una ETS, es posible que reduzca el riesgo.

Me aseguraron que toda la información que proporcione a alguna persona en esta clínica es confidencial y no se divulgará ni enviará a nadie, a menos que yo otorgue permiso por escrito, excepto según sea necesario para prestar servicios en la clínica o lo exija la ley. Con mi firma a continuación, indico que leí **ambos lados** de este formulario y que entiendo el contenido.

En caso de una emergencia o un problema grave, puedo llamar a la clínica al _____ o a la sala de emergencias al _____.

| Fecha | Firma del paciente | Firma del testigo |
|---|---|---|

Revisado:

| Fecha | Firma del paciente | Firma del testigo |
|---|---|---|
| Fecha | Firma del paciente | Firma del testigo |

PH-3397
(Rev.

White - Agency Copy
Canary - Patient Copy

RDA 150

## MATERIAL DIDÁCTICO: PÍLDORAS ANTICONCEPTIVAS ORALES COMBINADAS

**EXPLICACIÓN:** Los **anticonceptivos orales combinados** (AOC) impiden que el ovario libere un óvulo cada mes. La secreción mucosa del cuello del útero se hace más densa y esto ayuda a bloquear el acceso del esperma al útero. Con el uso perfecto, sólo el 0.1% de las mujeres que usan el método de AOC quedan embarazadas. Con el uso típico, el porcentaje de mujeres que quedan embarazadas es de cerca del 8%. Los AOC pueden empezar a tomarse el mismo día que se visita la clínica, siempre y cuando la mujer no esté embarazada (método de inicio rápido), o bien, el primer día del período menstrual siguiente, o el día domingo posterior al comienzo del período. Usted debe tomar una píldora diaria a la misma hora todos los días. La protección contra el embarazo comienza 7 días después de haber empezado a tomar las píldoras. Los anticonceptivos no protegen a la mujer del contagio de las enfermedades de transmisión sexual (ETS). Para ello, es necesario usar un preservativo. Ciertos medicamentos disminuyen la eficacia de los AOC; entre ellos, los fármacos anticonvulsivos como barbitúricos, fenitoína, sodio, carbamazepina, felbamato, oxcarbazepina y topiramato; la rifampina para el tratamiento de la tuberculosis; y el antimicótico griseofulvina. Otros fármacos que también pueden reducir la eficacia de los AOC son la fenilbutazona, un antiinflamatorio no esteroideo; el producto fitoterapéutico St. John's Wort (hierba de San Juan); y ciertos medicamentos contra el VIH. Los AOC pueden alterar los resultados de las pruebas de laboratorio. Asegúrese de recibir instrucciones escritas de lo que debe hacer si se salta una o más píldoras. Si tuvo relaciones sexuales sin protección, se cuenta con un anticonceptivo de emergencia. Usted puede suspender el método de los AOC en cualquier momento. No debe tomar los AOC si es hipersensible a algún componente del producto. Las mujeres que usan un método anticonceptivo con hormonas no deben fumar.

### VENTAJAS

- Menstruación regular con menos cólicos y menos sangrado
- Menor riesgo de cáncer de ovario y útero
- Menos tumores benignos en los senos y menos quistes de ovario
- Método anticonceptivo seguro y eficaz
- Menos acné
- Reduce el exceso de vello facial y en el cuerpo

### CONTRAINDICACIONES

- Hipertensión arterial controlada con tratamiento, o PA >140/90 en 3 visitas o PA 160+/100+ en una visita
- Factores de alto o bajo riesgo actuales o antecedentes de trombosis venosa profunda, embolia pulmonar u otra enfermedad vascular tromboembólica o mutación trombogénica conocida
- Cirugía mayor con inmovilización prolongada
- Cardiopatía isquémica o infarto de miocardio actual o antecedentes de estas enfermedades; valvulopatía complicada, miocardiopatía, angina de pecho o accidente cerebrovascular o varios factores de riesgo de enfermedades cardiovasculares
- Dolor de cabeza tipo migraña con síntomas neurológicos focales, a cualquier edad
- Dolor de cabeza tipo migraña sin síntomas neurológicos focales en pacientes de 35 o más años, o que comienza con el uso de ACO a cualquier edad
- Hiperlipidemia conocida (no se necesita prueba de detección de rutina)
- Anticuerpos antifosfolípidos positivos como se pueden ver en el lupus eritematoso sistémico (LES)
- Trasplante complicado de un órgano sólido
- Embarazo; lactancia y menos de un mes después del parto; o menos de 3 semanas después del parto si no está lactando
- Fumadoras de 35 o más años de edad
- Enfermedad de la vesícula biliar actual o antecedentes de esta enfermedad, o antecedentes con el uso de AOC y sin colecistectomía
- Todos los tipos de enfermedades hepáticas; problemas del hígado durante el embarazo o con el uso de píldoras anticonceptivas
- Cáncer de mama actual o antecedentes del mismo
- Diabetes por más de 20 años, o daño terminal en órgano, o con cualquier otra enfermedad vascular acompañante
- Sangrado vaginal sin explicación
- Enfermedad inflamatoria intestinal extensa con factores de riesgo de tromboembolismo venoso (TEV)
- Ciertos medicamentos contra el VIH, anticonvulsivos y rifampicina

### EFECTOS SECUNDARIOS

- Sangrado entre períodos
- Cambios de estado de ánimo
- Mastalgia
- Cambios en la receta de lentes de contacto
- Dolor de cabeza
- Mayor secreción vaginal
- Leve aumento de peso corporal
- Náusea

**PROBLEMAS IMPORTANTES:** Estos **NO SON NORMALES** y debe informarse de inmediato de ellos a la clínica u hospital.

- Cambios en el habla o la visión
- Debilidad o entumecimiento muscular
- Dolor intenso y repentino o hinchazón de piernas
- Dolores de cabeza intensos, desmayos o mareos
- Piel amarillenta (ictericia)
- Sangrado abundante entre períodos
- Depresión aguda

Tennessee Department of Health
Family Planning Program
**CONSENT FOR COPPER INTRAUTERINE DEVICE (IUD)**

**IMPORTANT:** *Make sure that you understand all information before signing.*

All procedures necessary for me to receive family planning services have been explained to me. I have been given information about all methods of birth control, including abstinence, and the risks and benefits of each. I understand that no method is 100% effective against pregnancy and that undesirable side effects may occur. I recognize that it is important to follow instructions given to me and to return for checkups on schedule.

I understand all the information provided. I consent to be a patient in the family planning program, to receive all that is required in a family planning examination, and any treatment that is deemed necessary. I have voluntarily chosen the **copper-bearing IUD** as my method of birth control. I have been given the chance to ask questions about the **copper-bearing IUD** and about this consent form. I accept the risks of this method and understand there may be other risks that the clinic is not aware of. Instructions for the use of this birth control method have been given to me in writing and orally. I have been given a copy of this consent form to refer to as needed. I may call the clinic during office hours if I have questions.

I understand that the **copper-bearing IUD** will not prevent me from getting a sexually transmitted disease (STD), including the AIDS virus. I have been advised to practice "safer sex" by also using condoms, especially if I have sex with more than one partner, or if I or my partner has possibly been exposed to an STD. Although the use of this second method does not insure that I or my partner will not get an STD, it may reduce the risk.

I was assured that all information that I give to anyone in this clinic is confidential and will not be given or sent to anyone, unless I give written permission, except as necessary to provide services at the clinic or as required by law. By my signature below, I indicate that I have read **both sides** of this form and that I understand its contents.

In case of an emergency or severe problem, I can call the clinic at _____ or the emergency room at_____.

| Date | Patient Signature | Witness Signature |
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| Date | Patient Signature | Witness Signature |
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# TEACHING TOOL –COPPER-BEARING INTRAUTERINE DEVICE (IUD)

**EXPLANATION**: A copper-bearing intrauterine device (IUD) is a method of contraception whose contraceptive effect is enhanced by copper ions that are released into the uterine cavity. It is placed into the uterus by a health care professional. Copper-bearing IUDs cause the cervical mucus to thicken and also inhibit sperm motility, sperm transport, and egg transport. The perfect use failure rate in the first year of use is 0.6%. Typical use failure rate in the first year is 0.8%. There is a 1:1000 risk of perforation at the time of insertion. One or more strings extend from the IUD into the vagina. You must check for the strings in order to insure that you have not expelled the IUD. If you cannot find the strings or if they are longer or shorter or if you feel the plastic of the IUD, you need to use a back-up method of contraception such as condoms or spermicide, and return to the clinic as soon as possible. If you have had unprotected sex, you can contact the clinic within 72 hours for emergency contraception. IUDs do not cause pelvic inflammatory disease (PID). PID is caused by STIs such as gonorrhea and chlamydia which can cause infertility and in rare instances, death. Your risk of PID increases if you or your partner has multiple sex partners. The risk of acquiring PID from any type of organism is highest the first 3 weeks after insertion of the IUD. Women requiring insulin, anticoagulants, or chronic corticosteroid therapy must be monitored carefully for infection. <u>If you have any of the major problems listed below, you must report to the nearest health care provider immediately</u>. If you have heart valve problems, prophylactic antibiotics may be needed at the time of insertion or removal to prevent endocarditis. If you become pregnant with the IUD in place, you are at particular risk for severe PID. It is recommended that the IUD be removed right away if you become pregnant and that this most likely will lead to a miscarriage. Infection during pregnancy with an IUD in place can lead to death. In this rare situation, elective abortion might need to be considered. You can have your IUD removed at any time.

## BENEFITS

- Extremely effective at preventing pregnancy
- No estrogen or progestin
- Up to 10 years of protection
- Does not interfere with sexual spontaneity
- Does not interfere with breastfeeding

## CONTRAINDICATIONS

- Known or suspected pregnancy
- Active, recent (last 3 months), or recurrent pelvic infection, all types
- Abnormalities of the inside of the uterus
- Untreated cervicitis, vaginitis, vaginosis and undiagnosed abnormal vaginal bleeding
- Initiation of method with complicated solid organ transplant
- Allergy to copper or any component and Wilson's Disease
- Increased risk of perforation if inserted prior to 4 weeks postpartum
- Puerperal sepsis or post-septic abortion in the last 3 months
- Benign or malignant trophoblastic disease
- HIV/AIDS or any condition or treatment leading to immunosuppression
- Cervical, endometrial, or ovarian cancer. Unresolved abnormal Pap smear.
- Initiation of method with severe thrombocytopenia as may be seen with SLE

**CAUTION:** If you have the following conditions, the IUD may not be the best choice for you.

- History of gonorrhea or chlamydia
- Previous problems with an IUD
- History of severe vasovagal response
- Difficult access to emergency follow-up
- Heavy, painful periods
- Sexual behaviors that put you at risk of infection

## SIDE EFFECTS

- Heavier menstrual bleeding and cramping
- Partner bothered by the strings

**MAJOR PROBLEMS:** These are **NOT NORMAL** and should be reported to the clinic or hospital at once.

- Abdominal or pelvic pain
- Prolonged or heavy bleeding/discharge/odor
- Painful sex
- Fever or chills
- Any signs of pregnancy
- Exposure to gonorrhea/chlamydia/any STD
- Cannot feel string or can feel plastic
- Missed period; abnormal spotting or bleeding
- Flu-like illness
- Delayed or slight menstrual bleeding with one-sided pelvic pain

Departamento de Salud de Tennessee
Programa de planificación familiar

# CONSENTIMIENTO PARA DISPOSITIVO INTRAUTERINO (DIU) DE COBRE

**IMPORTANTE:** *Asegúrese de entender toda la información antes de firmar.*

Se me explicaron todos los procedimientos necesarios para poder recibir servicios de planificación familiar. Recibí información sobre todos los métodos anticonceptivos, incluida la abstinencia, y los riesgos y las ventajas de cada uno. Entiendo que ningún método es 100% eficaz para evitar el embarazo, y que puede haber efectos secundarios. Reconozco que es importante seguir las instrucciones que recibí y volver a las revisiones en las fechas programadas.

Entiendo toda la información que recibí. Estoy de acuerdo en participar como paciente en el programa de planificación familiar, recibir todo tratamiento y lo necesario en un examen de planificación familiar. He optado voluntariamente por el **DIU de cobre** como método anticonceptivo para mí. Tuve oportunidad de hacer preguntas acerca del **DIU de cobre** y de este formulario de consentimiento. Acepto los riesgos de este método, y entiendo que puede haber otros riesgos que la clínica desconoce. Recibí verbalmente y por escrito las instrucciones para el uso de este método anticonceptivo. Se me entregó una copia de este formulario de consentimiento como referencia según sea necesario. Si tengo preguntas, puedo llamar a la clínica durante horas hábiles.

Entiendo que el **DIU de cobre** no evita que contraiga una enfermedad de transmisión sexual (ETS), ni el virus del SIDA. Se me aconsejó la práctica de 'relaciones sexuales seguras' mediante el uso de preservativos, especialmente si tengo más de una pareja sexual, o si es posible que mi pareja haya estado expuesta a una ETS. Aun cuando el uso de este segundo método no garantiza que mi pareja o yo contraigamos una ETS, es posible que reduzca el riesgo.

Me aseguraron que toda la información que proporcione a alguna persona en esta clínica es confidencial y no se divulgará ni enviará a nadie, a menos que yo otorgue permiso por escrito, excepto según sea necesario para prestar servicios en la clínica o lo exija la ley. Con mi firma a continuación, indico que leí **ambos lados** de este formulario y que entiendo el contenido.

En caso de una emergencia o un problema grave, puedo llamar a la clínica al _____ o a la sala de emergencias al _____.

| Fecha | Firma del paciente | Firma del testigo |
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| | | |

Revisado:

| Fecha | Firma del paciente | Firma del testigo |
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RDA 150

## MATERIAL DIDÁCTICO: DISPOSITIVO INTRAUTERINO (DIU) DE COBRE

**EXPLICACIÓN**: El dispositivo intrauterino (DIU) de cobre es un método anticonceptivo con efecto mejorado por los iones de cobre que se liberan hacia la cavidad del útero. Un profesional de la atención médica coloca el dispositivo en el útero. Los DIU de cobre hacen que la secreción mucosa del cuello del útero sea más densa, e inhiben la motilidad del esperma, el paso de los espermatozoides y del óvulo. Con el uso perfecto, la tasa de ineficacia es del 0.6% el primer año de uso. Con el uso típico, la tasa de ineficacia es del 0.8% el primer año. Existe un riesgo de 1 en 1,000 casos de perforación durante la inserción. Uno o más hilos se extienden desde el DIU hacia la vagina. Usted debe revisar los hilos para verificar que el DIU no haya sido expulsado. Si no encuentra los hilos, o si son más largos o más cortos, o si siente el plástico del DIU, es necesario que use un método anticonceptivo de refuerzo, como preservativos o espermicida, y que acuda a la clínica lo antes posible. Si tiene relaciones sexuales sin protección, comuníquese con la clínica en menos de 72 horas para recibir un anticonceptivo de emergencia. El DIU no causa la enfermedad pélvica inflamatoria (EPI). La EPI es causada por una infección de transmisión sexual (ITS) como gonorrea y clamidia que pueden causar esterilidad y, en casos inusuales, la muerte. El riesgo de contraer la EPI aumenta si usted o su pareja tienen varias parejas sexuales. Asimismo, el riesgo contraer la EPI de algún tipo de organismo es mayor en las primeras 3 semanas después de insertar el DIU. Se debe controlar con atención a las mujeres que necesitan insulina, anticoagulantes o tratamiento prolongado con corticoesteroides para detectar infecciones. Si tiene alguno de los problemas importantes que se indican más adelante, debe acudir de inmediato al proveedor de atención médica más cercano. Si tiene una valvulopatía, tal vez necesite antibióticos profilácticos cuando le inserten o extraigan el DIU, para prevenir una endocarditis. Si se embaraza con el DIU colocado, tiene un riesgo particular de contraer una EPI grave. Se recomienda extraer el DIU de inmediato si usted se embaraza, y es muy probable que esto cause un aborto espontáneo. Una infección durante el embarazo con un DIU colocado puede causarle la muerte. En este caso inusual, podría considerarse la posibilidad de un aborto provocado. El DIU puede ser extraído en cualquier momento.

### VENTAJAS

- Es un anticonceptivo sumamente eficaz.
- No contiene estrógeno ni progestina.
- Brinda protección hasta por 10 años.
- No interfiere en la espontaneidad sexual.
- No interfiere con la lactancia.

### CONTRAINDICACIONES

- Embarazo confirmado o sospecha de embarazo
- Infección pélvica activa, reciente (últimos 3 meses) o recurrente, todos los tipos
- Anomalías en la cavidad del útero
- Cervicitis, vaginitis y vaginosis sin tratamiento y sangrado vaginal anormal no diagnosticado
- Inicio del método con trasplante complicado de un órgano sólido
- Alergia al cobre o a algún componente, y enfermedad de Wilson
- Mayor riesgo de perforación si se inserta antes de las 4 semanas después del parto
- Infección puerperal o posterior a un aborto séptico en los últimos 3 meses
- Enfermedad trofoblástica benigna o maligna
- VIH/SIDA o toda enfermedad o tratamiento que cause inmunosupresión
- Cáncer de ovario, de endometrio o de cuello de útero. Papanicolaou anormal pendiente.
- Inicio del método con trombocitopenia grave como se puede ver en el lupus eritematoso sistémico (LES)

**PRECAUCIÓN:** Si usted tiene los problemas a continuación, es posible que el DIU no sea la mejor opción para usted.

- Antecedentes de gonorrea o clamidia
- Antecedentes de problemas con un DIU
- Antecedentes de respuesta vasovagal grave
- Acceso difícil a seguimiento de emergencia
- Menstruación abundante y dolorosa
- Conducta sexual que aumenta su riesgo de contraer una infección

### EFECTOS SECUNDARIOS

- Menstruación más abundante y cólicos menstruales
- Incomodidad de la pareja debido a los hilos

**PROBLEMAS IMPORTANTES:** Estos **NO SON NORMALES** y debe informarse de inmediato de ellos a la clínica u hospital.

- Dolor de pelvis o abdomen
- Sangrado prolongado o abundante, secreción u olor
- Relaciones sexuales dolorosas
- Fiebre o escalofríos
- Cualquier señal de embarazo
- Exposición a gonorrea, clamidia o alguna ETS
- No se sienten los hilos o se siente el plástico
- Falta de menstruación; sangrado o manchas de sangre anormales
- Enfermedad similar a la gripe
- Menstruación atrasada o escasa con dolor pélvico de un solo lado

Tennessee Department of Health
Family Planning Program
**CONSENT FOR DIAPHRAGM**

**IMPORTANT:** *Make sure that you understand all information before signing.*

All procedures necessary for me to receive family planning services have been explained to me. I have been given information about all methods of birth control, including abstinence, and the risks and benefits of each. I understand that no method is 100% effective against pregnancy and that undesirable side effects may occur. I recognize that it is important to follow instructions given to me and to return for checkups on schedule.

I understand all the information provided. I consent to be a patient in the family planning program, to receive all that is required in a family planning examination, and any treatment that is deemed necessary. I have voluntarily chosen the **DIAPHRAGM** as my method of birth control. I have been given the chance to ask questions about the **DIAPHRAGM** and about this consent form. I accept the risks of this method and understand there may be other risks that the clinic is not aware of. Instructions for the use of this birth control method have been given to me in writing and orally. I have been given a copy of this consent form to refer to as needed. I may call the clinic during office hours if I have questions.

I understand that the **DIAPHRAGM** will not prevent me from getting a sexually transmitted disease (STD), including the AIDS virus. I have been advised to practice "safer sex" by also using condoms, especially if I have sex with more than one partner, or if I or my partner has possibly been exposed to an STD. Although the use of this second method does not insure that I or my partner will not get an STD, it may reduce the risk.

I was assured that all information that I give to anyone in this clinic is confidential and will not be given or sent to anyone, unless I give written permission, except as necessary to provide services at the clinic or as required by law. By my signature below, I indicate that I have read **both sides** of this form and that I understand its contents.

In case of an emergency or severe problem, I can call the clinic at _____ or the emergency room at_____.

| Date | Patient Signature | Witness Signature |
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| Date | Patient Signature | Witness Signature |
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RDA 150

**TEACHING TOOL - DIAPHRAGM**

**EXPLANATION**: The diaphragm uses two mechanisms to prevent pregnancy. It acts as a physical barrier to sperm and it acts as a device to hold a spermicide in place at the cervix. It must be placed correctly in the vagina over the cervix. If used perfectly the first year failure rate is 6%. Typical failure rate in the first year of use is 16%. In order to protect against pregnancy the diaphragm should remain in place for six hours after the last act of sexual intercourse. If sex is repeated within the six hours, insert more spermicide without removing the diaphragm itself. To avoid toxic shock syndrome, never leave the diaphragm in place longer than 24 hours at one time. If you have unprotected sex, contact the clinic within 72 hours for emergency contraceptive pills. The diaphragm will not prevent sexually transmitted infections and nonoxynol-9, a common spermicide, may increase the likelihood of HIV infection when used frequently. You can stop using the diaphragm whenever you choose and you may become pregnant right away. Be sure you receive a written copy of instructions regarding insertion, removal, and care of you diaphragm.

**BENEFITS:**

- No hormonal effect
- Does not require partner involvement
- Available for intermittent use

**CONTRAINDICATIONS:**

- Known allergy to spermicide or silicone
- Vaginal abnormalities
- Inability to learn correct insertion techniques
- History of toxic shock syndrome
- History of repeated urogenital tract infections

**CAUTION:** I understand that if I have the following situations, the diaphragm may not be the best choice for me.

- Previous pregnancy while using a diaphragm
- Personal style or sexual patterns that make consistent use difficult
- Method failure (i.e. pregnancy) would be devastating

**SIDE EFFECTS**

- Allergic reactions to silicone or spermicide
- Pain, pressure, or vaginal trauma during use
- Partner discomfort during diaphragm use
- Foul odor or vaginal discharge
- Urogenital tract infection

**MAJOR PROBLEMS:** The following are **DANGER SIGNALS** of **TOXIC SHOCK SYNDROME**; these are **NOT NORMAL** and should be reported to the clinic as soon as possible:

- Sudden high fever
- Vomiting, diarrhea
- Sore throat, aching muscles and joints
- Dizziness, faintness, weakness
- Sunburn-like rash
- Pain or burning with urination (sign of bladder infection)

Departamento de Salud de Tennessee
Programa de planificación familiar

# CONSENTIMIENTO PARA DIAFRAGMA

**IMPORTANTE:** *Asegúrese de entender toda la información antes de firmar.*

Se me explicaron todos los procedimientos necesarios para poder recibir servicios de planificación familiar. Recibí información sobre todos los métodos anticonceptivos, incluida la abstinencia, y los riesgos y las ventajas de cada uno. Entiendo que ningún método es 100% eficaz para evitar el embarazo, y que puede haber efectos secundarios. Reconozco que es importante seguir las instrucciones que recibí y volver a las revisiones en las fechas programadas.

Entiendo toda la información que recibí. Estoy de acuerdo en participar como paciente en el programa de planificación familiar, recibir todo tratamiento y lo necesario en un examen de planificación familiar. He optado voluntariamente por el **DIAFRAGMA** como método anticonceptivo para mí. Tuve oportunidad de hacer preguntas acerca del **DIAFRAGMA** y de este formulario de consentimiento. Acepto los riesgos de este método, y entiendo que puede haber otros riesgos que la clínica desconoce. Recibí verbalmente y por escrito las instrucciones para el uso de este método anticonceptivo. Se me entregó una copia de este formulario de consentimiento como referencia según sea necesario. Si tengo preguntas, puedo llamar a la clínica durante horas hábiles.

Entiendo que el **DIAFRAGMA** no evita que contraiga una enfermedad de transmisión sexual (ETS), ni el virus del SIDA. Se me aconsejó la práctica de 'relaciones sexuales seguras' mediante el uso de preservativos, especialmente si tengo más de una pareja sexual, o si es posible que mi pareja haya estado expuesta a una ETS. Aun cuando el uso de este segundo método no garantiza que mi pareja o yo contraigamos una ETS, es posible que reduzca el riesgo.

Me aseguraron que toda la información que proporcione a alguna persona en esta clínica es confidencial y no se divulgará ni enviará a nadie, a menos que yo otorgue permiso por escrito, excepto según sea necesario para prestar servicios en la clínica o lo exija la ley. Con mi firma a continuación, indico que leí **ambos lados** de este formulario y que entiendo el contenido.

En caso de una emergencia o un problema grave, puedo llamar a la clínica al _____ o a la sala de emergencias al _____.

| Fecha | Firma del paciente | Firma del testigo |
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**MATERIAL DIDÁCTICO: DIAFRAGMA**

**EXPLICACIÓN**: El diafragma emplea dos mecanismos para evitar el embarazo: actúa como una barrera física del esperma y también como un dispositivo que mantiene el espermicida dentro del cuello del útero. Debe colocarse correctamente en la vagina sobre el cuello del útero. Con el uso perfecto, la tasa de ineficacia es del 6% el primer año. La tasa de ineficacia típica es del 16% el primer año de uso. Para lograr la protección contra el embarazo, el diafragma debe permanecer colocado durante las seis horas posteriores al último acto sexual. Si en ese lapso la mujer vuelve a tener relaciones, debe colocar más espermicida sin quitarse el diafragma. Para evitar el síndrome de shock tóxico, nunca deje el diafragma colocado por más de 24 horas seguidas. Si tiene relaciones sexuales sin protección, comuníquese con la clínica en menos de 72 horas para recibir las píldoras anticonceptivas de emergencia. El diafragma no previene las infecciones de transmisión sexual, y el nonoxynol-9, un espermicida de uso común, puede aumentar la probabilidad de contraer el VIH si se usa con frecuencia. Usted puede dejar de usar el diafragma cuando lo desee y quedar embarazada inmediatamente después de interrumpir su uso. Asegúrese de recibir instrucciones escritas sobre la colocación, extracción y cuidado del diafragma.

**VENTAJAS:**

No tiene efecto hormonal.
No es necesario que participe la pareja.
Se puede usar de manera intermitente.

**CONTRAINDICACIONES:**

Alergia conocida al espermicida o a la silicona
Anomalías vaginales
Incapacidad para aprender la técnica de inserción correcta
Antecedentes de síndrome de shock tóxico
Antecedentes de infecciones constantes del aparato genitourinario

**PRECAUCIÓN:** Entiendo que si tengo los problemas a continuación, es posible que el diafragma no sea la mejor opción para mí.

Embarazo anterior con el diafragma colocado
Uso inconstante debido al estilo de vida o a las prácticas sexuales
Falla del método (es decir, embarazo) con consecuencias devastadoras

**EFECTOS SECUNDARIOS**

Reacciones alérgicas al espermicida o a la silicona
Dolor, presión o traumatismo vaginal durante el uso
Incomodidad de la pareja durante el uso
Secreción vaginal u olor fétido
Infección de vías genitourinarias

**PROBLEMAS IMPORTANTES:** Estos son **SÍNTOMAS DE PELIGRO** del **SÍNDROME DE SHOCK TÓXICO,** que **NO SON NORMALES** y debe informarse de inmediato de ellos a la clínica:

Fiebre alta repentina
Vómito y diarrea
Dolor de garganta, de músculos y articulaciones
Mareo, desmayo, debilidad
Sarpullido como el de una quemadura de sol
Dolor o ardor al orinar (síntoma de infección de vejiga)

Affix Label

# Tennessee Department of Health
# Consent for
# Emergency Contraception

## INSTRUCTIONS TO THE PATIENT

Before giving your consent, be sure you understand emergency contraception and have had all your questions answered. Remember that your consent is voluntary. Please initial each statement below if you have read and understand it:

_____ ECPs contain hormones that act to prevent pregnancy. These pills are taken after having unprotected vaginal sex (without birth control). ECPs are to be used as an emergency treatment only and not as a main method of contraception. ECPs are not as effective regular birth control methods.

_____ ECPs are regular birth control pills taken differently. I understand that the US Food and Drug Administration has stated that the use of birth control pills is safe and effective for emergency contraception.

_____ If I am already pregnant, ECPs will **not** stop the pregnancy.

_____ ECPs work by preventing or delaying the release of an egg from the ovary or preventing sperm from fertilizing the egg. These are the most likely ways that ECPs prevent pregnancy. ECPs may change the lining of the uterus which would prevent implantation of a fertilized egg. Based on ECP studies and failure rates, this is less likely.

_____ ECPs only decrease the likelihood that I will become pregnant. ECPs do not guarantee that I will not get pregnant anyway. ECPs are not as effective as regular birth control methods.

_____ ECPs should be started as soon as possible after unprotected sex and should be started within 3 days (72 hours) of unprotected sex. However, many experts believe ECPs may be effective up to 120 hours after unprotected sex.

_____ If the treatment fails, and I become pregnant, there is no risk to the pregnancy. I can return to the health department for further counseling. I understand that early prenatal care is important to the success of a healthy pregnancy.

_____ Some reactions to the ECPs may include:

- nausea and vomiting
- fatigue
- dizziness
- breast tenderness
- early or late menstrual period
- vaginal bleeding or spotting

_____ I should return to the clinic or do a home pregnancy test if my period has **not** started within 3 weeks after treatment.

_____ ECPs do not prevent an ectopic pregnancy (pregnancy in the tubes). Ectopic pregnancy is a life-threatening condition.

_____ I should use some method of birth control if I have sex again before my next period.

_____ If I see a doctor for any reason before I get my period, I should tell him/her that I have taken ECPs.

_____ ECPs will not protect me from or treat sexually transmitted diseases. I should seek diagnosis and treatment if I am concerned about this.

_____ A nurse is available to answer any questions I may have.

_____ I have given a complete and accurate history.

_____ In case of an emergency or severe problem, I can call the clinic at _____ or go to the emergency room in my community.

Date _____ Patient Signature _____ Witness Signature

# EMERGENCY CONTRACEPTIVE PILLS (ECPS)
# INSTRUCTIONS FOR TAKING

There are different products available for emergency contraception. Your nurse will circle the instructions for your product:

1. For two-dose products, swallow the first dose of ECPs as soon as possible after unprotected sex (we advise no later than 72 hours after unprotected sex). Swallow the second dose 12 hours after you took the first dose. **Your nurse will tell you how many pills to take for each dose**.

2. For one-dose products, swallow the dose as soon as possible after unprotected sex (we advise no later than 72 hours after unprotected sex). **Your nurse will tell you how many pills are in your one-dose product.**

Many experts believe that there can be emergency contraceptive benefit even up to 120 hours after unprotected sex. However, the package labeling for these products recommends no later than 72 hours. Your nurse will consult a nurse-practitioner or doctor if you want the 120 hour option.

Do not take extra emergency contraception pills. Extra pills will make you more at risk for feeling sick to your stomach.

Eating a snack before taking any of the emergency contraception dose(s) will help prevent feeling sick to your stomach.

You may want to use an over-the-counter, anti-nausea medicine before each dose. Ask the nurse about this before you leave clinic today.

If you do feel sick to your stomach, this will only last for a day or so. If you throw up in less than one hour after you take emergency contraception, call your clinic.

During the week after taking emergency contraception, you may have vaginal bleeding or spotting. Your next period may be heavier than usual and start a few days early or late.

If your period does not start in three weeks, you could be pregnant. Make an appointment to come back to the clinic in three weeks if you have not had a period.

Watch for danger signs and call the clinic or report to the emergency room if any of the following happen:

| | |
|---|---|
| Chest or arm pain | Low abdominal pain |
| Shortness of breath | Eye problems (Blurred or double vision) |
| Unusual swelling/pain in legs | Yellowing of skin or eyes |
| Severe headaches/dizziness | Severe depression |

Emergency contraception is meant for emergency use only, and is not meant to be a regular method of birth control. Emergency contraception is not as effective as a regular method of birth control. Your nurse can give you information and handouts on methods of birth control that are available to you.

You can get something for birth control today.

Remember that emergency contraception does not protect you from HIV/AIDS or other sexually transmitted diseases. Always use condoms.
If you have questions after you get home, call the clinic.

Affix Label or Complete Blanks

DEPARTAMENTO DE SALUD DE TENNESSEE
OFICINA DE SERVICIOS DE SALUD

# CONSENTIMIENTO PARA PÍLDORAS ANTICONCEPTIVAS DE EMERGENCIA (PAE)

## INSTRUCCIONES PARA LA PACIENTE

Antes de dar su consentimiento, asegúrese de entender qué son los anticonceptivos de emergencia y de haber recibido respuesta a todas sus preguntas. Recuerde que usted da su consentimiento de manera voluntaria. Escriba las iniciales de su nombre en cada una de las afirmaciones a continuación, si las leyó y las entiende:

_____ Las píldoras anticonceptivas de emergencia (PAE) contienen hormonas que actúan para evitar el embarazo. Se toman después de haber tenido relaciones sexuales por vía vaginal sin protección ni método anticonceptivo. Las PAE se usan como tratamiento de emergencia únicamente, y no como método anticonceptivo principal, porque son menos eficaces que los métodos anticonceptivos habituales.

_____ Las PAE son píldoras anticonceptivas comunes que se toman de manera diferente. Entiendo que la Administración de Drogas y Alimentos de los Estados Unidos (*US Food and Drug Administration*) ha declarado que las píldoras anticonceptivas son seguras y eficaces como método anticonceptivo de emergencia.

_____ Si ya estoy embarazada, las PAE **no** interrumpirán el embarazo.

_____ Las PAE evitan o retrasan la ovulación, o impiden que el espermatozoide fecunde el óvulo. Estas son las maneras más probables en que las PAE evitan el embarazo. Pueden alterar el revestimiento del útero, lo cual evitaría la implantación del óvulo fecundado. Según los estudios sobre las PAE y las tasas de ineficacia, esto es menos probable.

_____ Las PAE sólo disminuyen la probabilidad de que yo quede embarazada; no garantizan que no quedaré embarazada. Asimismo, son menos eficaces que los métodos anticonceptivos habituales.

_____ Las PAE deben empezar a tomarse lo antes posible después de haber tenido relaciones sexuales sin protección, en los tres días (72 horas) posteriores a la última relación sexual sin protección. Sin embargo, muchos expertos creen que las PAE pueden ser eficaces hasta 120 horas después de las relaciones sexuales sin protección.

_____ Si el tratamiento falla y yo quedo embarazada, el embarazo no corre peligro. Puedo regresar al departamento de salud para obtener más asesoramiento. Entiendo que la atención prenatal temprana es importante para lograr un embarazo saludable.

_____ Algunas reacciones a las PAE pueden incluir:

- náusea y vómito
- mareo
- adelanto o retraso de la menstruación
- fatiga
- mastalgia
- sangrado vaginal o manchas de sangre

_____ Yo debo regresar a la clínica o hacerme una prueba de embarazo en casa si mi menstruación **no** empieza en las tres semanas posteriores al tratamiento.

_____ Las PAE no evitan el embarazo ectópico, es decir, el embarazo que se desarrolla en las trompas de Falopio. El embarazo ectópico es un problema potencialmente mortal.

_____ Yo debo usar algún método anticonceptivo si vuelvo a tener relaciones sexuales antes de mi próximo período.

_____ Si hago acudo al médico por cualquier motivo antes de mi período, debo informarle que he tomado PAE.

_____ Las PAE no me protegen de las enfermedades de transmisión sexual ni sirven para tratar estas enfermedades. Si estoy preocupada por una enfermedad de transmisión sexual, debo obtener diagnóstico y tratamiento.

_____ Una enfermera puede responder a todas las preguntas que yo haga.

_____ Proporcioné una historia clínica completa y con información precisa.

_____ En caso de una emergencia o un problema grave, puedo llamar a la clínica al _____ o acudir a la sala de emergencias de mi comunidad.

_____ _____ _____

Fecha | Firma de la paciente | Firma del testigo

## INSTRUCCIONES PARA TOMAR LAS PÍLDORAS ANTICONCEPTIVAS DE EMERGENCIA (PAE)

Existen distintos productos para la anticoncepción de emergencia. Su enfermera encerrará en un círculo las instrucciones correspondientes al que usted tome:

1. En el caso de productos de dos dosis de PAE, ingiera la primera lo antes posible después de haber tenido relaciones sexuales sin protección (recomendamos que no deje pasar más de 72 horas después de las relaciones sexuales sin protección). Ingiera la segunda dosis 12 horas después de la primera. **La enfermera le indicará cuántas píldoras debe tomar en cada dosis**.
2. En el caso de productos de una sola dosis de PAE, ingiérala lo antes posible después de haber tenido relaciones sexuales sin protección (recomendamos que no deje pasar más de 72 horas después de las relaciones sexuales sin protección). **La enfermera le indicará cuántas píldoras debe tomar del producto de una sola dosis.**

Muchos expertos opinan que las PAE pueden hacer efecto hasta 120 horas después de las relaciones sexuales sin protección. No obstante, en la etiqueta con información que acompaña estos productos, se recomienda no dejar pasar más de 72 horas. Su enfermera consultará a la enfermera practicante o al médico si usted prefiere la opción de 120 horas.

No tome más PAE de las que le indiquen. Si toma píldoras de más, aumentará el riesgo de sentir náusea.

Para prevenir las náuseas, coma un bocadillo antes de cualquiera de las dosis de PAE.

Sería conveniente que tome un antiemético de venta libre antes de cada dosis de PAE, para evitar o aliviar las náuseas. Consulte con la enfermera antes de irse de la clínica hoy.

Si tiene náuseas, sólo durarán aproximadamente un día. Si usted vomita en menos de una hora después de haber tomado las píldoras anticonceptivas de emergencia, llame a su clínica.

Durante la semana posterior al tratamiento con PAE, tal vez tenga un pequeño sangrado vaginal o manchas de sangre. Su próximo período puede ser más abundante, y adelantarse o retrasarse unos días.

Si su período no comienza en tres semanas, usted podría estar embarazada. Haga una cita para regresar a la clínica en tres semanas si no ha tenido su período.

Preste atención a las señales de peligro, y llame a la clínica o acuda a la sala de emergencias si tiene lo siguiente:

| | |
|---|---|
| Dolor en el pecho o los brazos | Dolor en la parte baja del abdomen |
| Disnea | Problemas oculares (visión doble o borrosa) |
| Hinchazón o dolor inusual de piernas | Piel u ojos amarillentos |
| Dolores de cabeza intensos o mareos | Depresión aguda |

Las PAE se usan como anticonceptivos de emergencia únicamente, y no como un método anticonceptivo habitual. La anticoncepción de emergencia es menos eficaz que los métodos anticonceptivos habituales. Su enfermera puede explicarle y darle folletos con información sobre los métodos anticonceptivos disponibles para usted.

Usted puede obtener un método anticonceptivo hoy mismo.

Recuerde que las píldoras anticonceptivas de emergencia no protegen contra el VIH/SIDA ni ninguna otra enfermedad de transmisión sexual. Use siempre un preservativo.
Si tiene preguntas después de regresar a casa, llame a la clínica.

Affix label here

| | | |
|---|---|---|
| | **Tennessee Department of Health**<br>**Consent for Progestin-only Implant(s)** | |

**IMPORTANT:** *Make sure that you understand all information before signing.*

All procedures necessary for me to receive family planning services have been explained to me. I have been given information about all methods of birth control, including abstinence, and the risks and benefits of each. I understand that no method is 100% effective against pregnancy and that undesirable side effects may occur. I recognize that it is important to follow instructions given to me and to return for checkups on schedule.

I understand all the information provided. I consent to be a patient in the family planning program, to receive all that is required in a family planning examination, and any treatment that is deemed necessary. I voluntarily choose contraception and the **progestin-only implant(s)** as my method of birth control. I have been given the chance to ask questions about the **progestin-only implant(s)** and about this consent form. I accept the risks of this method and understand there may be other risks that are yet unknown. Instructions for the use of this birth control method have been given to me in writing and orally. I have been given a copy of this consent form to refer to as needed. I may call the clinic during office hours if I have questions.

I understand that **progestin-only implant(s)** will not prevent me from getting a sexually transmitted disease (STD), including the AIDS virus. I have been advised to practice "safer sex" by also using condoms, especially if I have sex with more than one partner, or if I or my partner has possibly been exposed to an STD. Although the use of this second method does not insure that I or my partner will not get an STD, I understand that it may reduce the risk.

I was assured that all information that I give to anyone in this clinic is confidential and will not be given or sent to anyone, unless I give written permission, except as necessary to provide services at the clinic or as required by law. By my signature below, I indicate that I have read **both sides** of this form and that I understand its contents.

In case of an emergency or severe problem, I can call the clinic at _____ or the emergency room at _____.

| Date | Patient Signature | Witness Signature |
|---|---|---|

Reviewed:

| Date | Patient Signature | Witness Signature |
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| Date | Patient Signature | Witness Signature |

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**TEACHING TOOL – Progestin-only Implant(s)**

**EXPLANATION**: The progestin-only implant(s) is (are) a small flexible rod(s) placed just under the skin of the arm. It releases a progestin, a hormone that will prevent pregnancy. It is a highly effective method. Less than one woman in 100 in one year (0.3%) (Implanon® data) will get pregnant on this method. Progestins can prevent ovulation, thicken cervical mucous, and temporarily alter the lining of the uterus. Fertility will return quickly after the implant is removed. The single-rod implant, Implanon® can prevent pregnancy for 3 years. Other implant products may become available. Do not choose an implant if you know you want a baby sooner than the life of the implant. No implant will prevent STDs. Implant(s) must be placed correctly. If it is not, it may not prevent pregnancy and if not placed correctly, it may be difficult to remove requiring surgery in an operating room. Insertion and removal can involve pain, bruising, scarring, and infection. The timing of insertion is important in order to assure that you are not already pregnant. If you are not currently using a hormonal method of birth control or IUD or if you have not delivered a baby in the last 4 weeks, your insertion will be scheduled during the first 5 days of your menstrual period and you will need to use condoms for the first 7 days after insertion. After your implant(s) is placed, you should be able to feel it just under the skin of your arm. If you cannot feel your implant, report to your health care provider right away. Remember to keep your bandage clean and dry. Leave the top bandage on for 24 hours and the smaller bandage on for 3 to 5 days. The implant(s) will make your menstrual bleeding highly irregular and unpredictable for the entire time you use it. You may bleed more, less, or not at all. In between periods, expect to have spotting. There is a minimal weight gain with this method of 2-4 lbs. This method was not tested in significantly overweight women. We do not know if progestin-only implants will protect them as well as they protect women with normal weight. You must report to a health care provider to have an implant removed.

**BENEFITS**

- A highly effective method of birth control
- Protection that lasts for 3 years (Implanon®)
- Lactation use: After milk supply is well established
- Reversible with rapid return to fertility
- May be appropriate when estrogen is contraindicated

**CONTRAINDICATIONS** If you have the following conditions, you cannot use the implant or the risks outweigh the benefits

- Pregnancy (not appropriate if already pregnant)
- Current or past history of thrombosis or thromboembolic disorders
- After placement, client develops ischemic heart disease or stroke
- After placement, develops migraine with aura (any age)
- Benign or malignant hepatic tumors
- Use of rifampicin or anticonvulsants
- Known or suspected or history of breast cancer
- Active liver disease or severe decompensated cirrhosis of the liver
- Positive antiphospholipid antibodies as seen with SLE
- Undiagnosed abnormal genital bleeding
- Allergy to the components of the product

**CAUTION** If you have the following conditions, the benefits generally will outweigh the risks

- Multiple risk factors for cardiovascular disease
- Blood pressure $\geq$ 160/100
- Hypertension related diseases and renal disease
- Vascular disease
- History of deep vein thrombosis
- Major surgery with prolonged immobilization
- Known hyperlipidemias
- Usual menstrual bleeding pattern is irregular
- Usual menstrual bleeding is heavy or prolonged
- Prior to placement, history positive for ischemic heart disease or impaired function, stroke but no current disease
- Breastfeeding less than one month
- Solid organ transplant
- Mild compensated cirrhosis of the liver
- Untreated cervical intraepithelial neoplasia
- Cervical cancer awaiting treatment
- Undiagnosed breast mass
- On antiretroviral therapy or griseofulvin
- Insulin and non-insulin dependent diabetes
- Diabetes with kidney, retinal, nerve, or vascular damage
- Diabetes of more than 20 years duration
- Gallbladder disease
- Prior to placement, history of migraine with or without aura (any age)
- Severe thrombocytopenia as seen in SLE

**SIDE EFFECTS**

- Highly irregular, unpredictable menstrual bleeding & spotting
- Weight gain of 2-4 lbs
- Mood swings
- Headache
- Acne
- Depression

**MAJOR PROBLEMS:** These are **NOT NORMAL** and should be reported to the clinic or hospital at once.

- Heavy vaginal bleeding
- Severe or repeated painful headaches
- Blurred, double or loss of vision
- Coughing up blood, shortness of breath
- Severe chest, stomach, or leg pain
- Breast lump
- Pregnancy symptoms
- Allergic reaction (rare)
- Severe depression or symptoms such as fatigue, insomnia, sadness etc.
- Jaundice
- Pain, pus, or bleeding at insertion site

Departamento de Salud de Tennessee
Programa de planificación familiar

**CONSENTIMIENTO PARA IMPLANTES SÓLO DE PROGESTINA**

**IMPORTANTE:** *Asegúrese de entender toda la información antes de firmar*.

Se me explicaron todos los procedimientos necesarios para poder recibir servicios de planificación familiar. Recibí información sobre todos los métodos anticonceptivos, incluida la abstinencia, y los riesgos y las ventajas de cada uno. Entiendo que ningún método es 100% eficaz para evitar el embarazo, y que puede haber efectos secundarios. Reconozco que es importante seguir las instrucciones que recibí y volver a las revisiones en las fechas programadas.

Entiendo toda la información que recibí. Estoy de acuerdo en participar como paciente en el programa de planificación familiar, recibir todo tratamiento y lo necesario en un examen de planificación familiar. He optado voluntariamente por los **implantes sólo de progestina** como método anticonceptivo para mí. Tuve oportunidad de hacer preguntas acerca de los **implantes sólo de progestina** y de este formulario de consentimiento. Acepto los riesgos de este método, y entiendo que puede haber otros riesgos aún desconocidos. Recibí verbalmente y por escrito las instrucciones para el uso de este método anticonceptivo. Se me entregó una copia de este formulario de consentimiento como referencia según sea necesario. Si tengo preguntas, puedo llamar a la clínica durante horas hábiles.

Entiendo que los **implantes sólo de progestina** no evitan que contraiga una enfermedad de transmisión sexual (ETS), ni el virus del SIDA. Se me aconsejó la práctica de 'relaciones sexuales seguras' mediante el uso de preservativos, especialmente si tengo más de una pareja sexual, o si es posible que mi pareja haya estado expuesta a una ETS. Aun cuando el uso de este segundo método no garantiza que mi pareja o yo contraigamos una ETS, entiendo que es posible que reduzca el riesgo.

Me aseguraron que toda la información que proporcione a alguna persona en esta clínica es confidencial y no se divulgará ni enviará a nadie, a menos que yo otorgue permiso por escrito, excepto según sea necesario para prestar servicios en la clínica o lo exija la ley. Con mi firma a continuación, indico que leí **ambos lados** de este formulario y que entiendo el contenido.

En caso de una emergencia o un problema grave, puedo llamar a la clínica al _____
o a la sala de emergencias al _____.

| Fecha | Firma del paciente | Firma del testigo |
|---|---|---|
| _____ | _____ | _____ |

Revisado:

| Fecha | Firma del paciente | Firma del testigo |
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| _____ | _____ | _____ |
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**MATERIAL DIDÁCTICO: Implantes sólo de progestina**

**EXPLICACIÓN**: Los implantes sólo de progestina consisten en una o más varillas flexibles que se colocan debajo de la piel del brazo. Estos dispositivos liberan progestina, una hormona que evita el embarazo. Es un método muy eficaz: por cada 100 mujeres que lo usa, hay menos de un embarazo (0.3%) al año (datos de Implanon®). Las progestinas pueden inhibir la ovulación, hacer que la secreción mucosa del cuello del útero sea más densa y alterar temporalmente el revestimiento del útero. La mujer recupera la fecundidad inmediatamente después de quitar el implante. Implanon® es un implante de una varilla sola que puede evitar el embarazo por 3 años. Es posible que haya otros implantes disponibles. No escoja este método si sabe que desea tener un hijo antes de que termine la vida útil del implante. Los implantes no previenen las enfermedades de transmisión sexual (ETS) y deben colocarse correctamente. De lo contrario, tal vez no eviten el embarazo y puede ser necesario extraerlos mediante cirugía en un quirófano. La inserción y extracción pueden causar dolor, hematomas, cicatrices e infección. El momento de inserción es importante para asegurarse de que usted no esté ya embarazada. Si actualmente usted no usa un método anticonceptivo con hormonas o un dispositivo intrauterino (DIU), o si no ha tenido un parto en las últimas 4 semanas, la inserción se programará para los primeros 5 días del período menstrual, y tendrá que usar preservativos durante los primeros 7 días posteriores a la inserción. Después de la colocación del implante, debe sentirlo justo bajo la piel del brazo. Si no lo siente, acuda de inmediato al proveedor de atención médica. Recuerde mantener la venda limpia y seca. Deje la venda superior colocada por 24 horas y la más pequeña de 3 a 5 días. Durante el tiempo que use los implantes, el sangrado menstrual será muy irregular e impredecible. Es probable que usted sangre más, menos o que no sangre nada. También puede ocurrir que tenga manchas de sangre entre períodos. Con este método, hay un aumento mínimo de peso de 0.9 a 1.8 kg (de 2 a 4 libras). Este método no se probó en mujeres con un sobrepeso considerable; por lo tanto, no se sabe si los implantes sólo de progestina las protegen tanto como a las mujeres de peso normal. Usted debe acudir a un proveedor de atención médica para que extraiga el implante.

**VENTAJAS**

- Método anticonceptivo muy eficaz
- Protección que dura 3 años (Implanon®)
- Uso en lactancia: después de que el suministro de leche esté bien establecido
- Reversible con pronta recuperación de la fecundidad
- Puede ser adecuado cuando el estrógeno está contraindicado

**CONTRAINDICACIONES** Si usted tiene los problemas a continuación, no puede usar el implante, o los riesgos a los que se expone son mayores que las ventajas.

- Embarazo (no es adecuado si ya está embarazada)
- Trombosis o trastornos tromboembólicos actuales o antecedentes de estos
- Después de la colocación, cardiopatía isquémica o accidente cerebrovascular
- Después de la colocación, dolor de cabeza tipo migraña con aura (a cualquier edad)
- Tumores de hígado benignos o malignos
- Uso con rifampicina o anticonvulsivos
- Cáncer de mama confirmado, o antecedentes o sospechas del mismo
- Enfermedad hepática o cirrosis hepática descompensada grave
- Anticuerpos antifosfolípidos positivos como se ven en el lupus eritematoso sistémico (LES)
- Sangrado genital anormal sin diagnóstico
- Alergia a los componentes del producto

**PRECAUCIÓN** Si usted tiene los problemas a continuación, generalmente, las ventajas de este método superan los riesgos.

- Varios factores de riesgo de enfermedad cardiovascular
- Presión arterial $\geq$ 160/100
- Enfermedades relacionadas con hipertensión y enfermedad renal
- Enfermedad vascular
- Antecedentes de trombosis venosa profunda
- Cirugía mayor con inmovilización prolongada
- Hiperlipidemias conocidas
- Sangrado menstrual habitual irregular
- Sangrado menstrual habitual abundante o prolongado
- Antes de la colocación, antecedentes confirmados de cardiopatía isquémica o función disminuida, accidente cerebrovascular sin enfermedad actual
- Menos de un mes de lactancia
- Trasplante de órgano sólido
- Cirrosis hepática compensada leve
- Neoplasia intraepitelial cervical sin tratamiento
- Cáncer de cuello de útero en espera de tratamiento
- Tumor en los senos sin diagnóstico
- En tratamiento antirretroviral o con griseofulvina
- Diabetes con y sin dependencia de insulina
- Diabetes con daño renal, retinal, nervioso o vascular
- Diabetes por más de 20 años
- Enfermedad de la vesícula biliar
- Antes de la colocación, antecedentes de dolor de cabeza tipo migraña con o sin aura (a cualquier edad)
- Trombocitopenia grave como se ve en el lupus eritematoso sistémico (LES)

**EFECTOS SECUNDARIOS**

- Sangrado menstrual muy irregular e impredecible y manchas de sangre
- Aumento de peso de 0.9 a 1.8 kg (de 2 a 4 libras)
- Cambios de estado de ánimo
- Dolor de cabeza
- Acné
- Depresión

**PROBLEMAS IMPORTANTES:** Estos **NO SON NORMALES** y debe informarse de inmediato de ellos a la clínica u hospital.

- Sangrado vaginal abundante
- Dolores de cabeza intensos o recurrentes
- Visión borrosa o doble, o pérdida de visión
- Tos con sangre, disnea
- Dolor intenso de pecho, de estómago o de piernas
- Tumor en los senos
- Síntomas de embarazo
- Reacción alérgica (inusual)
- Depresión aguda o síntomas como fatiga, insomnio, tristeza, etc.
- Ictericia
- Dolor, pus o sangrado en el lugar de la inserción

# CONSENT FOR LEVONORGESTREL RELEASING INTRAUTERINE DEVICE

**IMPORTANT:** *Make sure that you understand all information before signing.*

All procedures necessary for me to receive family planning services have been explained to me. I have been given information about all methods of birth control, including abstinence, and the risks and benefits of each. I understand that no method is 100% effective against pregnancy and that undesirable side effects may occur. I recognize that it is important to follow instructions given to me and to return for checkups on schedule.

I understand all the information provided. I consent to be a patient in the family planning program, to receive all that is required in a family planning examination, and any treatment that is deemed necessary. I have voluntarily chosen the **levonorgestrel-releasing intrauterine device** (**LNG IUD**) as my method of birth control. I have been given the chance to ask questions about the **LNG IUD** and about this consent form. I accept the risks of this method and understand there may be other risks that the clinic is not aware of. Instructions for the use of this birth control method have been given to me in writing and orally. I have been given a copy of this consent form to refer to as needed. I may call the clinic during office hours if I have questions.

I understand that the **LNG IUD** will not prevent me from getting a sexually transmitted disease (STD), including the AIDS virus. I have been advised to practice "safer sex" by also using condoms, especially if I have sex with more than one partner, or if I or my partner has possibly been exposed to an STD. Although the use of this second method does not insure that I or my partner will not get an STD, it may reduce the risk.

I was assured that all information that I give to anyone in this clinic is confidential and will not be given or sent to anyone, unless I give written permission, except as necessary to provide services at the clinic or as required by law. By my signature below, I indicate that I have read **both sides** of this form and that I understand its contents.

In case of an emergency or severe problem, I can call the clinic at _____ or the emergency room at_____.

| Date | Patient Signature | Witness Signature |
|---|---|---|
| _____ | _____ | _____ |

Reviewed:

| Date | Patient Signature | Witness Signature |
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| _____ | _____ | _____ |
| _____ | _____ | _____ |

# TEACHING TOOL – LEVONORGESTREL-RELEASING INTRAUTERINE DEVICE (LNG IUD)

**EXPLANATION**: The LNG IUD is a T-shaped device that releases a low dose of levonorgestrel into the uterus. It is placed in the uterus by a health care professional. The LNG IUD is replaced every 5 years. It is recommended for women who have at least one child. Initially the LNG IUD releases 20 micrograms of levonorgestrel daily. This decreases to 14 micrograms daily after 5 years of use. Both the perfect and typical use failure rates in the first year are 0.2%. The LNG IUD works by thickening cervical mucus to prevent the passage of sperm into the uterus, inhibition of the ability of the sperm to fertilize an egg, and changes to the endometrium. Inhibition of ovulation is its secondary means of preventing pregnancy. There is a 1:1000 risk of perforation at the time of insertion. Strings extend from the LNG IUD into the vagina. You will check for the strings in order to insure that you have not expelled the LNG IUD. If you cannot find the strings or if they are longer or shorter or if you feel the plastic of the LNG IUD, you need to use a back-up method of contraception such as condoms or spermicide, and return to the clinic as soon as possible. If you have unprotected sex, contact the clinic within 72 hours for emergency contraception. Women with valvular heart disease should receive prophylactic antibiotics prior to insertion or removal of the LNG IUD. IUDs do not cause pelvic inflammatory disease (PID). PID is caused by STIs such as gonorrhea and chlamydia which can cause infertility and in rare instances, death. Your risk of PID increases if you or your partner has multiple sex partners. The risk of acquiring PID from any type of organism is highest the first 3 weeks after insertion of the IUD. Women requiring insulin, anticoagulants, or chronic corticosteroid therapy must be monitored carefully for infection. <u>If you have any of the problems listed below, you must report to the nearest health care provider at once.</u> If you become pregnant with the IUD in place (rare), you are at particular risk for severe PID. It is recommended that the IUD be removed right away if you become pregnant. This most likely will lead to a miscarriage. Infection during pregnancy with an IUD in place can lead to your death. Elective abortion may be needed. Also, if a pregnancy does occur it is likely to be an ectopic pregnancy. This is life threatening also. You may have your IUD removed at any time.

**BENEFITS**

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|---|---|
| Significantly decreased menstrual bleeding and cramping | Does not interfere with sexual spontaneity |
| Extremely effective contraception | Effective for 5 years |

**CONTRAINDICATIONS**

| | |
|---|---|
| Pregnancy | Develops migraine headache with focal neurologic symptoms at any age while on method |
| A previous IUD that has not yet been removed | Unexplained genital bleeding |
| Current, or in the last 3 months, puerperal sepsis or septic abortion | Benign or malignant trophoblastic disease |
| Distortions of the uterine cavity | Cervical cancer or unresolved abnormal Pap smear. Endometrial cancer |
| Current deep vein thrombosis or pulmonary embolism | Current or suspected or history of breast cancer |
| Develops ischemic heart disease while using method | Increased risk of STDs. Current PID or history of PID unless there has been a subsequent pregnancy |
| HIV/AIDS or any condition or treatment leading to immunosuppression | Untreated acute cervicitis, vaginitis, vaginosis, STD or other lower genital tract infection until infection is controlled |
| Acute liver disease or liver tumor (benign or malignant) | Hypersensitivity to any component of the product |
| Positive or unknown antiphospholipid antibodies as seen with SLE | Complicated solid organ transplant |

**SIDE EFFECTS**

| | |
|---|---|
| Initially there can be more break through bleeding | Vasovagal response (nausea/fainting) at the time of insertion or removal |
| Headache, acne, breast tenderness in first few months | Discomfort at time of insertion or removal |
| Strings occasionally uncomfortable for partner | Ovarian cysts that usually go away on their own |

**MAJOR PROBLEMS:** These are **NOT NORMAL** and should be reported to the clinic or hospital at once.

| | |
|---|---|
| Low abdominal pain (sign of ectopic or infection) | Exposure to gonorrhea/chlamydia/any STD |
| Vaginal discharge/odor (sign of infection) | No strings felt, or longer strings, or plastic felt |
| Painful sex | Unusual bleeding (sign of ectopic or infection) |
| Fever or chills (sign of infection) | Missed period |
| Any signs of pregnancy | Flu-like illness (sign of infection) |

Departamento de Salud de Tennessee
Programa de planificación familiar

# CONSENTIMIENTO PARA EL DISPOSITIVO INTRAUTERINO QUE LIBERA LEVONORGESTREL

**IMPORTANTE:** *Asegúrese de entender toda la información antes de firmar.*

Se me explicaron todos los procedimientos necesarios para poder recibir servicios de planificación familiar. Recibí información sobre todos los métodos anticonceptivos, incluida la abstinencia, y los riesgos y las ventajas de cada uno. Entiendo que ningún método es 100% eficaz para evitar el embarazo, y que puede haber efectos secundarios. Reconozco que es importante seguir las instrucciones que recibí y volver a las revisiones en las fechas programadas.

Entiendo toda la información que recibí. Estoy de acuerdo en participar como paciente en el programa de planificación familiar, recibir todo tratamiento y lo necesario en un examen de planificación familiar. Elegí voluntariamente el **dispositivo intrauterino que libera levonorgestrel** (**DIU-LNG**) como método anticonceptivo. Tuve oportunidad de hacer preguntas acerca del **DIU-LNG** y de este formulario de consentimiento. Acepto los riesgos de este método, y entiendo que puede haber otros riesgos que la clínica desconoce. Recibí verbalmente y por escrito las instrucciones para el uso de este método anticonceptivo. Se me entregó una copia de este formulario de consentimiento como referencia según sea necesario. Si tengo preguntas, puedo llamar a la clínica durante horas hábiles.

Entiendo que el **DIU-LNG** no evita que contraiga una enfermedad de transmisión sexual (ETS), ni el virus del SIDA. Se me aconsejó la práctica de 'relaciones sexuales seguras' mediante el uso de preservativos, especialmente si tengo más de una pareja sexual, o si es posible que mi pareja haya estado expuesta a una ETS. Aun cuando el uso de este segundo método no garantiza que mi pareja o yo contraigamos una ETS, es posible que reduzca el riesgo.

Me aseguraron que toda la información que proporcione a alguna persona en esta clínica es confidencial y no se divulgará ni enviará a nadie, a menos que yo otorgue permiso por escrito, excepto según sea necesario para prestar servicios en la clínica o lo exija la ley. Con mi firma a continuación, indico que leí **ambos lados** de este formulario y que entiendo el contenido.

En caso de una emergencia o un problema grave, puedo llamar a la clínica al _____ o a la sala de emergencias al _____.

| | | |
|---|---|---|
| _____ | _____ | _____ |
| Fecha | Firma del paciente | Firma del testigo |

Revisado

| | | |
|---|---|---|
| _____ | _____ | _____ |
| Fecha | Firma del paciente | Firma del testigo |
| _____ | _____ | _____ |
| Fecha | Firma del paciente | Firma del testigo |

# MATERIAL DIDÁCTICO: DISPOSITIVO INTRAUTERINO QUE LIBERA LEVONORGESTREL (DIU-LNG)

**EXPLICACIÓN**: El DIU-LNG es un dispositivo en forma de T que libera una dosis baja de levonorgestrel en el útero. Un profesional de atención médica lo coloca en el útero. El dispositivo se reemplaza cada 5 años, y se recomienda a las mujeres que tienen al menos un hijo. Al principio, el DIU-LNG libera 20 microgramos de levonorgestrel diarios. Después de 5 años de uso, baja a 14 microgramos diarios. El primer año, las tasas de ineficacia perfecta y la típica son de 0.2%. El DIU-LNG funciona al hacer más densa la secreción mucosa del cuello del útero para evitar el paso del esperma a éste, inhibir la capacidad del esperma para fecundar el óvulo y alterar el endometrio. La inhibición de la ovulación es un medio secundario para evitar el embarazo. Existe un riesgo de 1 en 1,000 casos de perforación durante la inserción. Los hilos van desde el DIU-LNG hasta la vagina. Usted revisará los hilos para verificar que el DIU-LNG no haya sido expulsado. Si no encuentra los hilos, o si son más largos o más cortos, o si siente el plástico del DIU-LNG, es necesario que use un método anticonceptivo de refuerzo, como preservativos o espermicida, y que acuda a la clínica lo antes posible. Si tiene relaciones sexuales sin protección, comuníquese con la clínica en menos de 72 horas para recibir un anticonceptivo de emergencia. Las mujeres que tienen una valvulopatía deben recibir antibióticos profilácticos antes de insertar o extraer el DIU-LNG. El DIU no causa la enfermedad pélvica inflamatoria (EPI). La EPI es causada por una infección de transmisión sexual (ITS) como gonorrea y clamidia que pueden causar esterilidad y, en casos inusuales, la muerte. El riesgo de contraer la EPI aumenta si usted o su pareja tienen varias parejas sexuales. Asimismo, el riesgo contraer la EPI de algún tipo de organismo es mayor en las primeras 3 semanas después de insertar el DIU. Se debe controlar con atención a las mujeres que necesitan insulina, anticoagulantes o tratamiento prolongado con corticoesteroides para detectar infecciones. Si tiene alguno de los problemas que se indican más adelante, debe acudir de inmediato al proveedor de atención médica más cercano. Si se embaraza con el DIU colocado (inusual), tiene un riesgo particular de contraer EPI grave, y se recomienda extraer el DIU de inmediato. Es muy probable que esto cause un aborto espontáneo. Una infección durante el embarazo con un DIU colocado puede causarle la muerte. Puede ser necesario un aborto provocado. Además, si hay un embarazo, es probable que sea un embarazo ectópico, el cual también es potencialmente mortal. El DIU puede ser extraído en cualquier momento.

**VENTAJAS**

- Disminuye considerablemente el sangrado y los cólicos menstruales.
- Es un anticonceptivo sumamente eficaz.
- No interfiere en la espontaneidad sexual.
- Tiene una eficacia de 5 años.

**CONTRAINDICACIONES**

- Embarazo
- Un DIU anterior que no haya sido extraído aún
- Infección puerperal o aborto séptico actual o en los últimos 3 meses
- Distorsiones de la cavidad uterina
- Trombosis venosa profunda o embolia pulmonar actuales
- Cardiopatía isquémica durante el uso
- VIH/SIDA o toda enfermedad o tratamiento que cause inmunosupresión
- Enfermedad hepática aguda o tumor de hígado (benigno o maligno)
- Anticuerpos antifosfolípidos positivos o desconocidos como se ven en el lupus eritematoso sistémico (LES)
- Dolor de cabeza tipo migraña con síntomas neurológicos focales a cualquier edad durante el uso
- Hemorragia genital sin explicación
- Enfermedad trofoblástica benigna o maligna
- Cáncer de cuello de útero o Papanicolau anormal pendiente. Cáncer de ovario o de endometrio
- Cáncer de mama actual, o antecedentes o sospechas del mismo
- Mayor riesgo de ETS. EPI actual o antecedentes de EPI, a menos que haya habido un embarazo intrauterino posterior
- Cervicitis, vaginitis, vaginosis, ETS u otra infección del aparato genital inferior agudas no tratadas, hasta que se controle la infección
- Hipersensibilidad a algún componente del producto
- Trasplante complicado de un órgano sólido

**EFECTOS SECUNDARIOS**

- Más hemorragias intermenstruales (metrorragia) al principio
- Dolor de cabeza, acné o mastalgia en los primeros meses
- Incomodidad ocasional de la pareja debido a los hilos
- Respuesta vasovagal (náusea o desmayo) durante la inserción o la extracción
- Malestar durante la inserción o la extracción
- Quistes ováricos que desaparecen por sí solos

**PROBLEMAS IMPORTANTES:** Estos **NO SON NORMALES** y debe informarse de inmediato de ellos a la clínica u hospital.

- Dolor en la parte baja del abdomen (señal de embarazo ectópico o infección)
- Secreción u olor vaginal (señal de infección)
- Relaciones sexuales dolorosas
- Fiebre o escalofríos (señal de infección)
- Cualquier señal de embarazo
- Exposición a gonorrea, clamidia o alguna ETS
- Los hilos se sienten más largos o no se sienten, o se siente el plástico
- Hemorragia inusual (señal de embarazo ectópico o infección)
- Falta de menstruación (amenorrea)
- Enfermedad similar a la gripe (señal de infección)

Tennessee Department of Health
Family Planning Program

# CONSENT TO FAMILY PLANNING SERVICES FOR NON-PRESCRIPTIVE METHODS

**IMPORTANT:** *Make sure that you understand all information before signing.*

All procedures necessary for me to receive family planning services have been explained to me. I have been told about all methods of birth control, including abstinence, and the risks and benefits of each. I understand that no method is 100% effective against pregnancy and that undesirable side effects may occur. I recognize that it is important to follow instructions given to me and to return for checkups on schedule.

I understand all the information provided. I consent to be a patient in the family planning program and to receive all that is required in a family planning examination and any treatment that is deemed necessary. I have voluntarily chosen a **NON-PRESCRIPTIVE METHOD** for my method of birth control. I have been given the chance to ask questions about the non-prescriptive method and about this consent form. I have been given a copy of this consent form to refer to as needed. I may call the clinic during office hours if I have questions.

I have been advised to practice "safer sex" by using condoms, especially if I have sex with more than one partner, or if I or my partner has possibly been exposed to an STD. Although the use of condoms does not insure that I or my partner will not get an STD, it may reduce the risk.

I was assured that all information that I give to anyone in this clinic is confidential and will not be given or sent to anyone, unless I give written permission, except as necessary to provide services at the clinic or as required by law. By my signature below, I indicate that I have read this form and that I understand its contents.

In case of an emergency or severe problem, I can call the clinic at _____ or the emergency room at_____.

| Date | Patient Signature | Witness Signature |
|---|---|---|
| | | |

Reviewed:

| Date | Patient Signature | Witness Signature |
|---|---|---|
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Departamento de Salud de Tennessee
Programa de Planificación Familia

CONSENTIMIENTO PARA SERVICIOS

**PLANICACIÓN FAMILIAR DE MÉTODOS SIN RECETA**

**IMPORTANTE:** *Asegúrese de que usted entiende toda la información antes de firmar.*

Me explicaron todos los procedimientos necesarios para que yo pueda recibir servicios de planificación familiar. Además recibí información sobre todos los métodos del control de la natalidad, incluyendo la abstinencia, y los riesgos y beneficios de cada uno. Entiendo que ningún método contra el embarazo es 100% efectivo y que yo pudiera experimentar efectos secundarios indeseables. Reconozco que es importante que yo siga las instrucciones que se me dieron y que regrese para los chequeos de rutina en el momento indicado.

Entiendo toda la información provista. Consiento ser paciente del programa de planificación familiar, recibir todo lo que se requiera en un examen de planificación familiar y recibir el tratamiento que sea necesario. Yo he escogido voluntariamente un **MÉTODO SIN RECETA** como mi método para el control de la natalidad. Me dieron la oportunidad de hacer preguntas sobre el método sin receta y sobre este formulario de consentimiento. Acepto los riesgos que este método conlleva y entiendo que pudieran haber otros riesgos que la clínica desconoce. Me dieron instrucciones escritas y orales sobre este método para el control de la natalidad. Me entregaron una copia de este formulario de consentimiento para mi referencia. Yo puedo comunicarme con la clínica durante horas laborables si tuviera alguna pregunta.

Me aconsejaron que practique "relaciones sexuales seguras" utilizando condones, especialmente si tengo relaciones con más de una persona, o si existe la posibilidad de que yo o mi pareja haya sido expuesta a una ETS. Aunque el uso de condones no garantiza que yo o mi pareja evite contraer una ETS, puede que reduzca el riesgo.

Se me aseguró que toda la información que yo dé al personal de esta clínica es confidencial y que no se divulgará ni se enviará a nadie, a menos que yo dé consentimiento por escrito, excepto cuando sea necesario para proveer servicios en la clínica o cuando sea requerido por ley. Por medio de mi firma abajo, yo indico que he leído este formulario y que entiendo su contenido.

En caso de emergencia o problema grave, yo puedo llamar a la clínica al _____ o a la sala de emergencia al _____.

| | | |
|---|---|---|
| _____ | _____ | _____ |
| Fecha | Firma del Paciente | Firma del Testigo |
| Revisado: _____ | _____ | _____ |
| Fecha | Firma del Paciente | Firma del Testigo |
| _____ | _____ | _____ |
| Fecha | Firma del Paciente | Firma del Testigo |

Tennessee Department of Health
Family Planning Program
**CONSENT FOR THE CONTRACEPTIVE PATCH**

**IMPORTANT:** *Make sure that you understand all information before signing.*

All procedures necessary for me to receive family planning services have been explained to me I have been given information about all methods of birth control, including abstinence, and the risks and benefits of each. I understand that no method is 100% effective against pregnancy and that undesirable side effects may occur. I recognize that it is important to follow instructions given to me and to return for checkups on schedule.

I understand all the information provided. I consent to be a patient in the family planning program, to receive all that is required in a family planning examination, and any treatment that is deemed necessary. I have voluntarily chosen the **contraceptive patch** as my method of birth control. I have been given the chance to ask questions about the **contraceptive patch** and about this consent form. I accept the risks of this method and understand there may be other risks that the clinic is not aware of. Instructions for the use of this birth control method have been given to me in writing and orally. I have been given a copy of this consent form to refer to as needed. I may call the clinic during office hours if I have questions.

I understand that the **contraceptive patch** will not prevent me from getting a sexually transmitted disease (STD), including the AIDS virus. I have been advised to practice "safer sex" by also using condoms, especially if I have sex with more than one partner, or if I or my partner has possibly been exposed to an STD. Although the use of this second method does not insure that I or my partner will not get an STD, it may reduce the risk.

I was assured that all information that I give to anyone in this clinic is confidential and will not be given or sent to anyone, unless I give written permission, except as necessary to provide services at the clinic or as required by law. By my signature below, I indicate that I have read **both sides** of this form and that I understand its contents.

In case of an emergency or severe problem, I can call the clinic at _____ or the emergency room at_____.

| Date | Patient Signature | Witness Signature |
|---|---|---|

Reviewed:

| Date | Patient Signature | Witness Signature |
|---|---|---|
| Date | Patient Signature | Witness Signature |

# TEACHING TOOL-THE CONTRACEPTIVE PATCH

**EXPLANATION: The contraceptive patch** prevents the ovary from releasing an egg each month. Mucus in the cervix gets thicker and helps keep sperm out of the uterus. With perfect use only 0.3% - 1% of women will become pregnant. The chance of becoming pregnant increases with incorrect use and when you weigh 198 lbs or more. The contraceptive patch is worn for 3 weeks followed by a patch-free week during which you get your period. The patch can be started in 2 ways: Apply the first patch on the day your period begins. This becomes the day of the week when each new patch is applied. It is called your patch change day. **OR** apply the first patch on Sunday after your period begins (If your period starts on Sunday, begin that day). Sunday will be your patch change day. Your protection from pregnancy begins after you have worn your first patch for 7 days. The patch does not protect you from sexually transmitted diseases (STDs). Certain medications will make the patch less effective. These include anti-seizure drugs such as barbiturates, phenytoin sodium, carbamazepine, felbamate, oxcarbazepine, and topiramate; the TB medication rifampin; and the antifungal griseofulvin. Phenylbutazone, a non-steroidal anti-inflammatory and St. John's Wort, an herbal preparation, may also decrease the effectiveness of the patch as can some anti-HIV medications. Laboratory tests may be affected. You can discontinue the patch at any time simply by removing it. Be sure you receive written instructions on how, when, and where to apply your patch and what to do if you are late changing your patch or your patch becomes detached. Emergency contraception is available if you have had unprotected sex. You should not use the patch if you are hypersensitive to any component of the product. No woman using a hormonal method of contraception should smoke cigarettes.

**BENEFITS**

- Regular periods with less cramping/bleeding
- Reduced risk of ovarian and uterine cancer
- Fewer benign breast lumps and ovarian cysts
- Safe and effective method of birth control
- Less acne
- Does not require daily attention

**CONTRAINDICATIONS**

- Controlled hypertension under treatment, or BP ≥140/90 on 3 visits or BP 160+/100+ on one visit
- History of or current or low or high risk factors for deep vein thrombosis, pulmonary embolism, or other thromboembolic vascular disease or known thrombogenic mutation
- Major surgery with prolonged immobilization
- History of or current ischemic heart disease/heart attack, complicated heart valve disease, cardiomyopathy, angina or stroke or multiple CV risk factors
- Migraine with focal neurologic symptoms, any age
- Migraines with no focal neurologic symptoms age≥ 35, or that start with the use of COCs any age
- Known hyperlipidemia (Routine screening not required)
- Positive Antiphospholipid Antibodies as may be seen with SLE
- Complicated solid organ transplantation
- Pregnancy, breastfeeding and less than 1 month after delivery, or < 3wks after delivery if not breastfeeding
- Cigarette smokers age 35 or older
- History of or current gallbladder disease or past history with the use of COCs and no cholecystectomy
- All types of liver disease; liver problems during a pregnancy or while using birth control pills
- Current or past history of breast cancer
- Diabetes > 20 years, or end organ damage, or with any other accompanying vascular disease
- Unexplained vaginal bleeding
- Extensive IBD with VTE risk factors
- Certain HIV drugs, anticonvulsants, and rifampicin

**SIDE EFFECTS**

- Spotting between periods
- Mood changes
- Significant breast tenderness
- Changes in contact lens prescription
- Headaches
- Application site irritation
- Menstrual cramps/abdominal pain
- Significant nausea

**MAJOR PROBLEMS:** These are **NOT NORMAL** and should be reported to the clinic or hospital at once.

- Chest pain and shortness of breath
- Speech or vision changes
- Muscle weakness or numbness
- Sudden severe pain or soreness in leg
- Severe headaches, blackouts, dizziness
- Severe abdominal pain
- Skin turns yellow (jaundice)
- Heavy bleeding between periods
- Severe depression

Departamento de Salud de Tennessee
Programa de planificación familiar
**CONSENTIMIENTO PARA EL PARCHE ANTICONCEPTIVO**

**IMPORTANTE:** *Asegúrese de entender toda la información antes de firmar*.

Se me explicaron todos los procedimientos necesarios para poder recibir servicios de planificación familiar. Recibí información sobre todos los métodos anticonceptivos, incluida la abstinencia, y los riesgos y las ventajas de cada uno. Entiendo que ningún método es 100% eficaz para evitar el embarazo, y que puede haber efectos secundarios. Reconozco que es importante seguir las instrucciones que recibí y volver a las revisiones en las fechas programadas.

Entiendo toda la información que recibí. Estoy de acuerdo en participar como paciente en el programa de planificación familiar, recibir todo tratamiento y lo necesario en un examen de planificación familiar. He optado voluntariamente por el **parche** como método anticonceptivo para mí. Tuve oportunidad de hacer preguntas acerca del **parche anticonceptivo** y de este formulario de consentimiento. Acepto los riesgos de este método, y entiendo que puede haber otros riesgos que la clínica desconoce. Recibí verbalmente y por escrito las instrucciones para el uso de este método anticonceptivo. Se me entregó una copia de este formulario de consentimiento como referencia según sea necesario. Si tengo preguntas, puedo llamar a la clínica durante horas hábiles.

Entiendo que el **parche anticonceptivo** no evita que contraiga una enfermedad de transmisión sexual (ETS), ni el virus del SIDA. Se me aconsejó la práctica de 'relaciones sexuales seguras' mediante el uso de preservativos, especialmente si tengo más de una pareja sexual, o si es posible que mi pareja haya estado expuesta a una ETS. Aun cuando el uso de este segundo método no garantiza que mi pareja o yo contraigamos una ETS, es posible que reduzca el riesgo.

Me aseguraron que toda la información que proporcione a alguna persona en esta clínica es confidencial y no se divulgará ni enviará a nadie, a menos que yo otorgue permiso por escrito, excepto según sea necesario para prestar servicios en la clínica o lo exija la ley. Con mi firma a continuación, indico que leí **ambos lados** de este formulario y que entiendo el contenido.

En caso de una emergencia o un problema grave, puedo llamar a la clínica al _____ o a la sala de emergencias al _____.

| Fecha | Firma del paciente | Firma del testigo |
|---|---|---|
| | | |

Revisado:

| Fecha | Firma del paciente | Firma del testigo |
|---|---|---|
| | | |
| | | |

# MATERIAL DIDÁCTICO: PARCHE ANTICONCEPTIVO

**EXPLICACIÓN:** El **parche anticonceptivo** impide que el ovario libere un óvulo cada mes. La secreción mucosa del cuello del útero se hace más densa y esto ayuda a bloquear el acceso del esperma al útero. Con el uso perfecto, sólo del 0.3% al 1% de las mujeres quedan embarazadas. La probabilidad de quedar embarazada aumenta si se usa incorrectamente o si la mujer pesa 90 kg (198 libras) o más. El parche anticonceptivo se usa tres semanas seguidas, con un intervalo de una semana sin uso, que corresponde al período de la menstruación. Hay dos maneras de iniciar el método: una es aplicar el primer parche el primer día de la menstruación, que se convierte en el día de la semana en que hay que cambiar el parche por uno nuevo. Este día se denomina el día del reemplazo del parche. **O BIEN,** la otra manera es aplicar el primer parche el día domingo después de que comenzó la menstruación (si su primer día de menstruación coincide con un domingo, empiece ese mismo día). El domingo será el día del reemplazo del parche. La protección para no quedar embarazada comienza 7 días después de haberse colocado el primer parche. El parche anticonceptivo no protege a la mujer del contagio de las enfermedades de transmisión sexual (ETS). Ciertos medicamentos disminuyen la eficacia del parche; entre ellos, los fármacos anticonvulsivos como barbitúricos, fenitoína, sodio, carbamazepina, felbamato, oxcarbazepina y topiramato; la rifampina para el tratamiento de la tuberculosis; y el antimicótico griseofulvina. Otros fármacos que también pueden reducir la eficacia del parche son la fenilbutazona, un antiinflamatorio no esteroideo; el producto fitoterapéutico St. John's Wort (hierba de San Juan); y ciertos medicamentos contra el VIH. El parche anticonceptivo puede alterar los resultados de las pruebas de laboratorio. Usted puede descontinuar el uso en cualquier momento con sólo quitarse el parche. Asegúrese de recibir instrucciones escritas sobre cómo, cuándo y dónde debe aplicarse el parche; y lo que debe hacer si lo cambia después del día que le corresponde o si el parche se desprende. Si tuvo relaciones sexuales sin protección, se cuenta con un anticonceptivo de emergencia. No debe usar el parche si es hipersensible a algún componente del producto. Las mujeres que usan un método anticonceptivo con hormonas no deben fumar.

**VENTAJAS**

- Menstruación regular con menos cólicos y menos sangrado
- Menor riesgo de cáncer de ovario y útero
- Menos tumores benignos en los senos y menos quistes de ovario
- Método anticonceptivo seguro y eficaz
- Menos acné
- No requiere atención diaria

**CONTRAINDICACIONES**

- Hipertensión arterial controlada con tratamiento, o PA $\geq$140/90 en 3 visitas o PA 160+/100+ en una visita
- Factores de alto o bajo riesgo actuales o antecedentes de trombosis venosa profunda, embolia pulmonar u otra enfermedad vascular tromboembólica o mutación trombogénica conocida
- Cirugía mayor con inmovilización prolongada
- Cardiopatía isquémica o infarto de miocardio actual o antecedentes de estas enfermedades; valvulopatía complicada, miocardiopatía, angina de pecho o accidente cerebrovascular o varios factores de riesgo de enfermedades cardiovasculares
- Dolor de cabeza tipo migraña con síntomas neurológicos focales, a cualquier edad
- Dolor de cabeza tipo migraña sin síntomas neurológicos focales en pacientes de 35 o más años, o que comienza con el uso de ACO a cualquier edad
- Hiperlipidemia conocida (no se necesita prueba de detección de rutina)
- Anticuerpos antifosfolípidos positivos como se pueden ver en el lupus eritematoso sistémico (LES)
- Trasplante complicado de un órgano sólido
- Embarazo; lactancia y menos de un mes después del parto; o menos de 3 semanas después del parto si no está lactando
- Fumadoras de 35 o más años de edad
- Enfermedad de la vesícula biliar actual o antecedentes de esta enfermedad, o antecedentes con el uso de AOC y sin colecistectomía
- Todos los tipos de enfermedades hepáticas; problemas del hígado durante el embarazo o con el uso de píldoras anticonceptivas
- Cáncer de mama actual o antecedentes del mismo
- Diabetes por más de 20 años, o daño terminal en órgano, o con cualquier otra enfermedad vascular acompañante
- Sangrado vaginal sin explicación
- Enfermedad inflamatoria intestinal extensa con factores de riesgo de tromboembolismo venoso (TEV)
- Ciertos medicamentos contra el VIH, anticonvulsivos y

**EFECTOS SECUNDARIOS**

- Sangrado entre períodos
- Cambios de estado de ánimo
- Mastalgia considerable
- Cambios en la receta de lentes de contacto
- Dolor de cabeza
- Irritación en el lugar de aplicación
- Cólicos menstruales y dolor abdominal
- Náusea considerable

**PROBLEMAS IMPORTANTES:** Estos **NO SON NORMALES** y debe informarse de inmediato de ellos a la clínica u hospital.

- Dolor en el pecho y disnea
- Cambios en el habla o la visión
- Debilidad o entumecimiento muscular
- Dolor intenso y repentino o hinchazón de piernas
- Dolores de cabeza intensos, desmayos o mareos
- Dolor abdominal intenso
- Piel amarillenta (ictericia)
- Sangrado abundante entre períodos
- Depresión aguda

**TENNESSEE DEPARTMENT OF HEALTH**

Family Planning Program

**CONSENT FOR PROGESTIN-ONLY INJECTABLE CONTRACEPTION**

**IMPORTANT:** *Make sure that you understand all information before signing.*

All procedures necessary for me to receive family planning services have been explained to me. I have been given information about all methods of birth control, including abstinence, and the risks and benefits of each. I understand that no method is 100% effective against pregnancy and that undesirable side effects may occur. I recognize that it is important to follow instructions given to me and to return for checkups on schedule.

I understand all the information provided. I consent to be a patient in the family planning program, to receive all that is required in a family planning examination, and any treatment that is deemed necessary. I have voluntarily chosen **Progestin-only injectable contraception** as my method of birth control. I have been given the chance to ask questions about **Progestin-only injectable contraception** and about this consent form. I accept the risks of this method and understand there may be other risks that the clinic is not aware of. Instructions for the use of this birth control method have been given to me in writing and orally. I have been given a copy of this consent form to refer to as needed. I may call the clinic during office hours if I have questions.

I understand that **Progestin-only injectable contraception** will not prevent me from getting a sexually transmitted disease (STD), including the AIDS virus. I have been advised to practice "safer sex" by also using condoms, especially if I have sex with more than one partner, or if I or my partner has possibly been exposed to an STD. Although the use of this second method does not insure that I or my partner will not get an STD, it may reduce the risk.

I was assured that all information that I give to anyone in this clinic is confidential and will not be given or sent to anyone, unless I give written permission, except as necessary to provide services at the clinic or as required by law. By my signature below, I indicate that I have read **both sides** of this form and that I understand its contents.

In case of an emergency or severe problem, I can call the clinic at _____ or the emergency room at_____.

| Date | Patient Signature | Witness Signature |
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Reviewed:

| Date | Patient Signature | Witness Signature |
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| Date | Patient Signature | Witness Signature |

**TEACHING TOOL - PROGESTIN-ONLY INJECTABLE CONTRACEPTION**

**EXPLANATION**: Progestin-only injectable contraception prevents the ovaries from releasing an egg each month. It also thickens mucus in the cervix which helps keep sperm from entering the uterus. About 0.3% of women using Progestin-only injectable contraception perfectly become pregnant. The risk of pregnancy for typical users is 3%. Progestin-only injectable contraception will prevent pregnancy for three months and you must return to the clinic for a shot every 13 weeks. If you do not get a shot every 13 weeks, you must use another form of birth control to protect against pregnancy. If you have unprotected sex, you can report to the health department for emergency contraception. Your first shot must be given in the first 5 days of your period, the first five days postpartum if not breastfeeding, or when the milk supply is well established if breastfeeding but no earlier than 1 month postpartum. You can stop taking Progestin-only injectable contraception at any time, but it may take several months for your periods to get back to normal. The shots do not change your ability to have a baby but they may delay it. Progestin-only injectable contraception decreases bone density especially during the early months of use. You will need to increase your calcium intake and participate in regular weight bearing exercise to maintain good bone health. Progestin-only injectable contraception has been associated with weight gain on average 5.4 lbs in the first year and increasing thereafter. You will need to monitor daily caloric intake and exercise regularly. Progestin-only injectable contraception will not work as well as it can if you are taking the drug Cytadren (aminoglutethimide), an anabolic steroid used to treat Cushing's Disease. Emergency contraception is available if you have had unprotected sex. Laboratory tests can be affected. Progestin-only injectable contraception does not prevent sexually transmitted diseases. No woman using a hormonal method of contraception should smoke cigarettes.

**BENEFITS**

- A highly effective method of birth control
- Protection that lasts for 13 weeks
- May be appropriate when estrogen is contraindicated
- Less bleeding and less cramps
- Many women will stop having periods
- Lower risk of endometrial cancer and ectopic pregnancy

**CONTRAINDICATIONS**

- Lactating and less than 1 month postpartum
- Lactating and milk supply not well established
- Multiple risks for cardiovascular disease
- BP>160/100
- Allergy or sensitivity to the product
- Current deep vein thrombosis or pulmonary embolism
- Current or history of ischemic heart disease
- Pregnancy
- History of stroke or other vascular disease
- Develops migraine with focal neurologic symptoms, at any age, while on method
- Unexplained vaginal bleeding
- Current or history of breast cancer
- Diabetes with nephropathy, retinopathy, neuropathy
- Diabetes with other vascular disease or > 20 years duration
- All types of liver disease or liver tumors
- Positive or unknown antiphospholipid antibodies as seen with SLE

**SIDE EFFECTS**

- Irregular periods, or no periods at all
- Decreased bone density
- Delay in return to fertility of up to 18 months
- Soreness from shot
- Weight gain
- Headaches
- Depressed mood
- Breast tenderness
- HDL cholesterol (good cholesterol) falls

**MAJOR PROBLEMS:** These are **NOT NORMAL** and should be reported to the clinic or hospital at once.

- Heavy vaginal bleeding
- Severe or repeated painful headaches
- Blurred, double or loss of vision
- Severe chest, stomach, or leg pain
- Pregnancy symptoms
- Allergic reaction (rare
- Severe depression
- Pain, pus, or bleeding at injection site

**DEPARTAMENTO DE SALUD DE TENNESSEE**

Programa de planificación familiar

**CONSENTIMIENTO PARA ANTICONCEPTIVO INYECTABLE SÓLO DE PROGESTINA**

**IMPORTANTE:** *Asegúrese de entender toda la información antes de firmar*.

Se me explicaron todos los procedimientos necesarios para poder recibir servicios de planificación familiar. Recibí información sobre todos los métodos anticonceptivos, incluida la abstinencia, y los riesgos y las ventajas de cada uno. Entiendo que ningún método es 100% eficaz para evitar el embarazo, y que puede haber efectos secundarios. Reconozco que es importante seguir las instrucciones que recibí y volver a las revisiones en las fechas programadas.

Entiendo toda la información que recibí. Estoy de acuerdo en participar como paciente en el programa de planificación familiar, recibir todo tratamiento y lo necesario en un examen de planificación familiar. He optado voluntariamente por el **anticonceptivo inyectable sólo de progestina** como método anticonceptivo para mí. Tuve oportunidad de hacer preguntas acerca del **anticonceptivo inyectable sólo de progestina** y de este formulario de consentimiento. Acepto los riesgos de este método, y entiendo que puede haber otros riesgos que la clínica desconoce. Recibí verbalmente y por escrito las instrucciones para el uso de este método anticonceptivo. Se me entregó una copia de este formulario de consentimiento como referencia según sea necesario. Si tengo preguntas, puedo llamar a la clínica durante horas hábiles.

Entiendo que el **anticonceptivo inyectable sólo de progestina** no evita que contraiga una enfermedad de transmisión sexual (ETS), ni el virus del SIDA. Se me aconsejó la práctica de 'relaciones sexuales seguras' mediante el uso de preservativos, especialmente si tengo más de una pareja sexual, o si es posible que mi pareja haya estado expuesta a una ETS. Aun cuando el uso de este segundo método no garantiza que mi pareja o yo contraigamos una ETS, es posible que reduzca el riesgo.

Me aseguraron que toda la información que proporcione a alguna persona en esta clínica es confidencial y no se divulgará ni enviará a nadie, a menos que yo otorgue permiso por escrito, excepto según sea necesario para prestar servicios en la clínica o lo exija la ley. Con mi firma a continuación, indico que leí **ambos lados** de este formulario y que entiendo el contenido.

En caso de una emergencia o un problema grave, puedo llamar a la clínica al _____ o a la sala de emergencias al _____.

| Fecha | Firma del paciente | Firma del testigo |
|---|---|---|
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Revisado:

| Fecha | Firma del paciente | Firma del testigo |
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## MATERIAL DIDÁCTICO: ANTICONCEPTIVO INYECTABLE SÓLO DE PROGESTINA

**EXPLICACIÓN**: El anticonceptivo inyectable sólo de progestina impide que el ovario libere un óvulo cada mes. Además, la secreción de la mucosa del cuello del útero se hace más densa y esto ayuda a bloquear el acceso del esperma al útero. Con el uso perfecto, cerca del 0.3% de las mujeres que usan el anticonceptivo inyectable sólo de progestina quedan embarazadas. Con el uso típico, el riesgo de embarazo es del 3%. El anticonceptivo inyectable sólo de progestina evita el embarazo por tres meses, y la mujer debe volver a la clínica para recibir la inyección cada 13 semanas. Si no lo hace, debe usar otro método anticonceptivo para evitar el embarazo. Si usted tiene relaciones sexuales sin protección, puede acudir al departamento de salud para recibir un anticonceptivo de emergencia. La primera inyección debe aplicarse en los primeros 5 días de la menstruación, los primeros 5 días después del parto si no está lactando, o después de que el suministro de leche esté bien establecido si está lactando, pero no antes de un mes después del parto. Usted puede dejar de usar este método anticonceptivo inyectable en cualquier momento, pero puede ser que sus períodos tarden varios meses en normalizarse. Las inyecciones no alteran su capacidad para quedar embarazada, pero sí pueden retrasarla. El método anticonceptivo inyectable sólo de progestina disminuye la densidad ósea, especialmente, en los primeros meses de uso. Usted necesitará consumir más calcio y hacer ejercicios con carga de peso regularmente para preservar la salud de los huesos. Se ha relacionado el anticonceptivo inyectable sólo de progestina con un aumento de peso promedio de 2.45 kg (5.4 libras) en el primer año, y un aumento mayor más adelante. Será necesario que usted controle el consumo de calorías y haga ejercicio habitualmente. Este método anticonceptivo es menos eficaz en las mujeres que toman Cytadren (aminoglutetimida), que es un esteroide anabólico que se usa para el tratamiento de la enfermedad de Cushing. Si tuvo relaciones sexuales sin protección, se cuenta con un anticonceptivo de emergencia. El anticonceptivo inyectable sólo de progestina puede alterar los resultados de las pruebas de laboratorio y no evita el contagio de enfermedades de transmisión sexual (ETS). Las mujeres que usan un método anticonceptivo con hormonas no deben fumar.

### VENTAJAS

- Método anticonceptivo muy eficaz
- Eficacia que dura hasta 13 semanas
- Puede ser adecuado cuando el estrógeno está contraindicado
- Menos sangrado y menos cólicos
- Ausencia de menstruación en muchas mujeres
- Menos riesgo de cáncer de endometrio y de embarazo ectópico

### CONTRAINDICACIONES

- Lactancia y menos de un mes después del parto
- Lactancia y suministro de leche no bien establecido
- Varios factores de riesgo de enfermedad cardiovascular
- PA>160/100
- Alergia o sensibilidad al producto
- Trombosis venosa profunda o embolia pulmonar actuales
- Cardiopatía isquémica actual o antecedentes de esta enfermedad
- Embarazo
- Antecedentes de accidente cerebrovascular u otras enfermedades vasculares
- Dolor de cabeza tipo migraña con síntomas neurológicos focales a cualquier edad durante el uso
- Sangrado vaginal sin explicación
- Cáncer de mama actual o antecedentes del mismo
- Diabetes con nefropatía, retinopatía, neuropatía
- Diabetes con otra enfermedad vascular o más de 20 años de diabetes
- Todos los tipos de enfermedad hepática o de tumores de hígado
- Anticuerpos antifosfolípidos positivos o desconocidos como se ven en el lupus eritematoso sistémico (LES)

### EFECTOS SECUNDARIOS

- Falta de menstruación o menstruación irregular
- Menor densidad ósea
- Demora de hasta 18 meses para recuperar la fecundidad
- Dolor debido a la inyección
- Aumento de peso
- Dolor de cabeza
- Depresión
- Mastalgia
- Descenso del nivel de colesterol bueno (HDL)

**PROBLEMAS IMPORTANTES:** Estos **NO SON NORMALES** y debe informarse de inmediato de ellos a la clínica u hospital.

- Sangrado vaginal abundante
- Dolores de cabeza intensos o recurrentes
- Visión borrosa o doble, o pérdida de visión
- Dolor intenso de pecho, de estómago o de piernas
- Síntomas de embarazo
- Reacción alérgica (inusual)
- Depresión aguda
- Dolor, pus o sangrado en el lugar de la inyección

Tennessee Department of Health
Family Planning Program

# CONSENT FOR PROGESTIN-ONLY ORAL CONTRACEPTIVE PILLS (POPs)

**IMPORTANT:** *Make sure that you understand all information before signing*.

All procedures necessary for me to receive family planning services have been explained to me. I have been given information on all methods of birth control, including abstinence, and the risks and benefits of each. I understand that no method is 100% effective against pregnancy and that undesirable side effects may occur. I recognize that it is important to follow instructions given to me and to return for checkups on schedule.

I understand all the information provided. I consent to be a patient in the family planning program, to receive all that is required in a family planning examination, and any treatment that is deemed necessary. I have voluntarily chosen **progestin-only pills** (**POPs**) as my method of birth control. I have been given the chance to ask questions about **progestin-only pills** and about this consent form. I accept the risks of this method and understand there may be other risks that the clinic is not aware of. Instructions for the use of this birth control method have been given to me in writing and orally. I have been given a copy of this consent form to refer to as needed. I may call the clinic during office hours if I have questions.

I understand that **progestin-only pills** will not prevent me from getting a sexually transmitted disease (STD), including the AIDS virus. I have been advised to practice "safer sex" by also using condoms, especially if I have sex with more than one partner, or if I or my partner has possibly been exposed to an STD. Although the use of this second method does not insure that I or my partner will not get an STD, it may reduce the risk.

I was assured that all information that I give to anyone in this clinic is confidential and will not be given or sent to anyone, unless I give written permission, except as necessary to provide services at the clinic or as required by law. By my signature below, I indicate that I have read **both sides** of this form and that I understand its contents.

In case of an emergency or severe problem, I can call the clinic at _____ or the emergency room at_____.

| Date | Patient Signature | Witness Signature |
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| Date | Patient Signature | Witness Signature |
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# TEACHING TOOL-PROGESTIN-ONLY ORAL CONTRACEPTIVE PILLS

EXPLANATION: Progestin-only pills (sometimes called minipills or POPs) work by making the mucus in the cervix thicker keeping sperm from entering the uterus. About half of the time they work by preventing the release of an egg from the ovary. Progestin-only pills require obsessive regularity in pill taking to work properly. If taken perfectly, only 0.3% of women using this method become pregnant. With typical use however, about 8% of women using this method become pregnant. Begin your progestin-only pills on the first day of your next period. If you decide to begin on another day, use a back-up method every time you have sex during the first 48 hours on these pills. Take your pill daily at the same time each day. If you are more than 3 hours late or you miss one pill, take your missed pill as soon as you remember it. Use a back-up method every time you have sex for the next 48 hours. Resume taking your pills daily at the same time everyday. If you miss 2 or more pills in a row your risk of pregnancy is high. Immediately begin your back-up method. Continue to use your back-up for the next 48 hours. Take 2 pills that day and 2 pills the next day. Then return to taking your pill daily at the same time everyday. If you have unprotected sex, call your clinic for emergency contraception. Be sure you receive a written copy of how to take your POPs and what to do if you forget to take them. Women who use POPs are at a slightly increased risk of ovarian cysts and ectopic pregnancy. Progestin-only pills do not protect you from sexually transmitted diseases (STDs). Use a condom to help prevent STDs. Certain medications will make your POPs work less effectively. If you must take rifampin, a TB medication, or anti-seizure medications such as barbiturates, phenytoin sodium, carbamazepine, or the antifungal medication griseofulvin, or the herbal medication, St. John's Wort, then you must choose another method of contraception. Some laboratory tests can be affected by POPs. You can stop your POPs at any time and you can become pregnant right away if you do not use another method of contraception. Do not take POPs if you are allergic to them. No woman using a hormonal method of contraception should smoke cigarettes.

## BENEFITS

- Lighter periods with less cramping
- Used during lactation after milk supply established
- May experience amenorrhea
- No estrogen side effects. Low dose progestin
- May decrease risk of endometrial cancer
- Rapidly reversible

## CONTRAINDICATIONS

- Malabsorptive bariatric procedures
- Unexplained vaginal bleeding
- Develops ischemic heart disease or stroke on POPs
- Develops migraine with focal neurologic symptoms at any age while on POPs
- Positive or unknown antiphospholipid antibodies as seen with SLE
- Pregnancy
- Current or history of breast cancer
- Any type of liver tumor or other active liver disease
- Certain anti-convulsant and HIV treatment drugs; also rifampicin

## SIDE EFFECTS

- Frequent and irregular menstrual bleeding
- Headache
- Breast Tenderness
- Nausea
- Dizziness
- Increased facial/body hair (rare)
- Weight gain (rare)
- Acne (rare)

**MAJOR PROBLEMS:** These are **NOT NORMAL** and should be reported to the clinic or hospital at once.

- Severe low abdominal pain
- Severe headaches or numbness in arm or leg
- Loss of vision or visual disturbance
- Severe chest pain
- Symptoms of pregnancy
- Severe leg pain

Departamento de Salud de Tennessee
Programa de planificación familiar
**CONSENTIMIENTO PARA PÍLDORAS ANTICONCEPTIVAS ORALES SÓLO DE PROGESTINA (PSP)**

**IMPORTANTE:** *Asegúrese de entender toda la información antes de firmar*.

Se me explicaron todos los procedimientos necesarios para poder recibir servicios de planificación familiar. Recibí información sobre todos los métodos anticonceptivos, incluida la abstinencia, y los riesgos y las ventajas de cada uno. Entiendo que ningún método es 100% eficaz para evitar el embarazo, y que puede haber efectos secundarios. Reconozco que es importante seguir las instrucciones que recibí y volver a las revisiones en las fechas programadas.

Entiendo toda la información que recibí. Estoy de acuerdo en participar como paciente en el programa de planificación familiar, recibir todo tratamiento y lo necesario en un examen de planificación familiar. He optado voluntariamente por las **píldoras sólo de progestina** (**PSP**) como método anticonceptivo para mí. Tuve oportunidad de hacer preguntas acerca de las **píldoras sólo de progestina** y de este formulario de consentimiento. Acepto los riesgos de este método, y entiendo que puede haber otros riesgos que la clínica desconoce. Recibí verbalmente y por escrito las instrucciones para el uso de este método anticonceptivo. Se me entregó una copia de este formulario de consentimiento como referencia según sea necesario. Si tengo preguntas, puedo llamar a la clínica durante horas hábiles.

Entiendo que las **píldoras sólo de progestina** no evitan que contraiga una enfermedad de transmisión sexual (ETS), ni el virus del SIDA. Se me aconsejó la práctica de 'relaciones sexuales seguras' mediante el uso de preservativos, especialmente si tengo más de una pareja sexual, o si es posible que mi pareja haya estado expuesta a una ETS. Aun cuando el uso de este segundo método no garantiza que mi pareja o yo contraigamos una ETS, es posible que reduzca el riesgo.

Me aseguraron que toda la información que proporcione a alguna persona en esta clínica es confidencial y no se divulgará ni enviará a nadie, a menos que yo otorgue permiso por escrito, excepto según sea necesario para prestar servicios en la clínica o lo exija la ley. Con mi firma a continuación, indico que leí **ambos lados** de este formulario y que entiendo el contenido.

En caso de una emergencia o un problema grave, puedo llamar a la clínica al _____ o a la sala de emergencias al _____.

| Fecha | Firma del paciente | Firma del testigo |
|---|---|---|
| _____ | _____ | _____ |

Revisado:

| Fecha | Firma del paciente | Firma del testigo |
|---|---|---|
| _____ | _____ | _____ |
| _____ | _____ | _____ |

## MATERIAL DIDÁCTICO: PÍLDORAS ANTICONCEPTIVAS ORALES SÓLO DE PROGESTINA

**EXPLICACIÓN:** Las píldoras anticonceptivas sólo de progestina (llamadas a veces minipíldoras o PSP) hacen más densa la secreción de la mucosa del cuello del útero y esto ayuda a evitar el acceso del esperma al útero. En casi la mitad de los casos, funcionan al impedir que el ovario libere un óvulo. Para que el método funcione debidamente, es necesario tomar las píldoras con absoluta regularidad. Con el uso perfecto, sólo el 0.3% de las mujeres que usan este método quedan embarazadas. Sin embargo, con el uso típico, cerca del 8% de las mujeres que lo usan quedan embarazadas. Empiece a tomar las píldoras sólo de progestina el primer día de su próximo período. Si escoge otro día para empezar, use un método de refuerzo cada vez que tenga relaciones sexuales durante las primeras 48 horas con el método de las PSP. Usted debe tomar una píldora diaria a la misma hora todos los días. Si se atrasa más de 3 horas o se olvida de tomar una píldora, tómela tan pronto como se acuerde de ello. Use un método anticonceptivo de refuerzo cada vez que tenga relaciones sexuales en las siguientes 48 horas. Continúe tomando una píldora diaria a la misma hora todos los días. Si se salta 2 o más píldoras seguidas, tiene un riesgo alto de quedar embarazada. Empiece a usar el método de refuerzo inmediatamente y siga usándolo en las 48 horas siguientes. Tome 2 píldoras ese mismo día y 2 píldoras el día siguiente. Luego, vuelva a tomar una píldora diaria a la misma hora todos los días. Si tiene relaciones sexuales sin protección, llame a la clínica para recibir un anticonceptivo de emergencia. Asegúrese de recibir instrucciones escritas de cómo debe tomar las PSP y de lo debe hacer si se olvida de tomarlas. Las mujeres que usan el método de las PSP tienen un riesgo un poco mayor de tener quistes de ovario y de un embarazo ectópico. Las píldoras sólo de progestina no protegen a la mujer del contagio de las enfermedades de transmisión sexual (ETS). Para ello, es necesario usar un preservativo. Ciertos medicamentos disminuyen la eficacia de las píldoras anticonceptivas sólo de progestina. Si usted debe tomar rifampina para el tratamiento de la tuberculosis, o fármacos anticonvulsivos como barbitúricos, fenitoína, sodio, carbamazepina, o el antimicótico griseofulvina, o el producto fitoterapéutico St. John's Wort (hierba de San Juan), debe escoger otro método anticonceptivo. Las PSP pueden alterar los resultados de las pruebas de laboratorio. Usted puede dejar de tomar las PSP en cualquier momento y quedar embarazada inmediatamente si no usa otro método anticonceptivo. No tome las PSP si es alérgica a estas píldoras. Las mujeres que usan un método anticonceptivo con hormonas no deben fumar.

### VENTAJAS

- Menstruación con menos cólicos y menos sangrado
- Sin los efectos secundarios del estrógeno y baja dosis de progestina
- Uso durante la lactancia después de establecer el suministro de leche
- Posible disminución del riesgo de cáncer de endometrio
- Posible ausencia de menstruación (amenorrea)
- Reversible rápidamente

### CONTRAINDICACIONES

- Procedimientos bariátricos para la absorción anormal
- Embarazo
- Sangrado vaginal sin explicación
- Cáncer de mama actual o antecedentes del mismo
- Cardiopatía isquémica o accidente cerebrovascular durante el uso
- Cualquier tipo de tumor de hígado u otra enfermedad hepática activa
- Dolor de cabeza tipo migraña con síntomas neurológicos focales a cualquier edad durante el uso
- Ciertos fármacos anticonvulsivos y para el tratamiento del VIH, y la rifampicina
- Anticuerpos antifosfolípidos positivos o desconocidos como se ven en el lupus eritematoso sistémico (LES)

### EFECTOS SECUNDARIOS

- Sangrado menstrual frecuente e irregular
- Mareo
- Dolor de cabeza
- Más vello facial y en el cuerpo (inusual)
- Mastalgia
- Aumento de peso (inusual)
- Náusea
- Acné (inusual)

**PROBLEMAS IMPORTANTES:** Estos **NO SON NORMALES** y debe informarse de inmediato de ellos a la clínica u hospital.

- Dolor intenso en la parte baja del abdomen
- Dolor intenso en pecho
- Dolores de cabeza intensos, o pierna o brazo entumecido
- Síntomas de embarazo
- Pérdida de visión o trastornos visuales
- Dolor de pierna intenso

Tennessee Department of Health
Family Planning Program
**CONSENT FOR THE VAGINAL CONTRACEPTIVE RING**

**IMPORTANT:** *Make sure that you understand all information before signing.*

All procedures necessary for me to receive family planning services have been explained to me I have been given information about all methods of birth control, including abstinence, and the risks and benefits of each. I understand that no method is 100% effective against pregnancy and that undesirable side effects may occur. I recognize that it is important to follow instructions given to me and to return for checkups on schedule.

I understand all the information provided. I consent to be a patient in the family planning program, to receive all that is required in a family planning examination, and any treatment that is deemed necessary. I have voluntarily chosen the **vaginal contraceptive ring** as my method of birth control. I have been given the chance to ask questions about the **vaginal contraceptive ring** and about this consent form. I accept the risks of this method and understand there may be other risks that the clinic is not aware of. Instructions for the use of this birth control method have been given to me in writing and orally. I have been given a copy of this consent form to refer to as needed. I may call the clinic during office hours if I have questions.

I understand that the **vaginal contraceptive ring** will not prevent me from getting a sexually transmitted disease (STD), including the AIDS virus. I have been advised to practice "safer sex" by also using condoms, especially if I have sex with more than one partner, or if I or my partner has possibly been exposed to an STD. Although the use of this second method does not insure that I or my partner will not get an STD, it may reduce the risk.

I was assured that all information that I give to anyone in this clinic is confidential and will not be given or sent to anyone, unless I give written permission, except as necessary to provide services at the clinic or as required by law. By my signature below, I indicate that I have read **both sides** of this form and that I understand its contents.

In case of an emergency or severe problem, I can call the clinic at _____ or the emergency room at_____.

| Date | Patient Signature | Witness Signature |
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Reviewed:

| Date | Patient Signature | Witness Signature |
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RDA 150

# TEACHING TOOL-VAGINAL CONTRACEPTIVE RING

**EXPLANATION:** The **vaginal contraceptive ring** prevents the ovary from releasing an egg each month. Mucus in the cervix gets thicker and helps keep sperm out of the uterus. With perfect use only 0.3% of women using the ring will become pregnant. There is no information yet on typical use failure rates. The vaginal contraceptive ring is worn for 3 weeks followed by a ring-free week during which time you get your period. See your client instruction sheet for directions on when to insert the ring, how to insert and remove it, and what to do in case of accidental removal, expulsion or prolonged ring-free days. Certain medications will make your ring work less effectively. These include anti-seizure drugs such as barbiturates, phenytoin sodium, carbamazepine, felbamate, oxcarbazepine, and topiramate; the TB medication rifampin; and the antifungal griseofulvin. Phenylbutazone, a non-steroidal anti-inflammatory and St. John's Wort, an herbal preparation, may also decrease the effectiveness of the ring as can some anti-HIV medications. Laboratory tests can be affected. You can discontinue the ring by simply removing and not replacing it. The ring should not be used by women who are hypersensitive to any component of the product. Be sure that you have been given written instructions on how to use the vaginal contraceptive ring. Emergency contraception is available if you have had unprotected sex. No woman using a hormonal method of contraception should smoke cigarettes.

**BENEFITS**

- Regular periods with less cramping/bleeding
- Probably reduced risk of ovarian and uterine cancer
- Probably fewer benign breast lumps and ovarian cysts
- Safe and effective method of birth control
- Less acne
- Low dose estrogen (15 mcg EE daily)

**CONTRAINDICATIONS**

- Controlled hypertension under treatment, or BP ≥140/90 on 3 visits or BP 160+/100+ on one visit
- History of or current or low or high risk factors for deep vein thrombosis, pulmonary embolism, or other thromboembolic vascular disease or known thrombogenic mutation
- Major surgery with prolonged immobilization
- History of or current ischemic heart disease/heart attack, complicated heart valve disease, cardiomyopathy, angina or stroke or multiple CV risk factors
- Migraine with focal neurologic symptoms, any age
- Migraines with no focal neurologic symptoms age≥ 35, or that start with the use of COCs any age
- Known hyperlipidemia (Routine screening not required)
- Positive Antiphospholipid Antibodies as may be seen with SLE
- Complicated solid organ transplantation
- Pregnancy, breastfeeding and less than 1 month after delivery, or < 3wks after delivery if not breastfeeding
- Cigarette smokers age 35 or older
- History of or current gallbladder disease or past history with the use of COCs and no cholecystectomy
- All types of liver disease; liver problems during a pregnancy or while using birth control pills
- Current or past history of breast cancer
- Diabetes > 20 years, or end organ damage, or with any other accompanying vascular disease
- Unexplained vaginal bleeding
- Extensive IBD with VTE risk factors
- Certain HIV drugs, anticonvulsants, and rifampicin

**SIDE EFFECTS**

- Spotting between periods
- Mood changes
- Breast tenderness
- Changes in contact lens prescription
- Foreign body sensations in vagina/ ring expulsion
- Headaches
- Heavier vaginal discharge, vaginitis, vaginal discomfort
- Slight weight gain
- Nausea
- Partner-related complaints due to foreign body sensation

**MAJOR PROBLEMS:** These are **NOT NORMAL** and should be reported to the clinic or hospital at once.

- Chest pain and shortness of breath
- Speech or vision changes
- Muscle weakness or numbness
- Sudden severe pain or soreness in leg
- Severe headaches, blackouts, dizziness
- Severe abdominal pain
- Skin turns yellow (jaundice)
- Heavy bleeding between periods
- Severe depression

Departamento de Salud de Tennessee
Programa de planificación familiar
**CONSENTIMIENTO PARA EL ANILLO VAGINAL ANTICONCEPTIVO**

**IMPORTANTE:** *Asegúrese de entender toda la información antes de firmar*.

Se me explicaron todos los procedimientos necesarios para poder recibir servicios de planificación familiar. Recibí información sobre todos los métodos anticonceptivos, incluida la abstinencia, y los riesgos y las ventajas de cada uno. Entiendo que ningún método es 100% eficaz para evitar el embarazo, y que puede haber efectos secundarios. Reconozco que es importante seguir las instrucciones que recibí y volver a las revisiones en las fechas programadas.

Entiendo toda la información que recibí. Estoy de acuerdo en participar como paciente en el programa de planificación familiar, recibir todo tratamiento y lo necesario en un examen de planificación familiar. He optado voluntariamente por el **anillo vaginal** como método anticonceptivo para mí. Tuve oportunidad de hacer preguntas acerca del **anillo vaginal anticonceptivo** y de este formulario de consentimiento. Acepto los riesgos de este método, y entiendo que puede haber otros riesgos que la clínica desconoce. Recibí verbalmente y por escrito las instrucciones para el uso de este método anticonceptivo. Se me entregó una copia de este formulario de consentimiento como referencia según sea necesario. Si tengo preguntas, puedo llamar a la clínica durante horas hábiles.

Entiendo que el **anillo vaginal anticonceptivo** no evita que contraiga una enfermedad de transmisión sexual (ETS), ni el virus del SIDA. Se me aconsejó la práctica de 'relaciones sexuales seguras' mediante el uso de preservativos, especialmente si tengo más de una pareja sexual, o si es posible que mi pareja haya estado expuesta a una ETS. Aun cuando el uso de este segundo método no garantiza que mi pareja o yo contraigamos una ETS, es posible que reduzca el riesgo.

Me aseguraron que toda la información que proporcione a alguna persona en esta clínica es confidencial y no se divulgará ni enviará a nadie, a menos que yo otorgue permiso por escrito, excepto según sea necesario para prestar servicios en la clínica o lo exija la ley. Con mi firma a continuación, indico que leí **ambos lados** de este formulario y que entiendo el contenido.

En caso de una emergencia o un problema grave, puedo llamar a la clínica al _____ o a la sala de emergencias al _____.

| Fecha | Firma del paciente | Firma del testigo |
|---|---|---|
| | | |

Revisado:

| Fecha | Firma del paciente | Firma del testigo |
|---|---|---|
| | | |
| | | |

## MATERIAL DIDÁCTICO: ANILLO VAGINAL ANTICONCEPTIVO

**EXPLICACIÓN:** El **anillo vaginal anticonceptivo** impide que el ovario libere un óvulo cada mes. La secreción mucosa del cuello del útero se hace más densa y esto ayuda a bloquear el acceso del esperma al útero. Con el uso perfecto, sólo el 0,3% de las mujeres que usan el anillo quedan embarazadas. No hay información aún sobre las tasas de ineficacia para el uso típico. El anillo vaginal anticonceptivo se usa tres semanas seguidas, con un intervalo de una semana sin uso, que corresponde al período de la menstruación. Lea la hoja de instrucciones para saber cuándo y cómo se debe colocar y quitar el anillo, y lo que debe hacer en caso de que sea sacado o expulsado por accidente, o de un período sin uso prolongado. Ciertos medicamentos disminuyen la eficacia del anillo vaginal anticonceptivo; entre ellos, los fármacos anticonvulsivos como barbitúricos, fenitoína, sodio, carbamazepina, felbamato, oxcarbazepina y topiramato; la rifampina para el tratamiento de la tuberculosis; y el antimicótico griseofulvina. Otros fármacos que también pueden reducir la eficacia del anillo son la fenilbutazona, un antiinflamatorio no esteroideo; el producto fitoterapéutico St. John's Wort (hierba de San Juan); y ciertos medicamentos contra el VIH. El anillo vaginal anticonceptivo puede alterar los resultados de las pruebas de laboratorio. Usted puede descontinuar el uso con sólo quitar el anillo vaginal sin remplazarlo. Las mujeres hipersensibles a algún componente del producto no deben usar el anillo vaginal anticonceptivo. Asegúrese de recibir instrucciones escritas sobre el uso del anillo vaginal anticonceptivo. Si tuvo relaciones sexuales sin protección, se cuenta con un anticonceptivo de emergencia. Las mujeres que usan un método anticonceptivo con hormonas no deben fumar.

### VENTAJAS

- Menstruación regular con menos cólicos y menos sangrado
- Menor probabilidad de riesgo de cáncer de ovario y útero
- Menor probabilidad de tumores benignos en los senos y menos quistes de ovario
- Método anticonceptivo seguro y eficaz
- Menos acné
- Dosis baja de estrógeno (15 mcg EE por día)

### CONTRAINDICACIONES

- Hipertensión arterial controlada con tratamiento, o PA ≥140/90 en 3 visitas o PA 160+/100+ en una visita
- Factores de alto o bajo riesgo actuales o antecedentes de trombosis venosa profunda, embolia pulmonar u otra enfermedad vascular tromboembólica o mutación trombogénica conocida
- Cirugía mayor con inmovilización prolongada
- Cardiopatía isquémica o infarto de miocardio actual o antecedentes de estas enfermedades; valvulopatía complicada, miocardiopatía, angina de pecho o accidente cerebrovascular o varios factores de riesgo de enfermedades cardiovasculares
- Dolor de cabeza tipo migraña con síntomas neurológicos focales, a cualquier edad
- Dolor de cabeza tipo migraña sin síntomas neurológicos focales en pacientes de 35 o más años, o que comienza con el uso de ACO a cualquier edad
- Hiperlipidemia conocida (no se necesita prueba de detección de rutina)
- Anticuerpos antifosfolípidos positivos como se pueden ver con el lupus eritematoso sistémico (LES)
- Trasplante complicado de un órgano sólido
- Embarazo; lactancia y menos de un mes después del parto; o menos de 3 semanas después del parto si no está lactando
- Fumadoras de 35 o más años de edad
- Enfermedad de la vesícula biliar actual o antecedentes de esta enfermedad, o antecedentes con el uso de AOC y sin colecistectomía
- Todos los tipos de enfermedades hepáticas; problemas del hígado durante el embarazo o con el uso de píldoras anticonceptivas
- Cáncer de mama actual o antecedentes del mismo
- Diabetes por más de 20 años, o daño terminal en órgano, o con cualquier otra enfermedad vascular acompañante
- Sangrado vaginal sin explicación
- Enfermedad inflamatoria intestinal extensa con factores de riesgo de tromboembolismo venoso (TEV)
- Ciertos medicamentos contra el VIH, anticonvulsivos y

### EFECTOS SECUNDARIOS

- Sangrado entre períodos
- Cambios de estado de ánimo
- Mastalgia
- Cambios en la receta de lentes de contacto
- Sensación de cuerpo extraño en la vagina o expulsión del anillo
- Dolor de cabeza
- Mayor secreción vaginal, vaginitis y molestia vaginal
- Leve aumento de peso corporal
- Náusea
- Incomodidad de la pareja por sensación de cuerpo extraño

**PROBLEMAS IMPORTANTES:** Estos **NO SON NORMALES** y debe informarse de inmediato de ellos a la clínica u hospital.

- Dolor en el pecho y disnea
- Cambios en el habla o la visión
- Debilidad o entumecimiento muscular
- Dolor intenso y repentino o hinchazón de piernas
- Dolores de cabeza intensos, desmayos o mareos
- Dolor abdominal intenso
- Piel amarillenta (ictericia)
- Sangrado abundante entre períodos
- Depresión aguda

# REQUIRED CLIENT INSTRUCTION SHEETS

**REQUIRED CLIENT INSTRUCTION SHEETS**
**English and Spanish**

| **Name** |
|---|
| Instructions for the ABCs of HIV Prevention |
| Instructions for Combined Oral Contraception |
| Instructions for Copper-bearing Intrauterine Device |
| Instructions for Diaphragm |
| Instructions for Domestic Violence Safety Plan |
| Instructions for Emergency Contraception |
| Instructions for Levonorgestrel-releasing Intrauterine Device |
| Instructions for Nonprescriptive Methods |
| Instructions for the Contraceptive Patch |
| Instructions for Progestin-only Implant(s) |
| Instructions for Progestin-only injectable Contraceptives |
| Instructions for Progestin-only Oral Contraceptives |
| Instructions for Reproductive Life Planning |
| Instructions for Instructions for the Vaginal Contraception Ring |
| |

# THE “ABCs” OF HIV PREVENTION

*A* is for abstain. If you abstain from vaginal, anal, or oral sex, you will not get HIV from sex.

*B* is for be faithful. If you and your sex partner are faithful to each other, you greatly reduce the risk of getting HIV.

*C* is for condom use. If you are sexually active, use condoms, especially if you have more than one partner.

## *Finally,*

People who believe their future holds no hope for happiness take more risks. If you feel hopeless, know this:

You are important.
You are needed.
You can have a bright future.

Contact any of the following for help:

1. _____

2. _____

3. _____

# LAS TRES CLAVES PARA PREVENIR EL VIH

1. Practique la abstinencia sexual. Si no tiene relaciones sexuales por vía vaginal, anal ni oral, no se contagiará del VIH por ese medio.

2. Sea fiel. Si existe fidelidad mutua entre su pareja sexual y usted, reducirán considerablemente el riesgo de contraer el VIH.

3. Use preservativos. Si tiene una vida sexual activa, especialmente, si tiene relaciones con más de una persona, use el preservativo.

## *Por último:*

Las personas que creen que no serán felices en el futuro son las que tienen conductas de mayor riesgo. Si ha perdido las esperanzas, no olvide que:

Usted es importante.
Alguien le necesita.
Su futuro puede ser brillante.

Acuda a cualquiera de estos contactos para recibir ayuda:

1. _____

2. _____

3. _____

## COMBINED ORAL CONTRACEPTIVES (COCs)

## CLIENT INSTRUCTIONS

1. How to Start Pills – They are a number of ways to begin. If your pregnancy test is negative and you are reasonably confident that you are not pregnant, take your first pill the day you get them. This gets you started quickly (called the Quick Start method) but you may have a few weeks of break through spotting until you have taken one or two packs of pills. You can also wait for your period and begin your pills on day one of your menstrual bleeding. The least effective way to begin pills is called the Sunday Start method. Begin your pills on Sunday after your period begins. For all start methods, your protection begins when you have taken 7 active pills in a row. Until you have taken 7 active pills in a row, **use a back-up method of birth control** if you have sexual intercourse.

2. Timing - Pills are very effective if swallowed at the same time every day. Try to think of taking your pill with something else that you do at about the same time every day such as brushing your teeth. Some women set a reminder on their cell phone or other electronic device.

3. Medication – The effectiveness of COCs may be slightly decreased by a number of drugs that change liver function or decrease the ability of the body to absorb the hormones in COCs. Call your provider to discuss an appropriate back-up plan if you are using any of the following: rifampin, Dilantin (phenytoin), Tegretol (carbamazepine), rifabutin, griseofulvin, phenobarbital, topiramate, and according to older science quoted in the package insert, possibly broad spectrum antibiotics such as ampicillin, and tetracycline. Experts now state that broad spectrum antibiotics do not decrease the effectiveness of COCs. If you remain concerned about your antibiotic and COCs, then use a back-up method such as condoms or spermicide for the duration of your antibiotic use. St. John's Wort may reduce the effectiveness of COCs. Also, decreased concentrations of acetaminophen and increased clearance of temazepam, salicylic acid, morphine, and clofibirc acid have been noted. Finally, contraceptive effectiveness may be reduced when hormonal contraceptives are co-administered with anti-HIV medications. Have your healthcare provider refer to the label of your individual anti-HIV medication for further drug interaction information.

4. Vomiting and Diarrhea – If you vomit within 2 hours of taking COCs, take another pill from a separate pack as soon as you feel better. (Arrange to have a spare pack for these situations.) If you have severe diarrhea or vomiting for more than 24 hours, keep taking your pills on schedule if you can. During your illness and for 7 days after you are well, use a back-up method of contraception such as a spermicide or condoms. If you have unprotected sex, contact your provider about Emergency Contraceptive Pills (ECPs).

5. Vaginal Bleeding – If you have bleeding between periods, be sure you are taking your pills at the same time every day. It is normal to have some break through bleeding in the first few months of being on COCs. Stress and smoking can cause irregular bleeding also. If the bleeding is heavy or painful or has a bad odor, contact your provider for an infection check.

6. After Giving Birth - COCs may be started 3 weeks after delivery in women who elect not to breastfeed. If you have not resumed your period, you should use a back-up method of contraception such as a condom or spermicide until you have taken 7 active pills. If you resumed sexual intercourse during the 3 weeks after delivery, the possibility of conception must be considered before beginning COCs. Breastfeeding mothers should wait at least until the child is 1 month old before starting COCs. After that time, the benefits of starting COCs while breastfeeding generally outweigh any proven or theoretical risks. Since milk volume might be affected, some breastfeeding experts advise waiting until your milk supply is well-established. Other breastfeeding experts recommend that you wait until the infant is weaned before starting COCs. Ask your baby's health care provider what they would recommend.

7. Missing Pills – COC-users have 7 hormone-free days in a row each month. The risk of pregnancy is increased when there are more than 7 hormone-free days in a row. If you have had more than 7 hormone-free days in a row, use a back-up method of birth control until you have been back on your pills for seven days. If you miss two pills or more in the third week, it is best to begin a new pack of pills as described below without having the 7 hormone-free days. This means there may be no period that month. This is not harmful. If you forget to take your COCs, follow these directions:

- **If you miss one pill** in weeks 1, 2, or 3 of the pill pack, take that tablet as soon as you remember it. Take your next tablet at the regular time. You do not need a 7 day back-up.
- **If you miss two pills** in a row in weeks 1 or 2 of the pill pack, take 2 tablets as soon as you remember and take 2 tablets the next day. Then return to your regular schedule. After missing pills, use a back-up method of birth control until you have been back on your pills for 7 days. If you have had unprotected sex, contact your provider immediately about ECPs.
- **If you miss two pills in week 3 of the pill pack or three pills in a row in any week**, you will probably get your period. If you are a Sunday starter, resume your active pills as soon as you remember them and take one pill daily until Sunday. Then set aside that pack and start a new pack of pills. (There will not be 7 hormone-free days between the packs.) Use a back-up method of birth control until you have been back on your pills for 7 days. If you have had unprotected sex, contact you provider immediately about ECPs. If you start your pills on any other day than Sunday, immediately set aside the pack with the missed pills and begin a new pack. (There will not be 7 hormone-free days between the packs.) Use a back-up method of birth control until you have been back on your pills for 7 days. If you have had unprotected sex, contact your provider immediately about ECPs.

8. If you do not have your menstrual period when expected while taking COCs, you may want to consult your provider. Remember that a drop of blood or a brown smudge on your tampon, pad, or underwear is considered a period when you are on the pill.
9. You may stop your COCs whenever you want. When you stop your COCs, your fertility will return right away. If you want to become pregnant, schedule a preconception care. If you do not want to become pregnant, schedule a family planning visit for a different method of contraception.
10. If you notice any major mood changes (depression, irritability, change in sex drive), see your provider.
11. Read the package insert.
12. Learn the pill warning signs:
    - **A** Abdominal pain (severe)
    - **C** Chest pain (severe), shortness of breath
    - **H** Headache (severe), new, more frequent, or one-sided; dizziness, weakness or numbness
    - **E** Eye problems (vision loss or blurring), speech problems
    - **S** Severe leg pain in calf or thigh
13. If you smoke, stop smoking.

## ANTICONCEPTIVOS ORALES COMBINADOS (AOC)

## INSTRUCCIONES PARA EL CLIENTE

1. Cómo comenzar a tomar las pastillas: puede hacerlo de varias maneras. Si la prueba de embarazo dio resultado negativo y usted está razonablemente segura de que no está embarazada, tome la primera pastilla el día que las obtenga. Así comenzará de inmediato (se le llama método de inicio rápido [*Quick Start*]), pero es posible que haya manchas de sangre entre períodos hasta que usted haya tomado uno o dos paquetes de pastillas. También puede esperar a que se presente la menstruación y empezar a tomar las pastillas el primer día de sangrado menstrual. La manera menos eficaz de comenzar las pastillas se llama el método de inicio en domingo. Comience a tomar las pastillas el domingo después del inicio de su período. En todos los métodos de inicio, la protección empieza después de haber tomado 7 píldoras activas seguidas. Si tiene relaciones sexuales durante este tiempo, **use un método anticonceptivo de refuerzo** hasta haber tomado 7 píldoras activas seguidas.

2. Horario: las pastillas son más efectivas si se toman a la misma hora todos los días. Trate de tomar la pastilla todos los días al mismo tiempo que hace otra cosa, como cepillarse los dientes. Algunas mujeres programan un recordatorio en su teléfono celular u otro dispositivo electrónico.

3. Medicamentos: la eficacia de los AOC puede disminuir levemente debido a varios medicamentos que cambian la función del hígado o que disminuyen la capacidad del cuerpo para absorber las hormonas de los AOC. Llame a su proveedor para hablar del plan apropiado de refuerzo si usa alguno de los siguientes medicamentos: rifampina, Dilantin (fentoína), Tegretol (carbamazepina), rifabutina, griseofulvina, fenobarbital, topiramato y, de acuerdo con otra información citada en las instrucciones del paquete, posiblemente los antibióticos de amplio espectro, como ampicilina y tetraciclina. Actualmente, los expertos señalan que los antibióticos de amplio espectro no disminuyen la eficacia de los AOC. Si aún le preocupa su antibiótico y los AOC, use un método anticonceptivo de refuerzo, como preservativos o un espermicida, durante el tiempo que tome el antibiótico. El producto St. John's Wort puede reducir la eficacia de los AOC. También se han observado concentraciones menores de paracetamol y mayor depuración de temazepam, ácido salicílico, morfina y ácido clofíbrico. Por último, la eficacia del anticonceptivo puede disminuir cuando los anticonceptivos hormonales se administran junto con medicamentos contra el VIH. Pida a su proveedor de atención médica que consulte la etiqueta de su medicamento contra el VIH para obtener más información sobre la interacción de los fármacos.

4. Vómito y diarrea: si usted vomita en las 2 horas siguientes después de tomar los AOC, tome otra pastilla de otro paquete aparte tan pronto como se sienta mejor. (Conserve un paquete adicional para estas situaciones.) Si tiene diarrea o vómitos graves por más de 24 horas, siga tomando las píldoras de acuerdo con su horario, si puede. Durante su enfermedad y en los 7 días siguientes después de recuperarse, use un método anticonceptivo de refuerzo, como un espermicida o preservativos. Si usted tiene relaciones sexuales sin protección, hable con su proveedor para obtener píldoras anticonceptivas de emergencia (PAE).

5. Sangrado vaginal: si tiene sangrados entre períodos, asegúrese de tomar las píldoras a la misma hora todos los días. Es normal que haya cierto sangrado intermenstrual en los primeros meses en que se toman los AOC. El estrés y el tabaquismo pueden causar también sangrados irregulares. Si el sangrado es abundante o doloroso, o si tiene mal olor, pida a su proveedor una revisión para detectar infecciones.

6. Después del parto: los AOC pueden comenzarse 3 semanas después del parto en las mujeres que decidan no amamantar. Si todavía no vuelve su período, debe usar un método anticonceptivo de refuerzo, como un espermicida o preservativo, hasta que haya tomado 7 píldoras activas. Si tiene relaciones sexuales durante las 3 semanas después del parto, debe considerarse la posibilidad del embarazo antes de comenzar los AOC. Las madres que amamantan deben esperar al menos hasta que el hijo tenga 1 mes de edad antes de comenzar a tomar los AOC. Después de ese tiempo, las ventajas de empezar a tomar los AOC durante la lactancia suelen superar todos los riesgos teóricos o comprobados. Debido a que el volumen de leche podría verse afectado, algunos expertos en lactancia aconsejan esperar hasta que el suministro de leche esté bien establecido. Otros recomiendan que espere hasta el destete del lactante

antes de comenzar a tomar los AOC. Pregunte al proveedor de atención médica de su bebé lo que recomendaría.

7. Pastillas faltantes: las mujeres que toman AOC tienen 7 días seguidos sin hormonas cada mes. El riesgo de embarazo aumenta cuando hay más de 7 días seguidos sin hormonas. Si tuvo más de 7 días seguidos sin hormonas, use un método anticonceptivo de refuerzo hasta que haya tomado de nuevo las pastillas por siete días. Si olvida tomar dos pastillas o más en la tercera semana, es mejor comenzar un nuevo paquete según se describe abajo, sin tener el intervalo de 7 días sin hormonas. Esto significa que tal vez no haya menstruación ese mes. Esto no es perjudicial. Si se olvida de tomar los AOC, siga las siguientes instrucciones:

   - **Si se le olvida tomar una pastilla** en las semanas 1, 2 ó 3 del paquete de pastillas, tómese esa pastilla tan pronto como se acuerde de ello. Tome la siguiente pastilla a la hora habitual. No necesita un método anticonceptivo de refuerzo por 7 días.

   - **Si se le olvida tomar dos pastillas** en las semanas 1 ó 2 del paquete de pastillas, tómese 2 pastillas tan pronto como se acuerde de ello y tome 2 pastillas al día siguiente. Luego, vuelva a su horario habitual. Después de tomar las pastillas faltantes, use un método anticonceptivo de refuerzo hasta que haya vuelto a tomar las pastillas por 7 días. Si tiene relaciones sexuales sin protección, hable de inmediato con su proveedor para obtener píldoras anticonceptivas de emergencia (PAE).

   - **Si se olvida de tomar dos pastillas en la semana 3 del paquete de pastillas o tres pastillas seguidas en cualquier semana**, probablemente tendrá su menstruación. Si usted comenzó a tomar las pastillas en domingo, siga tomando las píldoras activas tan pronto como se acuerde de ello, y tome una pastilla diaria hasta el domingo. Luego, deje ese paquete de pastillas y empiece uno nuevo. (No habrá intervalo de 7 días sin hormonas entre paquetes.) Use un método anticonceptivo de refuerzo hasta que haya vuelto a tomar las pastillas por 7 días. Si tiene relaciones sexuales sin protección, hable de inmediato con su proveedor para obtener píldoras anticonceptivas de emergencia (PAE). Si empezó a tomar las pastillas en cualquier otro día que no es domingo, deje de inmediato el paquete de las pastillas olvidadas y comience uno nuevo. (No habrá intervalo de 7 días sin hormonas entre paquetes.) Use un método anticonceptivo de refuerzo hasta que haya vuelto a tomar las pastillas por 7 días. Si tiene relaciones sexuales sin protección, hable de inmediato con su proveedor para obtener píldoras anticonceptivas de emergencia (PAE).

8. Si no tiene su menstruación cuando la espera durante el tiempo que toma los AOC, es conveniente que consulte con su proveedor. Recuerde que, cuando usted toma la píldora, una gota de sangre o una mancha color café en el tampón, la toalla sanitaria o la ropa interior se considera un período.
9. Puede suspender los AOC cuando lo desee. Al suspender los AOC, la fecundidad se recupera de inmediato. Si desea quedar embarazada, programe la atención previa a la concepción. Si no desea el embarazo, programe una visita de planificación familiar para seguir un método anticonceptivo diverso.
10. Si observa cambios importantes en su estado de ánimo (depresión, irritabilidad, cambios en la libido), consulte con su proveedor.
11. Lea las instrucciones que se incluyen en el paquete.
12. Conozca las señales de advertencia de la píldora:
    - **A** Dolor abdominal (intenso)
    - **C** Dolor (intenso) en el pecho y disnea (dificultad para respirar)
    - **H** Dolor de cabeza (intenso) reciente, más frecuente o de un solo lado; mareos, debilidad o entumecimiento
    - **E** Problemas de la vista (pérdida de visión o visión borrosa) y problemas del habla
    - **S** Dolor intenso en pantorrilla o muslo
13. Si fuma, deje de hacerlo.

## COPPER-BEARING INTRAUTERINE DEVICE

## CLIENT INSTRUCTION SHEET

1. After the placement of your copper-bearing intrauterine device, you most likely will have some bleeding and cramping. If you are not allergic to Ibuprofen, you may take Ibuprofen 2 tablets (400 mg) every 4 to 6 hours. If the cramping is severe or if the bleeding is heavier than your usual period, call your clinic. Call the emergency number if your clinic is closed.

2. Over the next few days or weeks, you may have intermittent spotting or break through bleeding with some cramping. This also can be treated with Ibuprofen as described above. If the cramping is severe or if the bleeding is heavier than your usual period, call your clinic. Call the emergency number if your clinic is closed.

3. You may have increased cramping with the first few periods after the IUD was placed. If you are not allergic to Ibuprofen, you may take Ibuprofen 2 tablets (400 mg) every 4 to 6 hours the first 1-3 days of your period.

4. The risk of infection is highest in the first 20 days after insertion. Report signs of infection immediately. Signs of infection include:

    - Severe abdominal pain
    - Pain during sex
    - Abnormal vaginal discharge
    - Long-lasting or heavy vaginal bleeding
    - Fever, chills and not feeling well

5. Pelvic inflammatory disease (PID) is a serious infection. The risk of this infection is greater if you have more than one sexual partner. Having more than one sexual partner puts you at risk for all sexually transmitted infections. Using a latex male condom may decrease the risk of infection. Having sex in a mutually faithful long term relationship will also decrease your risk of infection.

6. If you do not get your period, report to the clinic for a pregnancy test.

7. To be sure that your IUD is in place, check for the IUD strings located at the back of your vagina. WASH YOUR HANDS FIRST. Check your strings monthly after each period. If you cannot find the strings, if they have gotten longer, or if you feel hard plastic, report to the clinic immediately because you may not be protected from pregnancy. Do not have sex. If you have sex, use a back-up method such as male or female condoms, the contraceptive sponge or a spermicide. If you have had unprotected sex report to the clinic within 72 hours for emergency contraception.

8. Do not pull on the strings. Do not let your partner pull on the strings.

9. You may use tampons with your IUD. With all tampon use, respect the absorbency rules. Do not use a super absorbent tampon on a light bleeding or spotting day. Do not use a tampon when a panty liner will do.

10. Keep your follow-up visit so that your provider can check that the IUD is in place and that there are no signs of infection.

11. When you decide to have your IUD removed, schedule an appointment with your health care provider. After your health care provider removes the IUD, your fertility will return immediately. If you want to become pregnant, ask about preconception care. If you do not want to become pregnant, ask about other methods of contraception.

## DISPOSITIVO INTRAUTERINO DE COBRE

## HOJA DE INSTRUCCIONES PARA EL CLIENTE

1. Después de la colocación del dispositivo intrauterino (DIU) de cobre, es muy probable que usted tenga sangrado vaginal y cólicos. Si no es alérgica al ibuprofeno, puede tomar 2 tabletas (400 mg) de este medicamento cada 4 a 6 horas. Si los cólicos son muy fuertes o el sangrado vaginal es más abundante que su menstruación habitual, llame a la clínica. Si la clínica está cerrada, llame al número para emergencias.

2. En los próximos días o semanas, pueden presentarse manchas de sangre de forma intermitente o sangrado intermenstrual con cólicos. Estos problemas también se pueden tratar con ibuprofeno, como se explicó antes. Si los cólicos son muy fuertes o el sangrado vaginal es más abundante que su menstruación habitual, llame a la clínica. Si la clínica está cerrada, llame al número para emergencias.

3. Los cólicos pueden ser más intensos en los primeros períodos después de la colocación del DIU. Si usted no es alérgica al ibuprofeno, puede tomar 2 tabletas (400 mg) cada 4 a 6 horas los primeros tres días de la menstruación.

4. El riesgo de contraer una infección es mayor en los primeros 20 días después de la inserción del DIU. Informe de inmediato las señales de infección, que pueden ser:

    - Dolor abdominal intenso
    - Dolor durante la relaciones sexuales
    - Secreción vaginal anormal
    - Sangrado vaginal prolongado o abundante
    - Fiebre, escalofríos y malestar

5. La enfermedad pélvica inflamatoria (EPI) es una infección grave. El riesgo de contraer la EPI aumenta si usted tiene más de una pareja sexual. Si tiene varias parejas sexuales, usted corre el riesgo de contraer cualquier infección de transmisión sexual. El preservativo masculino de látex puede disminuir el riesgo de estas infecciones. Tener relaciones sexuales en una relación donde existe fidelidad mutua también disminuye el riesgo de estas infecciones.

6. Si usted no menstrúa, acuda a la clínica para que le realicen una prueba de embarazo.

7. Para asegurarse de que el DIU esté bien colocado, compruebe que los hilos estén en la parte posterior de la vagina. LÁVESE LAS MANOS PRIMERO. Revise la posición de los hilos todos los meses, después de la menstruación. Si no encuentra los hilos, si los hilos se alargaron o si siente el plástico duro, acuda a la clínica de inmediato porque es posible que no esté protegida contra el embarazo. No tenga relaciones sexuales. Si tiene relaciones sexuales, use un método de refuerzo, que puede ser un preservativo masculino o femenino, la esponja anticonceptiva o un espermicida. Si tiene relaciones sexuales sin protección, acuda a la clínica en las 72 horas siguientes para recibir un anticonceptivo de emergencia.

8. No jale los hilos. Tampoco deje que su pareja jale los hilos.

9. Usted puede usar tampones con el DIU colocado. Al usar tampones, respete las normas de absorbencia. No use un tampón superabsorbente en los días de poca menstruación o manchas escasas. No use un tampón cuando pueda usar un pantiprotector.

10. Acuda a las visitas de seguimiento de modo que su proveedor pueda revisar que el DIU esté bien colocado y que no haya señales de infección.

11. Cuando usted decida quitarse el DIU, programe una cita con su proveedor de atención médica. Después de la extracción del DIU, usted recuperará la fecundidad de inmediato. Si desea quedar embarazada, pregunte acerca de la atención previa a la concepción. Si no desea el embarazo, pida información sobre otros métodos anticonceptivos.

## DIAPHRAGM

## CLIENT INSTRUCTIONS

1. Use your diaphragm every time you have intercourse. Be sure that your diaphragm with spermicidal cream or jelly is in place before your partner's penis enters your vagina.
2. Learn the danger signs for toxic shock syndrome and watch for them. If you have high fever and one or more of the danger signs, you may have early toxic shock syndrome. Remove the diaphragm and contact your provider. Toxic shock danger signs:
   - Sudden high fever
   - Vomiting, diarrhea
   - Dizziness, faintness, weakness
   - Sore throat, aching muscles and joints
   - Rash (like a sunburn)
3. Wash your hands carefully with soap and water before inserting, checking, or removing your diaphragm. This precaution may reduce your risk for toxic shock syndrome and other infections as well.
4. If your partner or you are having problems with vaginal or penile irritation, try a different spermicide product. If you have problems with recurring bladder infections or vaginal yeast infections, discuss these with your health care provider.
5. If you feel unsure about the proper fit or placement of your diaphragm, your partner should use condoms until you see your health care provider to be sure that your insertion technique is correct.
6. Douching after intercourse is not recommended. If you are using a diaphragm and choose to douche, wait at least six hours after intercourse to avoid washing away essential spermicide.
7. Your partner can use condoms along with your diaphragm if you wish. Using this combination, you will have extremely effective protection against pregnancy and sexually transmitted infection.
8. Before intercourse check that you have all the supplies you need
   - Fresh spermicidal cream or jelly
   - Plastic applicator for inserting additional spermicide
   - Diaphragm (check your diaphragm to be sure it has no holes, cracks, or tears)
   - Plan ahead about when to insert your diaphragm. Try to find a routine that is comfortable for you. The diaphragm may be inserted just before intercourse, or anytime up to six hours beforehand.
9. Insertion technique
   - Wash your hands carefully with soap and water.
   - Apply spermicidal jelly or cream. Hold the diaphragm with the dome down (like a cup). Squeeze the jelly or cream from the tube into the dome (use about 1-2 teaspoons. Some instructions say fill the cup about two-thirds full. Read the spermicide instructions as amount can vary depending on the brand of spermicide). Spread a little bit of spermicide jelly or cream around the rim of the diaphragm with your finger. To insert the diaphragm hold it with the dome down (spermicide in the dome) and squeeze opposite sides of the rim together between your thumb and fingers. Spread the opening of your vagina with your other hand, and insert the folded diaphragm into your vaginal canal. This can be done standing with one foot propped up (on the edge of a chair, a bathtub, or a toilet), squatting, or lying on your back.
   - Push the diaphragm downward and along the back wall of your vagina as far as it will go. Then tuck the front rim up along the roof of your vagina behind your pubic bone. Once it is in place properly, you should not be able to feel the diaphragm except, of course, with your fingers. If it is uncomfortable, then most likely it is not in the correct position; take it out and reinsert it.
   - After insertion, check placement. When correctly placed, the back rim of the diaphragm is below and behind the cervix, and the front edge of the rim is tucked up behind the pubic bone. Often you may not be able to feel the back rim. You should check to be sure that you can feel that your cervix is covered by the soft rubber dome of the diaphragm and that the front rim is snugly in place behind your pubic bone. The spermicidal cream or jelly (inside the dome of the diaphragm) should be next to your cervix.
10. Instructions for repeated intercourse

- If you have intercourse more than once within the six hour time that your diaphragm must remain in place, an additional dose of spermicidal cream or jelly is recommended.
- Do not remove your diaphragm; use the plastic applicator to insert fresh jelly or cream in front of the diaphragm.

11. Instructions regarding your diaphragm after intercourse
    - Leave the diaphragm in place for at least six hours after intercourse. Douching is not recommended, but if you choose to douche, wait at least six hours.
    - Your diaphragm should not interfere with normal activities. Urination or a bowel movement should not affect its position, but you can check its placement afterward if you wish. It is fine to shower or bathe with a diaphragm in place.
    - Before removing your diaphragm, wash your hands carefully with soap and water.
    - Check the position of the device. If it is dislodged, or seems not to be in correct position, you may want to contact your health care provider about emergency contraception.
    - To remove: locate the front rim of the diaphragm with your finger. Hook your finger over the rim or behind it, then pull the diaphragm down and out. Wash the diaphragm with plain soap and water, and dry it. Hold it up to the light to check for holes, tears, or cracks.
12. How to care for your diaphragm
    - Store your supplies in a convenient location that is clean, cool and dark.
    - Wash your spermicide inserter and diaphragm after each use. Plain soap is best; avoid deodorant soap or perfumed soap. Do not use talcum powder on your diaphragm. You may dust your diaphragm with cornstarch.
    - Avoid contact with oil-based products, which can deteriorate a diaphragm. Do not use oil-based vaginal medications or lubricants when you are using the diaphragm. Some examples of oil-based substances include petroleum jelly (Vaseline), mineral oil, hand lotion, vegetable oil, cold cream, cocoa butter, as well as common vaginal yeast creams and vaginal hormone creams. If you need extra lubrication for intercourse, contraceptive jelly is a good choice, or you can try a water-soluble lubricant specifically intended for use with condoms.

13. If you stop using your diaphragm, you can become pregnant right away. If you want to become pregnant, schedule a preconception care visit. If you do not want to become pregnant, use a back-up method of contraception and schedule a family planning visit.

## DIAFRAGMA

## INSTRUCCIONES PARA EL CLIENTE

1. Use el diafragma cada vez que tenga relaciones sexuales. Asegúrese de colocar el diafragma y la crema o el gel espermicidas antes de que el pene de su compañero entre en la vagina.
2. Conozca y esté atenta a las señales de peligro del síndrome de shock tóxico. Si tiene fiebre alta y una o más de las señales de peligro, es posible que se encuentre en las primeras etapas del síndrome. Extraiga el diafragma y comuníquese con su proveedor. Las señales de peligro de shock tóxico son:
   - Fiebre alta repentina
   - Vómito y diarrea
   - Mareo, desmayo, debilidad
   - Dolor de garganta, de músculos y articulaciones
   - Sarpullido (como una quemadura solar)
3. Lávese bien las manos con agua y jabón antes de insertar, revisar o extraer el diafragma. Esta precaución puede reducir el riesgo de síndrome de shock tóxico y también de otras infecciones.
4. Si su compañero o usted tienen problemas de irritación en pene o vagina, pruebe un producto espermicida diverso. Si tiene problemas de infecciones recurrentes en vejiga o vagina (candidiasis), hable de ello con su proveedor de atención médica.
5. Si no está segura de la colocación o ajuste correcto del diafragma, su compañero debe usar el preservativo hasta que usted visite a su proveedor de atención médica para comprobar que su técnica de inserción sea la correcta.
6. No se recomienda la ducha vaginal después de las relaciones sexuales. Si usa un diafragma y opta por la ducha vaginal, espere al menos seis horas después de las relaciones sexuales para evitar la dilución del espermicida esencial.
7. Si lo desea, su compañero puede usar preservativos además del diafragma que usted se coloque. Con esta combinación, usted tendrá una protección sumamente eficaz contra el embarazo y las infecciones de transmisión sexual.
8. Antes de las relaciones sexuales, revise si tiene todo lo necesario:
   - Crema o gel espermicidas reciente.
   - Aplicador de plástico para insertar más espermicida.
   - Diafragma (revise el diafragma para comprobar que no tenga agujeros, grietas o desgarres).
   - Planifique con tiempo cuándo insertar el diafragma. Busque una rutina que sea cómoda para usted. Se puede insertar el diafragma apenas antes de las relaciones sexuales o en cualquier momento hasta seis horas antes.
9. Técnica de inserción:
   - Lávese bien las manos con agua y jabón.
   - Aplique el gel o la crema espermicidas. Sostenga el diafragma con la cúpula hacia abajo (como una taza). Exprima el tubo de gel o crema espermicida para aplicarlo en el domo (use de 1 a 2 cucharitas. Algunas instrucciones indican que llene la taza hasta unos dos tercios. Lea las instrucciones del espermicida porque la cantidad puede variar según la marca). Con el dedo, distribuya un poco de gel o crema espermicida alrededor del borde del diafragma. Para insertar el diafragma, sosténgalo con la cúpula hacia abajo (y el espermicida en la cúpula), y presione los lados opuestos del borde al mismo tiempo entre el pulgar y los dedos. Con la otra mano, separe la abertura de la vagina e inserte el diafragma doblado en el canal de la vagina. Esto se puede hacer estando de pie con un pie apoyado más arriba (sobre el borde de una silla, la tina de baño o el inodoro), en cuclillas o recostada de espaldas.
   - Empuje el diafragma hacia abajo y hacia la pared posterior de la vagina hasta donde llegue. Luego, coloque el borde delantero siguiendo la parte superior de la vagina, detrás del hueso púbico. Una vez colocado correctamente, no debe poder sentir el diafragma salvo, por supuesto, con los dedos. Si siente incomodidad, lo más probable es que no esté colocado en la posición correcta; sáquelo y vuelva a insertarlo.

- Después de insertarlo, verifique la colocación. Cuando está bien colocado, el borde posterior del diafragma se encuentra abajo y detrás del cuello del útero, y el borde delantero está colocado detrás del hueso púbico. Con frecuencia, es posible que no sienta el borde posterior. Debe revisarlo para comprobar que pueda sentir que el cuello del útero está cubierto por el hule suave de la cúpula del diafragma, y que el borde delantero esté cómodamente colocado detrás del hueso púbico. La crema o el gel espermicida (dentro de la cúpula del diafragma) debe estar enseguida del cuello del útero.

10. Instrucciones para casos de relaciones sexuales repetidas:
    - Si tiene relaciones sexuales más de una vez en las seis horas en las que el diafragma debe estar colocado, se recomienda aplicar una dosis adicional de crema o gel espermicida.
    - No extraiga el diafragma; use el aplicador de plástico para insertar más gel o crema frente al diafragma.
11. Instrucciones acerca del diafragma después de las relaciones sexuales:
    - Deje el diafragma colocado al menos seis horas después de las relaciones sexuales. No se recomienda la ducha vaginal pero, si opta por ella, espere un mínimo de seis horas.
    - El diafragma no debe interferir con las actividades normales. La colocación no debe verse afectada cuando orina o defeca, pero puede revisarla después si lo desea. Es posible bañarse en regadera o en tina con el diafragma colocado.
    - Antes de extraer el diafragma, lávese bien las manos con agua y jabón.
    - Verifique la colocación del dispositivo. Si se movió o parece que no está en la posición correcta, puede ser conveniente hablar con su proveedor de atención médica para obtener un anticonceptivo de emergencia.
    - Para extraerlo: busque el borde delantero del diafragma con el dedo. Enganche el dedo en el borde o detrás de este, y jale el diafragma hacia abajo para extraerlo. Lave el diafragma sólo con agua y jabón, y séquelo. Sosténgalo contra la luz para revisar que no tenga agujeros, desgarres o grietas.
12. Cuidado del diafragma:
    - Almacene sus suministros en un lugar conveniente, limpio, fresco y oscuro.
    - Lave el aplicador de espermicida y el diafragma después de cada uso. Lo mejor es usar un jabón sencillo; evite los jabones desodorantes o perfumados. No aplique talco al diafragma. Puede espolvorearlo con maicena.
    - Evite el contacto del diafragma con productos a base de aceite, los cuales pueden dañarlo. No use medicamentos ni lubricantes vaginales a base de aceite cuando tenga colocado el diafragma. Algunos ejemplos de sustancias a base de aceite incluyen el gel de petróleo (vaselina), aceite mineral, crema para las manos, aceite vegetal, crema hidratante o manteca de cacao, así como cremas vaginales comunes con hormonas y cremas contra la candidiasis. Si necesita más lubricación para las relaciones sexuales, el gel anticonceptivo es una buena opción, o puede probar un lubricante soluble en agua, formulado específicamente para el uso con preservativos.

13. Si deja de usar el diafragma, puede quedar embarazada de inmediato. Si desea quedar embarazada, programe una visita de atención previa a la concepción. Si no desea el embarazo, use un método anticonceptivo de refuerzo y programe una visita de planificación familiar.

**Domestic Violence: Safety Plan Guidelines**

Personal Safety with an Abuser
Getting Ready to Leave
General Guidelines for Leaving an Abusive Relationship
After Leaving the Abusive Relationship

These safety suggestions have been compiled from safety plans distributed by state domestic violence coalitions from around the country. Following these suggestions is **not a guarantee** of safety, but could help to improve your safety situation.

**Personal Safety with an Abuser**

- Identify your partner's use and level of force so that you can assess danger to you and your children before it occurs.
- Try to avoid an abusive situation by leaving.
- Identify safe areas of the house where there are no weapons and where there are always ways to escape. If arguments occur, try to move to those areas.
- Don't run to where the children are as your partner may hurt them as well.
- If violence is unavoidable, make yourself a small target; dive into a corner and curl up into a ball with your face protected and arms around each side of your head, fingers entwined.
- If possible, have a phone accessible at all times and know the numbers to call for help. Know where the nearest pay phone is located. Know your local battered women's shelter number. Don't be afraid to call the police.
- Let trusted friends and neighbors know of your situation and develop a plan and visual signal for when you need help.
- Teach your children how to get help. Instruct them not to get involved in the violence between you and your partner. Plan a code word to signal to them that they should get help or leave the house.
- Tell your children that violence is never right, even when someone they love is being violent. Tell them that neither you nor they are at fault or cause the violence, and that when anyone is being violent, it is important to keep safe.
- Practice how to get out safely. Practice with your children.
- Plan for what you will do if your children tell your partner of your plan or if your partner otherwise finds out about your plan.
- Keep weapons like guns and knives locked up and as inaccessible as possible.
- Make a habit of backing the car into the driveway and keeping it fueled. Keep the driver's door unlocked and others locked -- for a quick escape.
- Try not to wear scarves or long jewelry that could be used to strangle you.
- Create several plausible reasons for leaving the house at different times of the day or night. Call a domestic violence hotline periodically to assess your options and get a supportive understanding ear.

**Getting Ready to Leave**

- Keep any evidence of physical abuse, such as pictures, etc.
- Know where you can go to get help; tell someone what is happening to you.

- If you are injured, go to a doctor or an emergency room and report what happened to you. Ask that they document your visit.
- Plan with your children and identify a safe place for them (for example, a room with a lock or a friend's house where they can go for help). Reassure them that their job is to stay safe, not to protect you.
- Contact your local battered women's shelter and find out about laws and other resources available to you before you have to use them during a crisis.
- Keep a journal of all violent incidences, noting dates, events and threats made if possible.
- Acquire job skills as you can, such as learning to type or taking courses at a community college.
- Try to set money aside or ask friends or family members to hold money for you.

**General Guidelines for Leaving an Abusive Relationship**

- You may request a police stand-by or escort while you leave;
- If you need to sneak away, be prepared;
- Make a plan for how and where you will escape;
- Plan for a quick escape;
- Put aside emergency money as you can;
- Hide an extra set of car keys;
- Pack an extra set of clothes for yourself and your children and store them at a trusted friend or neighbor's house. Try to avoid using next-door neighbors, close family members and mutual friends;
- Take with you important phone numbers of friends, relatives, doctors, schools, etc., as well as other important items, including:
  - Driver's license;
  - Regularly needed medication;
  - List of credit cards held by self or jointly or the credit cards themselves if you have access to them;
  - Pay stubs;
  - and checkbooks and information about bank accounts and other assets.

**If time is available, also take:**

- Citizenship documents (such as your passport, greencard, etc.)
- Titles, deeds, and other property information
- Medical records
- Children's school and immunization records
- Insurance information
- Copy of marriage license, birth certificates, will, and other legal documents

- Verification of social security numbers
- Welfare identification; and
- Valued pictures, jewelry, or personal possessions
- Create a false trail. Call motels, real estate agencies, and schools in a town at least six hours away from where you plan to relocate. Ask questions that require a call back to your house in order to leave phone numbers on record.

**After Leaving the Abusive Relationship**

**If getting a restraining order and the offender is leaving:**

- Change locks and phone number
- Change work hours and route taken to work
- Change route taken to transport children to school
- Keep a certified copy of your restraining order with you at all times
- Inform friends, neighbors and employers that you have a restraining order in effect
- Give copies of restraining order to employers, neighbors, and schools along with a picture of the offender
- Call law enforcement to enforce the order.

**If you leave:**

- Consider renting a post office box or using the address of a friend for your mail
- Be aware that addresses are on restraining orders and police reports
- Be careful to whom you give your new address and phone number
- Change your work hours if possible
- Alert school authorities of situation
- Consider changing your children's schools
- Reschedule appointments that offender is aware of
- Use different stores and frequent different social spots
- Alert neighbors and request that they call the police if they feel you may be in danger
- Talk to trusted people about the violence
- Replace wooden doors with steel or metal doors. Install security systems if possible
- Install a lighting system that lights up when a person is coming close to the house (motion sensitive lights)
- Tell people you work with about the situation and have your calls screened by one receptionist if possible
- Tell people who take care of your children which individuals are allowed to pick up your children. Explain your situation to them and provide them with a copy of the restraining order

- Call the telephone company to request caller ID. Ask that your phone be blocked so that if you call, neither your partner nor anyone else will be able to get your new, unlisted phone number.

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Victims of IPV can also call the National Domestic Violence Hotline at: 1-800-799-7233 or 1-800-787-3224 (TTY) for help and support.

## Violencia doméstica: pautas para un plan de protección

Protección personal contra un abusador
Preparación para dejar una relación abusiva
Pautas generales para dejar una relación abusiva
Después de dejar una relación abusiva

Estas sugerencias de seguridad se compilaron de planes de protección distribuidos por las coaliciones estatales contra la violencia doméstica de todo el país. Seguir estas sugerencias **no es una garantía** de seguridad, pero podría ayudar a mejorar su situación de protección.

### Protección personal contra un abusador

- Determine el uso y nivel de fuerza de su compañero para que pueda evaluar el peligro que esto representa para usted y sus hijos antes de que ocurra.
- Trate de evitar una situación abusiva saliendo de ella.
- Identifique las zonas seguras de la casa, donde no haya armas y donde exista siempre manera de escapar. Si hay una discusión, trate de desplazarse a esas áreas.
- No corra hacia donde se encuentran sus hijos porque su compañero puede lastimarlos también a ellos.
- Si no puede evitar la violencia, conviértase en un blanco pequeño, colóquese en un rincón y acurrúquese con la cara protegida y los brazos a cada lado de la cabeza, con los dedos entrelazados.
- En lo posible, traiga con usted un teléfono en todo momento y conozca los números adonde puede llamar para pedir ayuda. Verifique dónde se encuentra el teléfono público más cercano. Conozca el número del refugio local para mujeres maltratadas. No tenga miedo de llamar a la policía.
- Hable con amigos y vecinos de confianza acerca de su situación, y prepare un plan y una señal visual para cuando necesite ayuda.
- Enseñe a sus hijos a obtener ayuda. Indíqueles que no deben intervenir en la violencia entre usted y su compañero. Planifique usar una palabra clave para advertirles que deben obtener ayuda o salir de la casa.
- Mencione a sus hijos que la violencia nunca es correcta, aun cuando la persona violenta sea algún ser querido. Dígales que ni usted ni ellos tienen la culpa ni son la causa de la violencia, y que cuando alguien se comporta con violencia, es importante mantenerse a salvo.
- Practique cómo salir de manera segura, y practíquelo con sus hijos.
- Planifique lo que hará si sus hijos advierten a su compañero de su plan o si su compañero se entera de ello de otra manera.
- Mantenga las armas, como pistolas y cuchillos, guardadas bajo llave y lo más inaccesible que pueda.
- Acostúmbrese a tener el auto listo para salir y lleno de combustible. Para escapar de inmediato, mantenga la puerta del conductor sin seguro y las demás cerradas con llave.
- Trate de no usar bufandas o joyas largas que podrían usarse para estrangularla.
- Invente varios motivos verosímiles para salir de casa a horas diversas del día o de la noche. Llame periódicamente a la línea directa para la violencia doméstica para evaluar sus opciones y tener alguien que la escuche y la apoye.

### Preparación para dejar una relación abusiva

- Conserve todas las pruebas de abuso físico, como fotografías, etc.
- Investigue adónde puede acudir para obtener ayuda. Informe a alguien de lo que le pasa.
- Si está lesionada, acuda al médico o a la sala de emergencias e informe de lo que le sucedió. Pídales que documenten su visita.
- Planifique con sus hijos y defina un lugar seguro para ellos (por ejemplo, una habitación con cerradura o la casa de un amigo adonde puedan acudir para obtener ayuda). Asegúreles que lo que ellos deben hacer es mantenerse a salvo, no protegerla a usted.
- Comuníquese con el refugio local para mujeres maltratadas, e infórmese de las leyes y demás recursos con los que usted cuenta antes de tener que usarlos en una crisis.
- Mantenga un diario de todas las incidencias violentas y, en lo posible, anote fechas, sucesos y las amenazas recibidas.
- Adquiera las habilidades para el trabajo que pueda, como aprender mecanografía o tomar cursos en una escuela superior comunitaria.
- Trate de ahorrar dinero o pida a amigos o parientes que conserven el dinero de usted.

**Pautas generales para dejar una relación abusiva**

- Usted puede pedir a la policía que la espere o la acompañe cuando se vaya.
- Si necesita escabullirse, esté preparada.
- Planifique cómo y dónde escapará.
- Haga planes para escapar con rapidez.
- Ahorre el dinero de emergencia que pueda.
- Oculte un juego adicional de llaves del automóvil.
- Empaque ropa para usted y para sus hijos, y guárdela en casa de un amigo o vecino de confianza. Evite pedir ayuda a los vecinos más próximos, parientes cercanos y amigos mutuos.
- Lleve con usted números de teléfono importantes de amigos, parientes, médicos, escuelas, etc., y otros artículos de importancia, entre ellos:
    - Licencia de conducir
    - Medicamentos que necesite periódicamente
    - Lista de las tarjetas de crédito individuales o conjuntas, o las tarjetas de crédito mismas, si tiene acceso a ellas
    - Comprobantes de pago
    - Chequeras e información de cuentas de banco y otros bienes

**Si tiene tiempo, lleve también con usted:**

- Documentos de ciudadanía (como pasaporte, tarjeta de residente permanente, etc.)
- Títulos, escrituras y demás información sobre propiedades
- Historias clínicas

- Registros escolares y de vacunación de sus hijos
- Información sobre seguros
- Copia del acta de matrimonio, actas de nacimiento, testamento y demás documentos legales
- Verificación de los números de Seguro Social
- Identificación del Departamento de Bienestar
- Fotografías, joyas y bienes personales de valor
- Cree una pista falsa. Llame a hoteles, agencias de bienes raíces y escuelas en una población alejada al menos seis horas del lugar en donde tiene planeado reubicarse. Haga preguntas que requieran devolver la llamada a su casa para dejar un registro de números de teléfono.

**Después de dejar una relación abusiva**

**Si obtiene una orden de alejamiento y el abusador deja la casa:**

- Cambie las cerraduras y el número de teléfono.
- Cambie el horario de trabajo y la ruta que sigue para ir a trabajar.
- Cambie la ruta que sigue para llevar a sus hijos a la escuela.
- Lleve con usted en todo momento una copia certificada de la orden de alejamiento.
- Informe a amigos, vecinos y empleadores que usted tiene una orden de alejamiento vigente.
- Proporcione copias de la orden de alejamiento a empleadores, vecinos y escuelas, así como una fotografía del abusador.
- Llame a las autoridades para hacer cumplir la orden.

**Si usted deja la casa:**

- Considere alquilar un apartado postal o usar el domicilio de un amigo para su correo.
- Recuerde que los domicilios aparecen en las órdenes de alejamiento y en los informes policiales.
- Tenga cuidado de a quién proporciona su domicilio y número de teléfono nuevos.
- Cambie su horario de trabajo, en lo posible.
- Advierta a las autoridades escolares de la situación.
- Considere cambiar a sus hijos de escuela.
- Reprograme las citas que el abusador conozca.
- Use tiendas diversas, y frecuente lugares sociales distintos.
- Advierta a los vecinos y pídales que llamen a la policía si consideran que usted puede estar en peligro.
- Hable con personas de confianza acerca de la violencia.
- Sustituya las puertas de madera con puertas de acero o metal. Instale sistemas de seguridad en lo posible.
- Instale un sistema de iluminación que se encienda cuando alguien se acerca a la casa (luces sensibles al movimiento).

- Informe a sus compañeros de trabajo de su situación, y si es posible, pida a una recepcionista que controle sus llamadas.
- Indique a quienes cuidan a sus hijos cuáles personas pueden recogerlos. Explíqueles su situación y proporcióneles una copia de la orden de alejamiento.
- Llame a la compañía de teléfonos para pedir el servicio de identificación de llamadas. Pida que bloqueen su teléfono de manera que, si usted llama, ni su compañero ni nadie más pueda obtener su número de teléfono nuevo y privado.

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Las víctimas de violencia por parte del compañero (IPV, *intimate partner violence*) también pueden llamar a la línea directa nacional para violencia doméstica (*National Domestic Violence*) al: 1-800-799-7233 o bien al 1-800-787-3224 (TTY) para obtener ayuda y apoyo.

**EMERGENCY CONTRACEPTIVE PILLS (ECPS)**
**INSTRUCTIONS FOR TAKING**

There are different products available for emergency contraception. Your nurse will circle the instructions for your product:

3. For two-dose products, swallow the first dose of ECPs as soon as possible after unprotected sex (we advise no later than 72 hours after unprotected sex). Swallow the second dose 12 hours after you took the first dose. **Your nurse will tell you how many pills to take for each dose**.

4. For one-dose products, swallow the dose as soon as possible after unprotected sex (we advise no later than 72 hours after unprotected sex). **Your nurse will tell you how many pills are in your one-dose product.**

Many experts believe that there can be emergency contraceptive benefit even up to 120 hours after unprotected sex. However, the package labeling for these products recommends no later than 72 hours. Your nurse will consult a nurse-practitioner or doctor if you want the 120 hour option.

Do not take extra emergency contraception pills. Extra pills will make you more at risk for feeling sick to your stomach.

Eating a snack before taking any of the emergency contraception dose(s) will help prevent feeling sick to your stomach.

You may want to use an over-the-counter, anti-nausea medicine before each dose. Ask the nurse about this before you leave clinic today.

If you do feel sick to your stomach, this will only last for a day or so. If you throw up in less than one hour after you take emergency contraception, call your clinic.

During the week after taking emergency contraception, you may have vaginal bleeding or spotting. Your next period may be heavier than usual and start a few days early or late.

If your period does not start in three weeks, you could be pregnant. Make an appointment to come back to the clinic in three weeks if you have not had a period.

Watch for danger signs and call the clinic or report to the emergency room if any of the following happen:

Chest or arm pain
Shortness of breath
Unusual swelling of legs or leg pain
Severe headache or dizziness
Low abdominal pain
Visual disturbance such as blurred or double vision
Yellowing of skin or the white part of the eye
Severe depression

Emergency contraception is for emergency use only, and is not meant to be a regular method of birth control. Emergency contraception is not as effective as a regular method of birth control. Your nurse can give you information and handouts on methods of birth control that are available to you.

You can get something for birth control today.

Remember that emergency contraception does not protect you from HIV/AIDS or other sexually transmitted diseases. Always use condoms. If you have questions after you get home, call the clinic.

**INSTRUCCIONES PARA TOMAR LAS PÍLDORAS ANTICONCEPTIVAS DE EMERGENCIA (PAE)**

Existen distintos productos para la anticoncepción de emergencia. Su enfermera encerrará en un círculo las instrucciones correspondientes al que usted tome:

1. En el caso de productos de dos dosis de PAE, ingiera la primera lo antes posible después de haber tenido relaciones sexuales sin protección (recomendamos que no deje pasar más de 72 horas después de las relaciones sexuales sin protección). Ingiera la segunda dosis 12 horas después de la primera. **La enfermera le indicará cuántas píldoras debe tomar en cada dosis**.

2. En el caso de productos de una sola dosis de PAE, ingiérala lo antes posible después de haber tenido relaciones sexuales sin protección (recomendamos que no deje pasar más de 72 horas después de las relaciones sexuales sin protección). **La enfermera le indicará cuántas píldoras debe tomar del producto de una sola dosis.**

Muchos expertos opinan que las PAE pueden hacer efecto hasta 120 horas después de las relaciones sexuales sin protección. No obstante, en la etiqueta con información que acompaña estos productos, se recomienda no dejar pasar más de 72 horas. Su enfermera consultará a la enfermera practicante o al médico si usted prefiere la opción de 120 horas.

No tome más PAE de las que le indiquen. Si toma píldoras de más, aumentará el riesgo de sentir náusea.

Para prevenir las náuseas, coma un bocadillo antes de cualquiera de las dosis de PAE.

Sería conveniente que tome un antiemético de venta libre antes de cada dosis de PAE, para evitar o aliviar las náuseas. Consulte con la enfermera antes de irse de la clínica hoy.

Si tiene náuseas, sólo durarán aproximadamente un día. Si usted vomita en menos de una hora después de haber tomado las píldoras anticonceptivas de emergencia, llame a la clínica.

Durante la semana posterior al tratamiento con PAE, tal vez tenga un pequeño sangrado vaginal o manchas de sangre. Su próximo período puede ser más abundante, y adelantarse o retrasarse unos días.

Si su período no comienza en tres semanas, usted podría estar embarazada. Haga una cita para regresar a la clínica en tres semanas si no ha tenido su menstruación.

Preste atención a las señales de peligro, y llame a la clínica o acuda a la sala de emergencias si tiene lo siguiente:

Dolor en el pecho o los brazos
Disnea (dificultad para respirar)
Hinchazón o dolor inusual de piernas
Dolor de cabeza intenso o mareo
Dolor en la parte baja del abdomen
Problemas oculares, como visión doble o borrosa
Piel u ojos amarillentos
Depresión aguda

Las PAE se usan como anticonceptivos de emergencia únicamente, y no como un método anticonceptivo habitual. La anticoncepción de emergencia es menos eficaz que los métodos anticonceptivos habituales. Su enfermera puede explicarle y darle folletos con información sobre los métodos anticonceptivos disponibles para usted.

Usted puede obtener un método anticonceptivo hoy mismo.

Recuerde que las píldoras anticonceptivas de emergencia no protegen contra el VIH/SIDA ni ninguna otra enfermedad de transmisión sexual. Use siempre un preservativo.

Si tiene preguntas después de regresar a casa, llame a la clínica.

## FEMALE CONDOMS, VAGINAL SPERMICIDES, CONTRACEPTIVE SPONGE

## CLIENT INSTRUCTIONS

### FEMALE CONDOM

1. Pregnancy prevention requires using your method of contraception with every act of intercourse. Use your method every time you have intercourse.
2. Follow the package instructions for proper insertion technique.
3. Learn the danger signs of toxic shock syndrome: Report to the emergency room immediately for:
   a. Sudden high fever
   b. Vomiting, diarrhea
   c. Dizziness, faintness, weakness
   d. Sore throat, aching muscles and joints
   e. Rash (like a sunburn)
4. Wash your hands with soap and water before inserting, checking, or removing your female condom. This precaution may reduce your risk for toxic shock syndrome and for other infections as well.
5. If you have problems with recurring bladder infections or vaginal yeast infections, discuss these with your health care provider.

### VAGINAL SPERMICIDES

1. Pregnancy prevention requires using your method of contraception with every act of intercourse. Use spermicide every time you have sex.
2. Follow the package instructions for proper insertion technique.
3. Frequent or multiple uses of spermicides can irritate the vagina and cervix making it easier to get an STD, especially HIV.
4. If you have problems with vaginal or penile irritation and may be at risk for an STD, see your clinician promptly.
5. You can use condoms along with spermicide if you wish. By using this combination, birth control protection is more effective.

### CONTRACEPTIVE SPONGE

1. The sponge is not recommended for persons with sulfa allergies because on of its preservatives is sodium metabisulfite.
2. Pregnancy prevention requires using your method with every act of intercourse.
3. Wash your hands with soap and water before inserting, checking, or removing your contraceptive sponge. This precaution may reduce your risk for toxic shock syndrome and for other infections as well
4. The sponge must be moistened with water prior to insertion.
5. Read and follow the package instructions regarding insertion and removal
6. The sponge <u>must</u> be removed after 24 hours.
7. Keeping the sponge in place longer than 24 hours increases your risk of toxic shock syndrome.
8. Learn the signs of toxic shock syndrome and report to the emergency room immediately for:
   a. Sudden high fever
   b. Vomiting, diarrhea
   c. Dizziness, faintness, weakness
   d. Sore throat, aching muscles and joints
   e. Rash (like a sunburn)

## PRESERVATIVOS FEMENINOS, ESPERMICIDAS VAGINALES, ESPONJA ANTICONCEPTIVA

## INSTRUCCIONES PARA EL CLIENTE

### PRESERVATIVO FEMENINO

1. Para evitar el embarazo, es necesario usar un método anticonceptivo en todas las relaciones sexuales. Use su método cada vez que tenga relaciones sexuales.
2. Siga las instrucciones del paquete para aplicar la técnica de inserción correcta.
3. Conozca las señales de peligro del síndrome de shock tóxico y acuda de inmediato a la sala de emergencias si tiene lo siguiente:
    a. Fiebre alta repentina
    b. Vómito y diarrea
    c. Mareo, desmayo, debilidad
    d. Dolor de garganta, de músculos y articulaciones
    e. Sarpullido (como una quemadura solar)
4. Lávese las manos con agua y jabón antes de insertar, revisar o extraer el preservativo femenino. Esta precaución puede reducir el riesgo de síndrome de shock tóxico y también otras infecciones.
5. Si tiene problemas de infecciones recurrentes en vejiga o vagina (candidiasis), hable de ello con su proveedor de atención médica.

### ESPERMICIDAS VAGINALES

1. Para evitar el embarazo, es necesario usar un método anticonceptivo en todas las relaciones sexuales. Use un espermicida cada vez que tenga relaciones sexuales.
2. Siga las instrucciones del paquete para aplicar la técnica de inserción correcta.
3. El uso frecuente o reiterado de espermicidas puede irritar la vagina y el cuello del útero; lo cual hace que la mujer se contagie más fácilmente enfermedades de transmisión sexual (ETS), especialmente, el VIH.
4. Si su compañero o usted tienen problemas de irritación en pene o vagina, y puede haber riesgo de contraer una ETS, acuda al médico de inmediato.
5. Usted puede usar el preservativo junto con el espermicida, si lo desea. La protección contra el embarazo es más eficaz con esta combinación.

### ESPONJA ANTICONCEPTIVA

1. La esponja no es un método anticonceptivo recomendado para las personas con alergia a las sulfamidas porque uno de sus conservantes es el metabisulfito de sodio.
2. Para evitar el embarazo, es necesario usar un método anticonceptivo en todas las relaciones sexuales.
3. Lávese las manos con agua y jabón antes de insertar, revisar o extraer la esponja anticonceptiva. Esta precaución puede reducir el riesgo de síndrome de shock tóxico y también otras infecciones.
4. La esponja debe humedecerse con agua antes de insertarla.
5. Lea y siga las instrucciones del paquete para insertar y extraer la esponja.
6. La esponja <u>debe</u> extraerse después de 24 horas.
7. Mantener la esponja colocada por más de 24 horas aumenta el riesgo de síndrome de shock tóxico.
8. Conozca las señales del síndrome de shock tóxico y acuda de inmediato a la sala de emergencias si tiene lo siguiente:
    a. Fiebre alta repentina
    b. Vómito y diarrea
    c. Mareo, desmayo, debilidad
    d. Dolor de garganta, de músculos y articulaciones
    e. Sarpullido (como una quemadura solar)

Levonorgestrel-Releasing IUD

Client Instruction Sheet

1. After the placement of your levonorgestrel-releasing intrauterine device, you most likely will have some bleeding and cramping. If you are not allergic to Ibuprofen, you may take Ibuprofen 2 tablets (400 mg) every 4 to 6 hours. If the cramping is severe or if the bleeding is heavier than your usual period, call your clinic. Call the emergency number if your clinic is closed.

2. For the first 3 to 6 months, your monthly periods may be irregular and you may have intermittent spotting or break through bleeding. If the bleeding is heavier than your usual period, call your clinic. This also may be treated with Ibuprofen as described above. Check with your clinic first. Heavy bleeding can be normal but it can also be a sign of infection.

3. As your body adjusts to this method, you may find that your periods stop altogether. This happens in about 2 out of 10 women. Not having a period is normal so long as you are not pregnant. The first time you go 6 weeks without a period, report to your clinic for a pregnancy test. Thereafter report for a pregnancy test anytime you have symptoms of pregnancy.

4. The risk of infection is highest in the first 20 days after insertion. Report signs of infection immediately. Signs of infection include:

5. Severe abdominal pain
6. Pain during sex
7. Abnormal vaginal discharge
8. Long-lasting or heavy vaginal bleeding
9. Fever, chills and not feeling well

10. Pelvic inflammatory disease (PID) is a serious infection. The risk of this infection is greater if you have more than one sexual partner. Having more than one sexual partner puts you at risk for all sexually transmitted infections. Using a latex male condom may decrease the risk of infection. Having sex in a mutually faithful long term relationship will also decrease your risk of infection.

11. To be sure that your IUD is in place, check for the IUD strings located at the back of your vagina. WASH YOUR HANDS FIRST. Check your strings monthly after each period. If you cannot find the strings, if they have gotten longer, or if you feel hard plastic, report to the clinic immediately because you may not be protected from pregnancy. Do not have sex. If you have sex, use a back-up method such as male or female condoms, the contraceptive sponge or a spermicide. If you have had unprotected sex report to the clinic within 72 hours for emergency contraception.

12. Do not pull on the strings. Do not let your partner pull on the strings.

13. You may use tampons with your IUD. With all tampon use, respect the absorbency rules. Do not use a super absorbent tampon on a light bleeding or spotting day. Do not use a tampon when a panty liner will do.

14. Keep your follow-up visit so that your provider can check that the IUD is in place and that there are no signs of infection.

15. When you decide to have your IUD removed, schedule an appointment with your health care provider. After your health care provider removes the IUD, your fertility will return immediately. If you want to become pregnant, ask about preconception care. If you do not want to become pregnant, ask about other methods of contraception.

Dispositivo intrauterino con levonorgestrel

Hoja de instrucciones para el cliente

1. Después de la colocación del dispositivo intrauterino (DIU) que libera levonorgestrel, es muy probable que usted tenga sangrado vaginal y cólicos. Si no es alérgica al ibuprofeno, puede tomar 2 tabletas (400 mg) de este medicamento cada 4 a 6 horas. Si los cólicos son muy fuertes o el sangrado vaginal es más abundante que su menstruación habitual, llame a la clínica. Si la clínica está cerrada, llame al número para emergencias.

2. En los primeros 3 a 6 meses, la menstruación puede ser irregular y pueden presentarse manchas de sangre de forma intermitente o sangrado intermenstrual. Si el sangrado vaginal es más abundante que su menstruación habitual, llame a la clínica. Estos problemas también se pueden tratar con ibuprofeno, como se explicó antes. Pero consulte con la clínica primero. El sangrado abundante puede ser normal pero también puede ser una señal de infección.

3. Cuando su organismo se adapte a este método, puede ocurrir que deje de menstruar por completo. Esto sucede en 2 de cada 10 mujeres. La falta de menstruación es normal siempre y cuando usted no esté embarazada. La primera vez que no tenga una menstruación en 6 meses, acuda a la clínica para una prueba de embarazo. A partir de ese momento, acuda a realizarse esa prueba cada vez que tenga síntomas de embarazo.

4. El riesgo de contraer una infección es mayor durante los primeros 20 días después de la inserción del DIU. Informe de inmediato de las señales de infección, que pueden ser:

5. Dolor abdominal intenso
6. Dolor durante la relaciones sexuales
7. Secreción vaginal anormal
8. Sangrado vaginal prolongado o abundante
9. Fiebre, escalofríos y malestar

10. La enfermedad pélvica inflamatoria (EPI) es una infección grave. El riesgo de contraer la EPI aumenta si usted tiene más de una pareja sexual. Si tiene varias parejas sexuales, usted corre el riesgo de contraer cualquier infección de transmisión sexual. El preservativo masculino de látex puede disminuir el riesgo de estas infecciones. Tener relaciones sexuales en una relación donde existe fidelidad mutua también disminuye el riesgo de estas infecciones.

11. Para asegurarse de que el DIU esté bien colocado, compruebe que los hilos estén en la parte posterior de la vagina. LÁVESE LAS MANOS PRIMERO. Revise la posición de los hilos todos los meses, después de la menstruación. Si no encuentra los hilos, si los hilos se alargaron o si siente el plástico duro, acuda a la clínica de inmediato porque es posible que no esté protegida contra el embarazo. No tenga relaciones sexuales. Si tiene relaciones sexuales, use un método de refuerzo, que puede ser un preservativo masculino o femenino, la esponja anticonceptiva o un espermicida. Si tiene relaciones sexuales sin protección, acuda a la clínica en las 72 horas siguientes para recibir un anticonceptivo de emergencia.
12.
13. No jale los hilos. Tampoco deje que su pareja jale los hilos.

14. Usted puede usar tampones con el DIU colocado. Al usar tampones, respete las normas de absorbencia. No use un tampón superabsorbente en los días de poca menstruación o manchas escasas. No use un tampón cuando pueda usar un pantiprotector.

15. Acuda a las visitas de seguimiento de modo que su proveedor pueda revisar que el DIU esté bien colocado y que no haya señales de infección.
16. Cuando usted decida quitarse el DIU, programe una cita con su proveedor de atención médica. Después de la extracción del DIU, usted recuperará la fecundidad de inmediato. Si desea quedar embarazada, pregunte acerca de la atención previa a la concepción. Si no desea el embarazo, pida información sobre otros métodos anticonceptivos.

## MALE CONDOMS

## CLIENT INSTRUCTIONS

### MALE CONDOM

1. Wash hands before handling condom.

2. Put the condom on the erect penis before the penis comes in contact with the woman's genitals.

3. Avoid tearing.

4. Unroll the condom a short distance over a finger before placing it onto the penis.

5. Unroll the condom down to the base of the erect penis. If the condom has been unrolled incorrectly, remove the condom from the penis and throw it away.

6. Leave 1/2 inch of empty space at the tip of the condom unless using a reservoir tip condom.

7. Ensure adequate lubrication.

8. For lubrication you may use water, K-Y Jelly, or spermicidal creams, jellies, foams, or suppositories. Do not use oil-based products such as anti-fungal creams, cold cream, mineral oil, cooking oil, petroleum jelly, shortening, lotions, massage oil or baby oil, all of which can degrade the quality of the condom.

9. If at any time during intercourse you or your partner believes the condom may have torn or slipped, stop and check the condom. Replace if needed.

10. During withdrawal of the penis after ejaculation (while the penis is still erect), hold the rim of the condom against the base of the penis.

11. When the penis is clearly away from the woman’s genitals, slowly slide the condom off the penis without spilling semen.

12. Check the condom for visible damage.

13. If the condom is torn (or slipped off), call the clinic within 72 hours for emergency contraceptive pills.

14. Store condoms in a cool, dry, and dark place.

15. Check expiration date.

## PRESERVATIVOS MASCULINOS

## INSTRUCCIONES PARA EL CLIENTE

### PRESERVATIVO MASCULINO

1. Lávese las manos antes de manipular el preservativo.

2. Coloque el preservativo en el pene erecto antes de que el pene entre en contacto con los genitales de la mujer.

3. Evite que el preservativo se rasgue.

4. Antes de colocarlo en el pene, desenrolle una pequeña parte sobre un dedo.

5. Luego desenrolle el resto hasta la base del pene erecto. Si desenrolló el preservativo incorrectamente, quítelo del pene y deséchelo.

6. Deje menos de 1.5 cm (½ pulgada) de espacio libre en la punta del preservativo, a menos que esté usando un preservativo que tenga una punta con reservorio.

7. Asegúrese de que haya lubricación suficiente.

8. Para la lubricación, puede usar agua, jalea K-Y, o cremas, geles, espumas o supositorios espermicidas. No use productos con aceite como cremas antifúngicas, crema hidratante, aceite mineral, aceite de cocina, gel de petróleo, manteca vegetal, lociones, aceite para masajes o para bebés. Estos productos pueden deteriorar la calidad del preservativo.

9. Si durante la relación sexual, usted o su pareja creen que el preservativo se salió o se rasgó, revísenlo. Reemplace el preservativo, si es necesario.

10. Al retirar el preservativo del pene después de la eyaculación (mientras el pene está erecto), mantenga el borde del preservativo sobre la base del pene.

11. Una vez que el pene esté totalmente separado de los genitales de la mujer, deslice el preservativo lentamente para sacarlo sin derramar el semen.

12. Compruebe que el preservativo no esté dañado.

13. Si el preservativo se rasgó (o se salió), llame a la clínica dentro de las 72 horas siguientes para obtener píldoras anticonceptivas de emergencia.

14. Almacene los preservativos en un lugar fresco, seco y sin luz.

15. Verifique la fecha de vencimiento del producto.

**Contraceptive Patch Client Instructions**

The contraceptive patch is worn for 3 weeks followed by a patch-free week during which you get your period. The patch can be started in 2 ways:

Apply the first patch on the day your period begins. (This is the preferred start method). This becomes the day of the week when each new patch is applied. It is called your patch change day.

**OR** apply the first patch on Sunday after your period begins (If your period starts on Sunday begin that day). Sunday will be your patch change day.

Apply the patch to clean, dry, healthy, lotion-free, and powder-free skin. Avoid touching the patches sticky surface by removing half of the protective liner, apply the sticky side to the chosen site and then remove the other side of the protective liner. Press down firmly on the patch with the palm of your hand for 10 seconds making sure the edges stick well. You may apply the patch to your buttock, abdomen, upper outer arm, or upper torso (front or back but never on the breasts.). To avoid irritation, apply each new patch to a different place. Wear the patch for 7 days, then any time on your patch change day, remove the old patch and apply a new one. You will wear patches for 3 weeks. Then you will have a patch-free week. During your patch-free week you will get your period. At the end of your patch-free week, begin a new patch on your patch change day. It doesn't matter if you are still bleeding; apply the patch on your patch change day.

Patches rarely come off by themselves. A patch should not be reapplied if it is no longer sticky, has become stuck to itself or another surface. It should not be used if it has other material stuck under it or if it has previously become loose or fallen off. If your patch comes off or is partially detached, follow these instructions:

Off or partially detached up to 24 hours – Try to reapply the patch to the same place or replace it with a new patch immediately. No backup method is needed. The patch change day remains the same.

Off or partially detached for 24 hours or more – **OR if you do not know how long it has been off or partially detached** – You may not be protected from pregnancy. Call the clinic for emergency contraception if you have had unprotected intercourse. Begin a new cycle of 3 patches. Apply the first patch. This is now your new patch change day. You must use a backup method until you have worn this new patch for 7 days.

Follow these instructions if you forget to change your patch:

If you forget to put on your patch at the end of your patch-free week – You could become pregnant because you have been without protection for more than 7 days in a row. Call the clinic for emergency contraception if you have had unprotected intercourse. Apply the new patch as soon as you think of it. This is your new patch change day. Use a backup method until you have been back on the patch for 7 days.

If you forget to change your week 2 or week 3 patch by one or two days, apply a new patch as soon as you remember. Your patch change day remains the same. You do not need a backup method of contraception.

If you forget to change your week 2 or week 3 patch by **more** than two days, you could become pregnant. Call the clinic for emergency contraception if you have had unprotected intercourse. Open and begin a new box of patches as soon as you remember. You now have a new patch change day. You must use a backup until you have been back on the patch for 7 days.

If you forget to remove your third patch, remove the patch as soon as you think of it and begin a new patch on your regular patch change day. No backup is needed.

REMEMBER you should never have the patch off more than 7 days.

After you have been on the patch awhile, you might have a month where you do not get your period. However, if you miss two periods in a row you will need a pregnancy test.

Common side effects that usually resolve in 3-4 months include nausea, breast tenderness, and breakthrough bleeding. See your consent form for more information.

Your fertility will return right away after you stop using the Patch. If you want to become pregnant, schedule a preconception care visit. If you do not want to become pregnant, use a back-up method of contraception and schedule a family planning appointment.

Read the package insert.

Learn the patch warning signs:

- **A** Abdominal pain (severe)
- **C** Chest pain (severe), shortness of breath
- **H** Headache (severe), new, more frequent, or one-sided; dizziness, weakness or numbness
- **E** Eye problems (vision loss or blurring), speech problems
- **S** Severe leg pain in calf or thigh

If you smoke, stop smoking.

**Parche anticonceptivo**
**Instrucciones para el cliente**

El parche anticonceptivo se usa 3 semanas seguidas, con un intervalo de una semana sin uso, que corresponde al período de la menstruación. Hay dos maneras de iniciar el método:

El método de inicio preferido es aplicar el primer parche el primer día de la menstruación, que se convierte en el día de la semana en que hay que cambiar el parche por uno nuevo. Este día se denomina el día de reemplazo del parche.

**O BIEN**, la otra manera es aplicar el primer parche el día domingo después de que comenzó la menstruación (si su primer día de menstruación coincide con un domingo, empiece ese mismo día). El domingo será el día de reemplazo del parche.

Aplique el parche sobre la piel sana, limpia, seca, sin cremas ni talcos. Evite tocar la superficie adherente del parche. Para ello, quite sólo la mitad de la cinta protectora y aplique el lado adherente en el lugar elegido, y luego haga lo mismo con la otra mitad. Presione diez segundos firmemente con la palma de la mano, y asegúrese de que los bordes queden bien adheridos. El parche se puede aplicar en glúteos, abdomen, parte superior externa del brazo, torso superior (frente o espalda, pero nunca sobre los senos). Para prevenir la irritación de la piel, aplique cada parche nuevo en un lugar distinto. Use el parche por 7 días y cámbielo por uno nuevo el día de reemplazo del parche a cualquier hora. El parche se usa 3 semanas seguidas, con un intervalo de 1 semana sin uso, que corresponde al período de la menstruación. Después de la semana sin parche, coloque uno nuevo el día de reemplazo del parche. No importa si aún tiene sangrado menstrual. Aplique el parche el día de reemplazo establecido.

Es muy difícil que un parche se despegue por sí solo, pero no intente volver a aplicarlo si perdió adherencia, si se pegó a sí mismo o a otra superficie. El parche no debe usarse si se le adhirió algún material por debajo, o si ya se despegó o soltó anteriormente. Si el parche se despega total o parcialmente, siga estas instrucciones:

Si se despega total o parcialmente hasta por 24 horas: intente volver a aplicarlo en el mismo lugar o reemplácelo por uno nuevo de inmediato. No necesita un método anticonceptivo de refuerzo. El día de reemplazo sigue siendo el mismo.

Si se despega total o parcialmente por 24 horas o más, **O BIEN, si usted no sabe cuánto tiempo estuvo despegado total o parcialmente**, es posible que no esté protegida contra el embarazo. Si tuvo relaciones sexuales sin protección, llame a la clínica para recibir un anticonceptivo de emergencia. Empiece un nuevo ciclo de 3 parches. El día que aplique el primero será su nuevo día de reemplazo del parche. Deberá usar un método anticonceptivo de refuerzo durante los primeros 7 días de uso consecutivo del parche nuevo.

Si se olvida de cambiar el parche, siga las instrucciones a continuación:

Si se olvida de aplicar un parche nuevo después de la semana sin parche, podría quedar embarazada debido a que no usó protección por más de 7 días seguidos. Si tuvo relaciones sexuales sin protección, llame a la clínica para recibir un anticonceptivo de emergencia. Aplique el parche nuevo en cuanto se acuerde de ello. Este será su nuevo día de reemplazo del parche. Use un método anticonceptivo de refuerzo durante los primeros 7 días de uso consecutivo del parche nuevo.

Si se olvida de cambiar el parche de la semana 2 o la semana 3 por uno o dos días, aplique el parche nuevo tan pronto se acuerde de ello. El día de reemplazo del parche sigue siendo el mismo. No necesita un método anticonceptivo de refuerzo.

Si se olvida de cambiar el parche de la semana 2 o la semana 3 por **más** de dos días, podría quedar embarazada. Si tuvo relaciones sexuales sin protección, llame a la clínica para recibir un anticonceptivo de emergencia. Empiece una nueva caja de parches en cuanto se acuerde de ello. Su día de reemplazo del

parche ahora es otro. Debe usar un método anticonceptivo de refuerzo durante los primeros 7 días de uso consecutivo del parche nuevo.

Si se olvida de quitar el tercer parche, hágalo tan pronto se acuerde de ello y empiece a usar uno nuevo el día de reemplazo del parche habitual. No necesita un método anticonceptivo de refuerzo.

RECUERDE: nunca deje de usar el parche por más de 7 días.

Después de usar el parche por un algún tiempo, podría suceder que usted no menstruara por un mes. Sin embargo, si el período no se presenta por dos meses seguidos, necesita hacer la prueba del embarazo.

Los efectos secundarios más comunes suelen desaparecer en tres a cuatro meses, e incluyen: náusea, mastalgia y sangrado intermenstrual. Para obtener más información, lea el formulario de consentimiento.

Cuando deje de usar el parche, recuperará la fecundidad de inmediato. Si desea quedar embarazada, programe una visita de atención previa a la concepción. Si no desea el embarazo, use un método anticonceptivo de refuerzo y programe una visita de planificación familiar.

Lea las instrucciones que se incluyen en el paquete.

Conozca las señales de advertencia del parche:

- **A** Dolor abdominal (intenso)
- **C** Dolor (intenso) en el pecho y disnea (dificultad para respirar)
- **H** Dolor de cabeza (intenso) reciente, más frecuente o de un solo lado; mareos, debilidad o entumecimiento
- **E** Problemas de la vista (pérdida de visión o visión borrosa) y problemas del habla
- **S** Dolor intenso en pantorrilla o muslo

Si fuma, deje de hacerlo.

## PROGESTIN-ONLY IMPLANT(S)

## CLIENT INSTRUCTION SHEET

1. Some users of progestin-only implants may have no menstrual bleeding for long periods of time. But most users of progestin-only implants will have highly irregular and unpredictable menstrual bleeding. Purchase sanitary protection products (pads, liners etc.) now.

2. Usually you will have two bandages at the insertion site. Keep them both clean and dry. Leave the outer bandage (called a pressure bandage) on 24 hours. Leave the smaller, inner bandage on 3-5 days. Report pain, pus, or bleeding from the insertion site.

3. You must be able to feel your implant under the skin where it was placed. If you cannot feel your implant, it may not protect you from pregnancy or it may become very difficult to remove. Report to your health care provider if you cannot feel the implant and use a back-up method of contraception such as condoms.

4. If you have received your implant during the first five days of your menstrual period, you will need to use a back-up method of contraception for pregnancy prevention for the first 7 days.

5. If you are transitioning directly from the pill, patch, ring, shot, or an IUD, then you will not need a back-up method for 7 days.

6. Implant(s) do not protect you from sexually transmitted infections. Use male latex or polyurethane condoms or female condoms to help prevent sexually transmitted infections.

7. Whenever you see a health care provider for any reason, tell them that you are using a contraceptive implant to prevent pregnancy.

8. Know when your device must be removed (for Implanon® the device must be removed in 3 years. It can also be replaced at that time if you so choose.)

9. If you decide to have your Implant removed, schedule an appointment with your health care provider. After your health care provider removes the Implant, your fertility will return immediately. If you want to become pregnant, ask about preconception care. If you do not want to become pregnant, ask about other methods of contraception.

10. Report the following danger signs to an emergency room immediately:

    - Heavy vaginal bleeding
    - Severe or repeated painful headaches
    - Blurred , double, or loss of vision
    - Coughing up blood, shortness of breath
    - Severe chest, stomach, or leg pain
    - Allergic reaction (rare)
    - Jaundice (yellowing of the skin)
    - Pain, pus, or bleeding at insertion site

11 Report the following to a health care provider as soon as possible

    - Severe depression or symptoms of depression such as fatigue, insomnia, sadness etc.
    - Pregnancy symptoms
    - Breast lump

## IMPLANTES SÓLO DE PROGESTINA

## HOJA DE INSTRUCCIONES PARA EL CLIENTE

1. Algunas mujeres que usan el implante sólo de progestina pueden no tener menstruaciones por un tiempo prolongado. La mayoría, sin embargo, presenta sangrados menstruales muy irregulares e impredecibles. Tenga preparados productos de higiene femenina como toallas sanitarias, pantiprotectores, etc.

2. Por lo general, se colocan dos vendas en el lugar de la inserción del implante. Manténgalas limpias y secas. Deje la venda externa (llamada venda de presión) colocada por 24 horas. Y deje la venda interna (la más pequeña) colocada de 3 a 5 días. Informe si siente dolor, u observa pus o sangrado en el lugar de la inserción.

3. Usted debe sentir el implante bajo la piel en el lugar donde se colocó. Si no lo siente, es posible que no esté protegida contra el embarazo o que sea muy difícil extraer el implante. Acuda a su proveedor de atención médica si no siente el implante, y use un método anticonceptivo de refuerzo, como los preservativos.

4. Si el implante fue colocado en los primeros 5 días del período menstrual, usted necesitará usar un método anticonceptivo de refuerzo durante los primeros 7 días para evitar el embarazo.

5. El método de refuerzo de los primeros 7 días no será necesario si está cambiando de método y pasando de la píldora, el parche, el anillo, el anticonceptivo inyectable o el DIU directamente al implante.

6. Los implantes no la protegen de las infecciones de transmisión sexual. Para prevenir estas infecciones, use preservativos masculinos de látex o poliuretano, o preservativos femeninos.

7. Cuando acuda a un proveedor de atención médica por cualquier motivo, infórmele que está usando un implante para evitar el embarazo.

8. Sepa cuándo deben extraerle el implante (el de Implanon® debe extraerse a los 3 años y, si lo desea, puede reemplazarse por uno nuevo al finalizar ese período).

9. Si usted decide quitarse el implante, programe una cita con su proveedor de atención médica. Después de la extracción del implante, usted recuperará la fecundidad de inmediato. Si desea quedar embarazada, pregunte acerca de la atención previa a la concepción. Si no desea el embarazo, pida información sobre otros métodos anticonceptivos.

10. Informe de inmediato a la sala de emergencias de las siguientes señales de peligro:

    - Sangrado vaginal abundante
    - Dolores de cabeza intensos o recurrentes
    - Visión borrosa o doble, o pérdida de visión
    - Tos con sangre, disnea (dificultad para respirar)
    - Dolor intenso de pecho, de estómago o de piernas
    - Reacción alérgica (inusual)
    - Ictericia (piel amarillenta)
    - Dolor, pus o sangrado en el lugar de la inserción

11. Informe cuanto antes al proveedor de atención médica de lo siguiente:

    - Depresión aguda o síntomas de depresión como fatiga, insomnio, tristeza, etc.
    - Síntomas de embarazo
    - Tumor en los senos

**PROGESTIN-ONLY INJECTIONS**
**CLIENT INSTRUCTIONS**

1. Timing of injections -. There are different ways to begin your injections. If your pregnancy test is negative and if you are reasonably confident that you are not pregnant, you may be able to get your first injection today. This is called DMPA Now. Otherwise, your first injection is given on your period (the first five days of your menstrual cycle) or the first five days following a first trimester abortion. After that you return for your injections every 13 weeks (91 days). It is better to come early for your injection than late. Your injection can be given as soon as 10-11 weeks after the previous one. If you are late for your injection, you will need to be tested for pregnancy. If you are late for your injection and have unprotected intercourse, contact your clinic immediately for emergency contraception.
2. After childbirth – If you are not breastfeeding, Progestin-Only Injection can be started in the first 5 days after you deliver.
3. Breastfeeding - If you are exclusively breastfeeding (i.e., no bottle supplements of any kind) and breastfeeding frequently night and day, you should have some natural contraceptive protection and so you may wait to begin Progestin-only injections until 6 weeks after delivery. If you are partially breastfeeding and sexually active you may consider starting Progestin-Only Injections as early as 4 weeks after delivery.
4. Medication – Progestin Only Contraception may not work as well as it can if you are taking the drug Cytadren (aminoglutethimide). This is a medication used to treat Cushing's Disease.
5. Vaginal Bleeding – Irregular menstrual bleeding is expected with progestin-only contraception. Your clinic may be able to help if you are having menstrual irregularities that you cannot tolerate. Expect these menstrual changes:
    - Breakthrough bleeding and spotting may occur daily for several weeks or months
    - Possibly (though rarely) heavy bleeding
    - Eventually may stop having periods altogether
6. Missed injection – If you return late for your injection, you will need a pregnancy test. If you do not return on time for your injection be sure you use a back up method of contraception or you may become pregnant. If you have unprotected sex, call the health department for emergency contraception.
7. STD/HIV - Progestin-Only Injection will not prevent STD/HIV. Use a female condom or latex male condom, limit number of lifetime partners, and avoid high-risk sexual behavior to help prevent STD/HIV.
8. Fertility - If you decide you want to become pregnant, do not return for your next injection. Instead schedule a preconception care visit. While you could become pregnant immediately. There sometimes is a delay in the return of fertility of up to 10-18 months.
9. Bone Density – Progestin-only injectable contraception decreases bone density especially during the early months of use. The decrease is similar to the decrease in bone density seen during breastfeeding. You should increase your vitamin D and calcium intake and participate in regular weightbearing exercise to maintain good bone health. Studies show that bone density recovers in the years after a woman stops using progestin-only injections. If you are concerned about bone density, it is recommended that you change your contraceptive method after 2 years of injections.
10. Weight gain – Progestin- only injectable contraception is associated with increase appetite and a weight gain on average of 3.5 to 5.4 lbs in the first year. This gain can increase to 7-8 lbs at 2 years. At five years, users of this method may gain up to 11.2 lbs. This is about 5 lbs more than users of non-hormonal methods of contraception. Monitor your daily caloric intake and exercise regularly.

11. Depression - If you notice any major mood changes (depression, irritability, change in sex drive), see your provider.

12. Read – Read the package insert.

13. Learn the warning signs to report for all hormonal methods of contraception:
    - **A** Abdominal pain (severe)
    - **C** Chest pain (severe), shortness of breath
    - **H** Headache (severe), new, more frequent, or one-sided; dizziness, weakness or numbness
    - **E** Eye problems (vision loss or blurring), speech problems
    - **S** Severe leg pain in calf or thigh
14. Smoking - If you smoke, stop smoking.

**INYECCIONES SÓLO DE PROGESTINA**
**INSTRUCCIONES PARA EL CLIENTE**

1. Momento de aplicación de las inyecciones: Hay varias maneras de comenzar a aplicar las inyecciones. Si la prueba de embarazo dio resultado negativo y usted está razonablemente segura de que no está embarazada, puede recibir hoy mismo la primera inyección. Esta técnica se conoce como *DMPA Now* (DMPA o acetato de medroxiprogesterona de depósito ahora). Otra opción es aplicar la primera inyección durante los primeros 5 días del ciclo menstrual, o los primeros 5 días después de un aborto provocado en el primer trimestre. A partir de entonces, se deberá aplicar las inyecciones cada 13 semanas (91 días). Es mejor recibir la inyección con anticipación que con retraso. La inyección siguiente puede aplicarse entre 10 y 11 semanas después de la anterior. Si se retrasa la aplicación de la inyección, es necesario hacer una prueba de embarazo. Si se retrasa la aplicación de la inyección y tiene relaciones sexuales sin protección, comuníquese con la clínica de inmediato para recibir un anticonceptivo de emergencia.
2. Después del parto: si no está lactando, puede empezar el método de inyecciones sólo de progestina en los primeros 5 días posteriores al parto.
3. Lactancia: si está alimentando a su bebé con leche materna exclusivamente (es decir, no usa suplementos de biberón de ninguna clase) y lo hace frecuentemente de día y de noche, debe usar un método anticonceptivo natural. En ese caso, tal vez deba esperar hasta 6 semanas después del parto para la aplicación de las inyecciones sólo de progestina. Si alimenta al bebé parcialmente con leche materna y mantiene relaciones sexuales en ese período, se recomienda aplicar la primera inyección de sólo progestina 4 semanas después del parto.
4. Medicamentos: el método anticonceptivo sólo de progestina es menos eficaz si la mujer toma Cytadren (aminoglutetimida), un medicamento que se emplea para el tratamiento de la enfermedad de Cushing.
5. Sangrado vaginal: es normal que el sangrado menstrual sea irregular con el método anticonceptivo de sólo progestina. Si a usted le resulta difícil tolerar este problema, puede obtener ayuda en la clínica. Los posibles cambios en la menstruación son:
    - Manchas de sangre y sangrado intermenstrual que pueden presentarse todos los días durante varias semanas o meses
    - Posible sangrando abundante (inusual)
    - Posible falta de menstruación por completo con el paso del tiempo
6. Inyecciones no aplicadas: si se retrasa la aplicación de la inyección, es necesario hacer una prueba de embarazo. Si no acude para que le apliquen la inyección cuando corresponda, recuerde usar un método anticonceptivo de refuerzo para evitar el embarazo. Si tiene relaciones sexuales sin protección, llame al departamento de salud para recibir un anticonceptivo de emergencia.
7. ETS/VIH: el anticonceptivo inyectable sólo de progestina no previene contra las enfermedades de transmisión sexual (ETS) ni el VIH. Para prevenir el contagio, use preservativos femeninos o preservativos masculinos de látex, limite el número de parejas sexuales a lo largo de su vida y evite las conductas sexuales de alto riesgo.
8. Fecundidad: si desea quedar embarazada, no se aplique otra inyección, y programe una visita de atención previa a la concepción. Aunque podría quedar embarazada de inmediato, en ocasiones, la recuperación de la fecundidad puede tardar hasta entre 10 y 18 meses.
9. Densidad ósea: el anticonceptivo inyectable sólo de progestina disminuye la densidad ósea, especialmente, en los primeros meses de uso. Esta disminución es similar a la que ocurre durante la lactancia. Usted debe consumir más vitamina D y calcio, además de hacer ejercicio regularmente con carga de peso para mantener la buena salud de los huesos. Los estudios demuestran que la mujer recupera la densidad ósea con los años, después de dejar de usar inyecciones sólo de progestina. Si usted está preocupada por la densidad ósea, se le recomienda que cambie de método anticonceptivo después de 2 años de aplicarse inyecciones.
10. Aumento de peso: se ha relacionado el anticonceptivo inyectable sólo de progestina con un aumento del apetito y con un aumento de peso promedio de 1.60 a 2.45 kg (3.5 a 5.4 libras) en el primer año de uso. Este aumento puede llegar a ser de 3.20 a 3.50 kg (7 a 8 libras) en dos años. Las mujeres que usan este método durante cinco años pueden llegar a aumentar hasta 5 kg (11.2 libras) de peso. Esto equivale a 2.30 kg (5 libras) más que las mujeres que usan métodos anticonceptivos sin hormonas. Controle el consumo diario de calorías y haga ejercicio habitualmente.

11. Depresión: si observa cambios en su estado de ánimo (depresión, irritabilidad, cambios en la libido), consulte con su proveedor de atención médica.

12. Lea las instrucciones que se incluyen en el paquete.

13. Conozca las señales de advertencia aplicables a todos los métodos anticonceptivos con hormonas:
   - **A** Dolor abdominal (intenso)
   - **C** Dolor (intenso) en el pecho y disnea (dificultad para respirar)
   - **H** Dolor de cabeza (intenso) reciente, más frecuente o de un solo lado; mareos, debilidad o entumecimiento
   - **E** Problemas de la vista (pérdida de visión o visión borrosa) y problemas del habla
   - **S** Dolor intenso en pantorrilla o muslo

14. Tabaquismo: si fuma, deje de hacerlo.

## PROGESTIN ONLY PILLS

## CLIENT INSTRUCTIONS

1. Progestin only pills (POPs) must be taken at the same time every day, so choose a time and then take the pill at that same time every day. Every time you take a pill late, and especially if you miss a pill, you are more likely to get pregnant. Always have a back-up method of birth control on hand such as a spermicide or condoms.
2. Take your first POP on the first day of your menstrual period. You will need no back-up method.
3. Or you may start your POPs on the day you get them (called Quick Start).This is the preferred method of starting your POPs. You may have a few weeks of break through spotting with Quick Start but it gets your protection from pregnancy started right away. You will need to use a back-up method of birth control for the first 48 hours if you use the Quick Start method.
4. If you start on any day other than the first day of your menstrual period, use a back-up method of birth control every time you have sex during the first 48 hours on POPs.
5. POPs do not prevent sexually transmitted diseases. Use a condom to decrease the risk of acquiring a sexually transmitted disease.
6. Start each new pack the day after the last pack is finished. There is no break between packs. Always have your next pack ready.
7. If you vomit soon after taking a pill, use a back-up method for 48 hours.
8. If you are more than 3 hours late taking your POP, take it as soon as you remember and use a back-up method of birth control for 48 hours.
9. If you miss one of your POPs, take the missed pill as soon as you remember. Then go back to taking your POPs at the regular time even if this means taking two pills in one day. Be sure to use a back-up method of birth control for the next 48 hours.
10. If you miss two POPs in a row, restart as soon as you remember by taking 2 pills then and 2 pills the next day. Be sure to use a back-up method of birth control for the next 48 hours.
11. If at any time you have unprotected sex, call your clinic for instructions on receiving emergency contraception (ECPs).
12. If you are not sure what to do about the pills you have missed, keep taking your POPs and use a back-up method until you can call the clinic.
13. If you do not have a period within four to six weeks of the last period, schedule a pregnancy test and exam with your clinic.
14. POPs will make your period less regular and spotting between periods is fairly common. Some women stop having periods completely. This is normal also. If you are concerned about your bleeding pattern, schedule an appointment with your clinic. Do not stop taking your POPs.
15. If you stop taking your POPs, your ability to become pregnant will return right away. Schedule a preconception care visit if you want to become pregnant. If you do not want to become pregnant, use a back-up method of birth control and schedule an appointment with your family planning clinic.
16. If you have sudden severe pain in your lower abdomen or stomach area, or repeated severe headaches, contact a doctor or your clinic right away.

## PÍLDORAS ANTICONCEPTIVAS SÓLO DE PROGESTINA

## INSTRUCCIONES PARA EL CLIENTE

1. Las píldoras anticonceptivas sólo de progestina (PSP) deben tomarse todos los días a la misma hora. Por lo tanto, escoja una hora y tome una píldora al día a la misma hora. Cada vez que se demore en tomar la píldora, y especialmente si se olvida de tomarla, aumentará la probabilidad de quedar embarazada. Tenga siempre al alcance un método anticonceptivo de refuerzo, como un espermicida o preservativos.
2. Tome la primera PSP el primer día de su período menstrual. No necesitará un método anticonceptivo de refuerzo.
3. O bien, puede empezar a tomar las PSP el mismo día que las obtenga. Este es el método de preferencia para empezar a tomarlas y se conoce como método de inicio rápido (*Quick Start*). Aunque de esta manera es posible que haya sangrado intermenstrual durante varias semanas, quedará protegida contra el embarazo de inmediato. Si usa el método de inicio rápido, necesitará usar un método anticonceptivo de refuerzo las primeras 48 horas.
4. Si empieza a tomar las PSP en un día que no es el primer día de su menstruación, use un método anticonceptivo de refuerzo cada vez que tenga relaciones sexuales en las primeras 48 horas.
5. Las PSP no previenen las enfermedades de transmisión sexual (ETS). Para disminuir el riesgo de contraer una ETS, use un preservativo.
6. Empiece un paquete nuevo el día después de haber terminado el paquete anterior. No hay período de descanso entre un paquete de píldoras y otro. Siempre tenga listo el paquete siguiente.
7. Si vomita después de tomar la píldora, use un método anticonceptivo de refuerzo durante las 48 horas siguientes.
8. Si se demora más de 3 horas en tomar la PSP, tómela tan pronto se acuerde de ello, y use un método anticonceptivo de refuerzo durante las siguientes 48 horas.
9. Si se olvida de tomar una PSP, tómela en cuanto se acuerde de ello. Luego, vuelva a tomar la PSP a la hora habitual, aunque deba tomar dos píldoras en un mismo día. Recuerde usar un método anticonceptivo de refuerzo durante las siguientes 48 horas.
10. Si se olvida de tomar 2 píldoras seguidas, reinicie el método tan pronto se acuerde, tomando 2 píldoras ese mismo día y 2 píldoras al día siguiente. Recuerde usar un método anticonceptivo de refuerzo durante las siguientes 48 horas.
11. Si tiene relaciones sexuales sin protección, llame a la clínica y pida información sobre cómo obtener las píldoras anticonceptivas de emergencia (PAE).
12. Si no está segura de lo que debe hacer respecto a las píldoras que olvidó tomar, siga tomando las PSP y use un método anticonceptivo de refuerzo hasta que pueda comunicarse con la clínica.
13. Si no tiene una menstruación en las cuatro a seis semanas después de la anterior, programe un examen y una prueba de embarazo en la clínica.
14. Con las PSP, la menstruación es menos regular y es muy común tener manchas de sangre entre períodos. En algunas mujeres se suspende la menstruación por completo, y esto también es normal que suceda. Si usted está preocupada por su ciclo menstrual, programe una cita en la clínica. No deje de tomar las PSP.
15. Si deja de tomar las píldoras sólo de progestina, recuperará la fecundidad de inmediato. Si desea quedar embarazada, programe una visita de atención médica previa a la concepción. Si no desea el embarazo, use un método anticonceptivo de refuerzo y programe una visita en la clínica de planificación familiar.
16. Si siente un dolor repentino e intenso en la parte inferior del abdomen o el estómago, o dolor de cabeza recurrente, llame de inmediato al médico o a la clínica.

## Reproductive Life Planning

What is a Reproductive Life Plan?

A reproductive life plan is a tool to help you protect your fertility; decide when or if to have children and how many children; and understand the role of contraception in planning your family. It can also help you understand the normal feelings that might make you risk an unplanned pregnancy. A reproductive health plan will include preconception health care visits to prepare for a planned pregnancy. And reproductive health plans can change as time goes by. But when you take the time to create a reproductive health plan, you become a sexually responsible person, in charge of your fertility, and ready to make planned decisions about the birth of your children.

The following is a list of topics to learn about and questions to ask yourself as you establish your reproductive health plan.

1. Learn about reproduction, the menstrual cycle, and fertility awareness

   It is difficult to make a plan if you do not understand how your reproductive system works. This includes menstruation, ovulation, fertilization, implantation and pregnancy.

1. Learn about STD prevention to preserve fertility

   Sexually transmitted diseases (STDs) (sometimes called sexually transmitted infections) can lead to infertility. To protect yourself from STDs, avoid high risk sexual behaviors. High risk sexual behaviors include sex without a male or female condom; having sex with different individuals or a partner who does so; having sex with many individuals in your life time or a partner who has done so; having sex with strangers (or a partner who has done so); having sex with a man who has sex with men; having sex with a man who is using IV drugs.

2. When do you want to become pregnant or when do you want to become pregnant again? Why?

   Think about it. What do you want to be doing a year from now? Two years from now? Don't let pregnancy "just happen" by "accident". An unplanned pregnancy will change your life. Are you ready? Remember, planning is the key to a healthy baby.

3. How many children would you like to have? Why?

   You decide the size of your family. This number could change as your life changes.

4. Learn about spacing each "birth to next conception" 18-23 months apart

   Experts agree that the healthiest time to conceive your next child is when the child in your arms is 18-23 months old. You will be healthier with good spacing and so will the next child.

5. Learn about contraceptive options including emergency contraception

   There are many good methods of contraception. Look at each one. How would each one work in your lifestyle? What will you do if you have unprotected intercourse? Do you have emergency contraception on hand? Emergency contraception is available at your local health department. And women 17 and older can get emergency contraception without a prescription at a pharmacy.

6. Learn about Pregnancy Ambivalence

It is normal for women of reproductive age to want to become pregnant and to fantasize about becoming pregnant. Even women who say they know that this is not a good time to get pregnant can feel this way from time to time especially during sex. It is common for women to become ambivalent about using contraception as they begin to long for a pregnancy. This ambivalence can lead to an unplanned pregnancy which satisfies the longing but creates new problems associated with unplanned pregnancy. If you know this is not a good time for you to be pregnant but you find yourself longing for a baby, seek a method of contraception that will work no matter how you are feeling such as an implant or IUD or contraceptive shot.

7. Learn about Planning

   Planning is the opposite of ambivalence. Planning means accepting your desire to become pregnant and acting on that desire in the most positive way for your health and for the health of the baby. Planned pregnancies are more likely to produce a healthy baby than unplanned pregnancies are.

8. The preconception health care visit is a part of planning.

   A good preconception health care visit will include a general health examination and testing. It will also include counseling regarding nutrition, alcohol use, prescription medications and over-the-counter medications. You will need to update any needed immunizations (including rubella status). You will need counseling regarding any possible familial genetic disorders. It is important to start prenatal vitamins with folic acid prior to conception. Chronic medical problems should be addressed before becoming pregnant. Smoking cessation would also be a part of this visit for women who smoke.

## Planificación de la vida reproductiva

¿En qué consiste un plan de la vida reproductiva?

El plan de la vida reproductiva es un instrumento que le ayuda a la mujer a proteger su fecundidad; a decidir el momento y el número de hijos que desea tener, y si desea tenerlos; y a comprender la función de la anticoncepción en la planificación de su familia. También le ayuda a entender los sentimientos normales que podrían ponerla en riesgo de un embarazo no planificado. Un plan de salud reproductiva incluirá visitas de atención médica previa a la concepción en preparación para un embarazo planificado. Aun cuando el plan puede modificarse con el transcurso del tiempo, la mujer que se dedica a elaborar un plan de salud reproductiva asume la responsabilidad de su vida sexual y de fecundidad, y se prepara para tomar decisiones planificadas sobre el nacimiento de sus hijos.

A continuación, enumeramos los temas de interés y las preguntas que usted puede plantearse al formular su plan de salud reproductiva.

1. Aprenda sobre la reproducción, el ciclo menstrual y la fecundidad.

   Para establecer un plan, es necesario entender el funcionamiento del aparato reproductor. Esto incluye la menstruación, la ovulación, la fecundación, la implantación y el embarazo.

2. Aprenda sobre la prevención de las enfermedades de transmisión sexual (ETS) para preservar la fecundidad.

   Las ETS (a veces conocidas como infecciones de transmisión sexual) pueden dar lugar a la esterilidad. Para protegerse de las ETS, evite las conductas sexuales de alto riesgo, que incluyen: tener relaciones sexuales sin preservativo masculino o femenino; tener relaciones sexuales con diferentes personas o con una persona que a su vez tiene varias parejas sexuales; tener muchas parejas sexuales a lo largo de la vida o una pareja sexual que haya tenido esta conducta; tener relaciones sexuales con personas desconocidas o con una pareja que haya tenido esta conducta; tener relaciones sexuales con un hombre que tiene relaciones sexuales con hombres o que consume drogas por vía intravenosa.

3. ¿Cuándo desea quedar embarazada por primera vez o nuevamente? ¿Por qué?

   Piénselo. ¿Qué desea estar haciendo dentro de un año? ¿Y dentro de dos años? No deje que el embarazo “suceda” por “accidente”. El embarazo no planificado cambiará su vida. ¿Está preparada para eso? Recuerde: la planificación es la clave para tener un bebé sano.

4. ¿Cuántos hijos querría tener? ¿Por qué?

   Usted decide el tamaño de su familia. El número de hijos que desea podría variar a medida que cambie su vida.

5. Aprenda sobre el espaciamiento de 18 a 23 meses entre un nacimiento y la concepción del próximo hijo

   Los expertos concuerdan en que el momento más sano para concebir el siguiente hijo es cuando el anterior tiene entre 18 y 23 meses de edad. Este espaciamiento contribuye a la salud de la madre y de su próximo hijo.

6. Aprenda sobre las opciones de métodos anticonceptivos, incluida la anticoncepción de emergencia

Existen muchos métodos anticonceptivos eficaces. Analice uno por uno. ¿Cómo funcionaría con su estilo de vida? ¿Qué hará si tiene relaciones sexuales sin protección? ¿Tiene un anticonceptivo de emergencia disponible? Los anticonceptivos de emergencia se pueden obtener en el departamento de salud local. Y las mujeres de 17 o más años de edad pueden obtenerlos en las farmacias, sin receta.

7. Aprenda sobre la ambivalencia del embarazo

   Es normal que las mujeres en edad de procreación deseen quedar embarazadas y fantaseen con la idea. Incluso las que afirman que saben que este no es un buen momento para embarazarse pueden desearlo de tanto en tanto, especialmente, durante la relación sexual. Es común que la mujer que empieza a desear el embarazo tenga sentimientos contradictorios respecto al uso de anticonceptivos. Esta ambivalencia puede dar lugar a un embarazo no planificado que puede satisfacer el deseo de la mujer pero le crea nuevos problemas asociados con la falta de planificación. Si usted sabe que este no es un buen momento para quedar embarazada pero desea tener un hijo, escoja un método anticonceptivo que funcione sin importar cómo se sienta, como puede ser un implante, un dispositivo intrauterino (DIU) o un anticonceptivo inyectable.

8. Aprenda sobre planificación

   La planificación es lo opuesto a la ambivalencia. Planificar significa aceptar que usted desea quedar embarazada y realizar las acciones más positivas para el bien de su salud y la de su bebé. Es más probable que un bebé nazca sano cuando el embarazo es planificado que cuando no lo es.

9. La visita de atención médica previa a la concepción es parte de la planificación.

   Una buena visita de atención médica previa a la concepción incluirá pruebas y exámenes generales También incluye orientación acerca de la nutrición, el consumo de alcohol, y los medicamentos con receta y de venta libre. Será necesario reforzar todas las vacunas necesarias (incluida la antirrubeólica). También necesitará asesoramiento sobre posibles trastornos genéticos hereditarios. Es importante comenzar a tomar vitaminas prenatales con ácido fólico antes de la concepción. Se debe tratar el tema de los problemas médicos crónicos antes del embarazo. Para las mujeres que fuman, dejar el hábito sería un tema a tratar durante la visita.

## Vaginal Contraceptive Ring Client Instructions

### General Information

The vaginal contraceptive ring is a type of hormonal birth control. It is similar to oral contraceptives. It contains an estrogen and a progestin delivered in a vaginal ring. This ring is worn for 3 weeks followed by a ring-free week during which time menstruation occurs. The vaginal contraceptive ring comes in a foil pouch. Save this pouch after you open it to use for disposing of the ring after the three weeks. Store your supply of rings at room temperature (approximately 59-86 degrees Fahrenheit).

### When to Insert the Vaginal Contraceptive Ring

The vaginal contraceptive ring is worn for 3 weeks followed by a ring-free week during which you get your period. The ring can be started in several ways:

1. Insert the first ring during the first five days of the menstrual cycle whether or not you are still menstruating. Three weeks after the day of insertion, on this same day of the week, at about the same time, you will remove the ring. You will leave the ring out for one week during which time you will have your period. Then, you will insert a new ring one week later, again, on the same day of the week at about the same time whether or not you are still menstruating. For example, if you put your first ring in the vagina on a Sunday at 10:00 PM, you will remove it three weeks later on Sunday at about 10:00 PM. On the next Sunday at about 10:00 PM you will insert the next ring whether or not you are still menstruating. Your protection from pregnancy begins after you have worn your first ring for 7 days. Use a back-up method of contraception, such as a male or female condom or a spermicide if you have sex during the first seven days of ring use. A diaphragm is NOT recommended as a back-up method for the vaginal contraceptive ring because the ring may interfere with the proper placement of the diaphragm.

2. You can begin using the ring 3 weeks after childbirth (if you are not breastfeeding). If you are breastfeeding, the risks of beginning the ring 1 month after childbirth generally outweigh any proven or theoretical risk. Some breastfeeding experts recommend waiting until your milk supply is well-established. Others recommend waiting until the infant is weaned. Check with your baby's health care provider for their recommendation.

3. If you are switching to the ring from birth control pills, you can begin the ring anytime during the seven hormone-free days or on the day you would have begun a new pack of pills. No back-up contraception is needed.

4. If you are switching from an IUD, you can insert the ring on the day the IUD is removed. Your protection begins when you have worn your ring for 7 days. Use a back-up method of contraception if you have sex during these first 7 days.

5. If you have been using a progestin-only method, you can begin your ring as follows. In each of these cases your protection begins after you have worn your ring for 7 days. Use a back-up method of contraception if you have sex during these first 7 days.

- Any day of the month when switching from a progestin-only pill; do not skip any days between the last pill and the first day of the ring.
- On the same day as a contraceptive implant is removed
- On the same day as the removal of a progestin–containing IUD
- On the day when the next contraceptive injection (Progestin-only injectable contraception) would be due.

6. The ring may be started within the first five days after a miscarriage or first trimester abortion. In this case, no back-up will be needed during the first seven days of ring use. You can begin using the vaginal

contraceptive ring 3 weeks after a second trimester abortion You will need a back-up method of contraception for the first seven days of ring use.

**How to Insert the Vaginal Contraceptive Ring**

To insert the vaginal ring, hold it between the thumb and index finger and press the opposite sides together. Gently push the folded ring into the vagina. The exact position of the ring is not important for it to work. Some women may be aware of the ring in the vagina but most do not. There can be discomfort if the ring is not inserted far enough to the back. The ring cannot be pushed too far to the back and be lost. The male partner may or may not be feel the ring during sex.

**How to Remove the Vaginal Contraceptive Ring**

Remove the ring by hooking your finger under the forward rim or by holding the rim between two fingers and pulling it out. Place the used ring in the saved foil pouch and dispose of it in the trash out of reach of children and pets. Do not flush down the toilet.

**Accidental Removal, Expulsion, or Prolonged Ring-Free Days**

The ring can be accidentally expelled during sexual intercourse or when straining with a bowel movement especially with constipation. Some women will remove their ring during sexual intercourse, but this practice is strongly discouraged. If the ring has been removed or expelled during the three-week use period, it should be rinsed with cool to lukewarm (not hot) water and re-inserted as soon as possible, at the latest **within three hours** of removal or expulsion. If the ring has been out of the vagina **for more than three hours**, contraceptive effectiveness may be reduced and an additional method of contraception must be used until the ring has been used continuously for seven days. If the ring is lost, a new ring should be inserted and the course continued without change. For example, if it is lost in week 2, insert a new ring to complete weeks 2 and 3. Remove at the end of week three and so on.
If the vaginal contraceptive ring has been left in the vagina for an extra 1-7 days (that is, up to an extra week), remove it and insert a new ring after taking the one week break for menstruation. If the ring is left in place **for more than 7 extra days** (that is, for more than an extra week), you may not be protected from pregnancy. A pregnancy test should be done. If the test is negative, insert a new ring and use a back-up method until the ring has been in place for seven days in a row. No one week break for menstruation would be taken.

In case of an error, ask your clinic for information regarding the use of emergency contraceptive pills (ECPs) for unprotected sex. Ask if they provide ECPs in advance of need.

**What To Do If You Miss a Period**

Always check for pregnancy if:

- There is a missed period
- There is a missed period and you left the ring out of the vagina for more than three hours sometime during the three week period of ring use.
- There is a missed period and you waited longer than one week to insert a new ring.
- You left the ring in place longer than four weeks.
- Despite following all instructions, you have missed two periods in a row

**Other Information**

Common side effects that include headache, vaginal irritation, increased vaginal discharge, weight gain, nausea, awareness of sensations related to the presence of the ring itself, and moodiness. Any of the side effects listed for birth control pills could potentially be experienced as well. See your consent form for more information.

The ring does not protect you from sexually transmitted diseases (STDs). Use a condom to help prevent STDs, limit the number of sexual partners that you have in your lifetime, and avoid high risk sexual behaviors.

Whenever you are receiving testing or treatment from a healthcare provider, tell them that you are using the vaginal contraceptive ring to prevent pregnancy. The hormones in the ring may affect the results of certain laboratory tests.

REMEMBER you should never have the ring out more than 7 days.

When you stop using the ring, your fertility will return right away. If you want to become pregnant, schedule a preconception care visit. If you do not want to become pregnant, use a back-up method and schedule a family planning visit for another method of contraception.

Read the package insert.

Learn the vaginal contraceptive ring warning signs:

- **A** Abdominal pain (severe)
- **C** Chest pain (severe), shortness of breath
- **H** Headache (severe), new, more frequent, or one-sided; dizziness, weakness or numbness
- **E** Eye problems (vision loss or blurring), speech problems
- **S** Severe leg pain in calf or thigh

If you smoke, stop smoking.

**Anillo vaginal anticonceptivo**
**Instrucciones para el cliente**

## Información general

El anillo vaginal anticonceptivo es un tipo hormonal de control de la natalidad, similar a las píldoras anticonceptivas. Libera estrógeno y progestina contenidos en un anillo vaginal. El anillo se usa 3 semanas seguidas, seguidas de una semana sin uso durante la cual se presenta la menstruación. El anillo viene en un sobre de papel aluminio que usted debe conservar después de abrirlo para desechar allí el anillo que haya usado durante las 3 semanas. Almacene el suministro de anillos a temperatura ambiente: entre 15ºC y 30ºC (59ºF y 86ºF) aproximadamente.

## Cuándo se debe colocar el anillo vaginal anticonceptivo

El anillo vaginal anticonceptivo se usa 3 semanas seguidas, con un intervalo de una semana sin uso, que corresponde al período menstrual. Hay varias maneras de iniciar el método:

1. Inserte el primer anillo durante los primeros 5 días del ciclo menstrual, aun cuando ya no esté sangrando. Extráigalo 3 semanas más tarde, en el mismo día de la semana y a la misma hora aproximadamente. Deje pasar una semana sin usar un anillo. En ese intervalo, tendrá su menstruación. Después de esos siete días, inserte un anillo nuevo, otra vez el mismo día de la semana y a la misma hora aproximadamente, esté o no menstruando. Por ejemplo: si inserta el primer anillo un día domingo a las 10:00 p.m., debe quitárselo tres semanas más tarde, en un día domingo alrededor de las 10:00 p.m. El domingo siguiente a este último, también cerca de las 10:00 p.m., debe insertar el siguiente anillo, esté o no menstruando. La protección para no quedar embarazada comienza 7 días después de haberse colocado el primer anillo. Si durante esos primeros 7 días tiene relaciones sexuales, use un método anticonceptivo de refuerzo, como ser un preservativo masculino o femenino, o un espermicida. El diafragma NO se recomienda como método de refuerzo para las mujeres que usan el anillo vaginal anticonceptivo ya que el anillo puede interferir con la colocación correcta del diafragma.

2. Usted puede empezar a usar el anillo 3 semanas después del parto (si no está lactando). Si está lactando, los riesgos de iniciar el método del anillo 1 mes después de dar a luz suelen ser mayores que los riesgos teóricos o comprobados. Algunos expertos en lactancia recomiendan esperar a que el suministro de leche esté bien establecido. Otros aconsejan esperar hasta el destete del lactante. Consulte la recomendación del proveedor de atención médica de su hijo.

3. Si usted está cambiando la píldora anticonceptiva por el anillo, puede empezar a usar el anillo en cualquier momento del intervalo de 7 días en los que no debe tomar píldoras o el día que tendría que empezar un nuevo paquete de píldoras. No necesita un método anticonceptivo de refuerzo.

4. Si usted está cambiando el dispositivo intrauterino (DIU) por el anillo, puede insertarlo el mismo día que le extraigan el DIU. La protección comienza a los 7 días de haber empezado a usar el anillo. Use un método anticonceptivo de refuerzo si tiene relaciones sexuales en esos primeros 7 días.

5. Si usted ha estado usando un método sólo de progestina, puede comenzar a usar el anillo como se explica a continuación. En todos los casos, la protección comienza a los 7 días de haber empezado a usar el anillo. Use un método anticonceptivo de refuerzo si tiene relaciones sexuales en esos primeros 7 días.

- Si cambia las píldoras sólo de progestina por el anillo, empiece a usar el anillo cualquier día del mes. No deje pasar ningún día entre la última píldora y el primer día del anillo.
- Si le extraen un implante anticonceptivo, empiece a usar el anillo ese mismo día.
- Si le extraen un dispositivo intrauterino (DIU) de progestina, empiece a usar el anillo ese mismo día.
- Si cambia un anticonceptivo inyectable sólo de progestina por el anillo, empiece a usar el anillo el día que tendrían que aplicarle la nueva inyección.

6. El método del anillo puede iniciarse en los primeros 5 días después de un aborto espontáneo o de un aborto provocado en el primer trimestre. En este caso, no necesitará un método anticonceptivo de refuerzo durante los primeros 7 días de uso del anillo. Usted puede iniciar el anillo vaginal anticonceptivo 3 semanas después de un aborto provocado en el segundo trimestre. Necesitará un método anticonceptivo de refuerzo durante los primeros 7 días de uso del anillo.

**Cómo se debe colocar el anillo vaginal anticonceptivo**

Para insertar el anillo vaginal, una los lados opuestos presionando con los dedos índice y pulgar. Empuje cuidadosamente el anillo doblado dentro de la vagina. La posición exacta del anillo no tiene importancia para que funcione. La mayoría de las mujeres no sienten el anillo después de colocarlo, pero algunas sí. Si no lo inserta con suficiente profundidad dentro de la vagina, puede ser incómodo. Es imposible empujar demasiado el anillo y que se pierda en el interior. El hombre puede o no sentir el anillo durante las relaciones sexuales.

**Cómo se debe extraer el anillo vaginal anticonceptivo**

Enganche un dedo debajo del borde de adelante o sostenga el borde con dos dedos para jalar y extraer el anillo de la vagina. Coloque el anillo usado en el sobre de papel aluminio que usted guardó al abrirlo, y deséchelo en la basura, fuera del alcance de niños y mascotas. No deseche el anillo en el inodoro.

**En caso de expulsión o extracción accidental, o de más días sin anillo**

El anillo puede ser expulsado por accidente durante la relación sexual o al hacer esfuerzo para defecar, especialmente cuando hay estreñimiento. Algunas mujeres se quitan el anillo vaginal durante la relación sexual, aunque es una práctica muy desaconsejada. Si el anillo es expulsado o extraído en el transcurso de las 3 semanas de uso, enjuáguelo con agua entre fría y tibia (no caliente) y vuelva a colocarlo lo antes posible, a más tardar **en las 3 horas siguientes** a la expulsión o extracción. Si el anillo permaneció fuera de la vagina **por más de 3 horas**, es posible que sea menos eficaz y que usted necesite un método anticonceptivo de refuerzo hasta que haya vuelto a usarlo por 7 días consecutivos. Si pierde el anillo vaginal, debe colocar uno nuevo y continuar el proceso sin cambios. Por ejemplo, si lo pierde en la segunda semana, inserte un anillo nuevo para completar esa semana y la tercera. Extraiga el anillo al final de la tercera semana, y así sucesivamente.
Si el anillo vaginal anticonceptivo permaneció en la vagina casi una semana más (es decir, de 1 a 7 días más de lo indicado), extráigalo y coloque uno nuevo después de una semana de descanso, correspondiente al período menstrual. Si el anillo permanece colocado **más de 7 días extra** (es decir, más de una semana adicional), es posible que usted no esté protegida contra el embarazo. Debe hacerse la prueba del embarazo. Si el resultado de la prueba es negativo, inserte un anillo nuevo y use un método anticonceptivo de refuerzo durante los primeros 7 días de uso consecutivo. En ese caso, no se tomaría la semana de descanso correspondiente a la menstruación.

En caso de error, solicite información en la clínica acerca de las píldoras anticonceptivas de emergencia (PAE) para las relaciones sexuales sin protección. Pregúnteles si proporcionan las PAE antes de que sean necesarias.

**Qué debe hacer si no tiene el período menstrual**

Siempre compruebe si está embarazada en los casos siguientes:

- No tiene un período menstrual.
- No tiene un período menstrual y extrajo el anillo por más de 3 horas en algún momento durante las 3 semanas que debe usarlo.
- No tiene un período menstrual y dejó pasar más de una semana para insertar un anillo nuevo.
- Se dejó el anillo colocado por más de 4 semanas.
- A pesar de que siguió todas las instrucciones, no tiene dos períodos menstruales consecutivos.

**Otra información**

Los efectos secundarios más comunes incluyen dolor de cabeza, irritación de la vagina, mayor secreción vaginal, aumento de peso, náusea, sensación de presencia del anillo y cambios de estado de ánimo. También podrían aparecer los efectos secundarios correspondientes a las píldoras anticonceptivas. Para obtener más información, lea el formulario de consentimiento.

El anillo no protege a la mujer del contagio de las enfermedades de transmisión sexual (ETS). Para prevenir las ETS, limite el número de parejas sexuales a lo largo de su vida, y evite las conductas sexuales de alto riesgo.

Toda vez que un proveedor de atención médica le realice un tratamiento o pruebas, infórmele que está usando un anillo vaginal anticonceptivo para evitar el embarazo. Las hormonas que libera el anillo pueden afectar a los resultados de ciertas pruebas de laboratorio.

RECUERDE: nunca deje de usar el anillo por más de 7 días.

Cuando deje de usar el anillo, recuperará la fecundidad de inmediato. Si desea quedar embarazada, programe una visita de atención previa a la concepción. Si no desea el embarazo, use un método anticonceptivo de refuerzo y programe una visita de planificación familiar para cambiar de método.

Lea las instrucciones que se incluyen en el paquete.

Conozca las señales de advertencia del anillo vaginal anticonceptivo:

- **A** Dolor abdominal (intenso)
- **C** Dolor (intenso) en el pecho y disnea (dificultad para respirar)
- **H** Dolor de cabeza (intenso) reciente, más frecuente o de un solo lado; mareos, debilidad o entumecimiento
- **E** Problemas de la vista (pérdida de visión o visión borrosa) y problemas del habla
- **S** Dolor intenso en pantorrilla o muslo

Si fuma, deje de hacerlo.