

PUBLIC HEALTH

NURSING PROTOCOL

Tennessee Department of Health
Community Health Services
Patient Care Services

PREFACE

The Public Health Nursing (PHN) protocol represents a detailed written set of instructions to guide medical management of our patients, thereby establishing a standard of care for the Public Health Nurse's practice. The PHN Protocol was developed, and is maintained, by the Public Health Nursing Practice Committee. These Protocols represent an enormous amount of work from a variety of nurses, physicians and other staff throughout the State. They have been reviewed by the State Medical Director, State Nursing Director, Nursing Leadership Team, Medical Leadership Team, and specific individuals that are involved in developing program guidelines that impact nursing practice.

The manual is divided into seven distinct sections. **Section I** includes those protocols related to **Emergency Management**. **Section II** includes those protocols related to **Family Planning**. **Section III** is the **General section** which addresses treatments for various conditions that are not included in the other distinct sections. This section also includes recommended periodicity schedules for maintenance of child health. **Section IV** includes the **Immunization** protocols. **Section V** includes those protocols related to **Sexually Transmitted Diseases**. **Section VI** includes protocols related to **Disaster Preparedness and Bioterrorism**. Finally, an **Appendix** section (**section VII**), includes additional program specific information and the **List of Standard Abbreviations**.

As always, we welcome your comments and suggestions with regards to additions, revisions, format changes etc. It is our goal to maintain an accurate, viable, and user friendly document.

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PUBLIC HEALTH NURSING PROTOCOL AGREEMENT

Region _____

County/Site _____

This protocol has been jointly prepared by public health nurses and physicians and is approved for use by all licensed nurses. The health providers whose names are signed below agree that this protocol establishes the standard for public health nursing practice for those conditions included in the protocol. **Two protocols within this manual (2.010 and 3.025) are deemed to be outside of the scope of practice for Licensed Practical Nurses and therefore may be performed by the RN only**

This protocol expires one year from the date of signatures. It shall be renewed, or revised, and signed annually and more frequently as deemed necessary.

Name	Date
_____	_____
	Regional Medical Director Date
_____	_____
	Regional Nursing Director Date
_____	_____
	County Health Officer Date
_____	_____
	County Nursing Supervisor Date
_____	_____
_____	_____
_____	_____
_____	_____

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HUMAN PAPILOMAVIRUS (HPV) VACCINE: HPV4 and HPV9 (GARDASIL[®] or GARDASIL[®]9 by Merck)

GENERAL INFORMATION

Human Papillomavirus (HPV) is the most common sexually-transmitted virus in the United States, with over 40 known strains infecting the genital areas of men and women. It is transmitted through intimate skin to skin contact: about 80% of sexually-active men and women are infected with HPV at some point in their lives. Most HPV infections are undetectable and go away on their own without causing problems; however, certain HPV types can cause head and neck cancers and cancers of the cervix and anogenital areas. Each year in the US, HPV causes about 360,000 cases of genital warts, about 17,600 cancers in women and 7,300 cancers in men.

HPV vaccine is an inactivated vaccine, administered intramuscularly. There are two types made by Merck. Gardasil[®] (HPV4) is licensed by the Food and Drug Administration (FDA) for administration to males and females aged 9 years through 26 years; it protects against HPV 6 and 11 (causes of 90% of genital warts) and HPV 16 and 18 (causes of 65% of HPV-associated invasive cancers in men and women). Gardasil[®] 9 (HPV9) is currently licensed for females 9 through 26 years and males 9 through 15; however, the Advisory Committee on Immunization Practices (ACIP) recommends either brand in males through 26 for whom HPV vaccination is indicated. TDH protocols follow ACIP recommendations. HPV9 protects against 5 additional strains, protecting against an *additional* 14% of HPV cancers in females and 4% of HPV cancers in males. Both vaccines are given in a three-dose series. HPV vaccine has no effect on pre-existing infections; however, sexually active and HPV-infected patients for whom vaccination is recommended will benefit from protection against strains not yet acquired and should be vaccinated.

GlaxoSmithKline produces the HPV vaccine Cervarix[®], which targets HPV 16 and 18. It is licensed for females 9-25 only, on the same schedule as HPV4 and HPV9. It is not widely used in the US and not typically stocked in health departments. If a woman has started the vaccine series with Cervarix[®], any available HPV vaccine may be used to complete the series.

HPV vaccine may be simultaneously administered with other vaccines, including live virus vaccines. It is stored in standard refrigerated conditions at 2-8°C (35-46°F).

To determine if a patient in an ACIP recommended group is eligible for free federal vaccine, refer to the current Tennessee Immunization Program Policy on the use of federal vaccine.

Contraindications to giving the vaccine include the following:

Severe allergic (anaphylactic) reaction to a previous dose of HPV4 or HPV9 or any component (including yeast). The vaccine contains no preservatives.

Precautions:

Moderate to severe acute illness (defer until recovery) [Note: Low grade fever <100.5°F or mild illnesses are not reasons for deferring immunization]

Pregnancy: the vaccine has not been associated with adverse events when given during pregnancy; however it is not recommended if recipient is known to be pregnant.

Special Situations (per ACIP):

Breastfeeding is not a precaution or contraindication to immunization

A history of abnormal Pap smears, genital warts or other HPV infection is not a precaution or contraindication to vaccination. Such persons can benefit from protection against strains they have not yet acquired. Recipients should be advised that the vaccine does not protect against any strains they have already acquired.

Adverse Reactions:

Soreness, swelling or redness around the injection site is common

Syncope (especially common in adolescents)

PLAN

ACIP Recommendations for Use of either HPV9 or HPV4:

Females

- Routine Recommendation: Give first dose to all pre-teens at age 11 or 12 years (may begin at 9 years).
- Catch-up vaccination of all females age 13 through 26 years who have not completed the series.
- Females who have initiated the series before turning 27 may complete the series even if past age 26.

Males

- Routine Recommendation: Give first dose to all pre-teens at age 11 or 12 years (may begin at 9 years).
- Catch-up vaccination of all males 13 through 21 years who have not completed the series.
- The vaccine *may* be given to older males 22-26 who have not completed the series.
- It is *recommended* for previously unvaccinated older males 22-26 who have sex with men or whose immune system is weakened by HIV infection, other illness or medication.
- Males who have initiated the series before turning 27 may complete the series even if past age 26.

If a person has already started a vaccine series with HPV4, continue to use HPV4 if available unless HPV9 is requested or HPV4 supplies have run out. Either HPV4 or HPV9 may be used to complete the series as health department clinics transition to HPV9.

	Recommended Interval	Minimum Interval
Dose 2	1 to 2 months after dose 1	4 weeks after dose 1
Dose 3	6 months after dose 1	12 weeks after dose 2 and 24 weeks after dose 1

- ✓ Counsel regarding HPV benefits, side effects, and management
- ✓ Ask parent/guardian or recipient about contraindications, precautions
- ✓ Have parent/guardian or recipient read Vaccine Information Statement
- ✓ Administer the 0.5 mL dose of vaccine intramuscularly according to manufacturer instructions
- ✓ Advise parent/guardian or recipient to return for the next dose at the appropriate interval
- ✓ Advise to wait in clinic for 20 minutes after administration of vaccine
- ✓ Record manufacturer and lot number of the vaccine administered, date vaccine and VIS given, address of facility, and name and title of person administering vaccine
- ✓ Instruct patient/guardian to contact Health Department if adverse reaction occurs

REFERENCES

Use of 9-Valent Human Papillomavirus (HPV) Vaccine: Updated HPV Vaccination Recommendations of the Advisory Committee on Immunization Practices, MMWR March 27, 2015; pp. 300-304. <http://www.cdc.gov/mmwr/pdf/wk/mm6411.pdf>

GARDASIL®9 [Human Papillomavirus 9-valent Recombinant Vaccine] Vaccine package insert, Merck, copyright 2014, Revised February 2015.

GARDASIL® [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine] Vaccine package insert, Merck, copyright 2006, Revised June 2014.

Cervarix [Bivalent Human Papillomavirus (Types 16, 18) Vaccine, Recombinant] Prescribing Information, GlaxoSmithKline, copyright 2009. Revised February 2015. http://us.gsk.com/products/assets/us_cervarix.pdf

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 (VAERS), 7.010
Vaccines and Route of Administration,
 7.010
Varicella, 3.530
Varicella Vaccine, 4.290
Vasovagal Reaction, 1.150
Vaginal Contraceptive Ring, *see Quick Start*

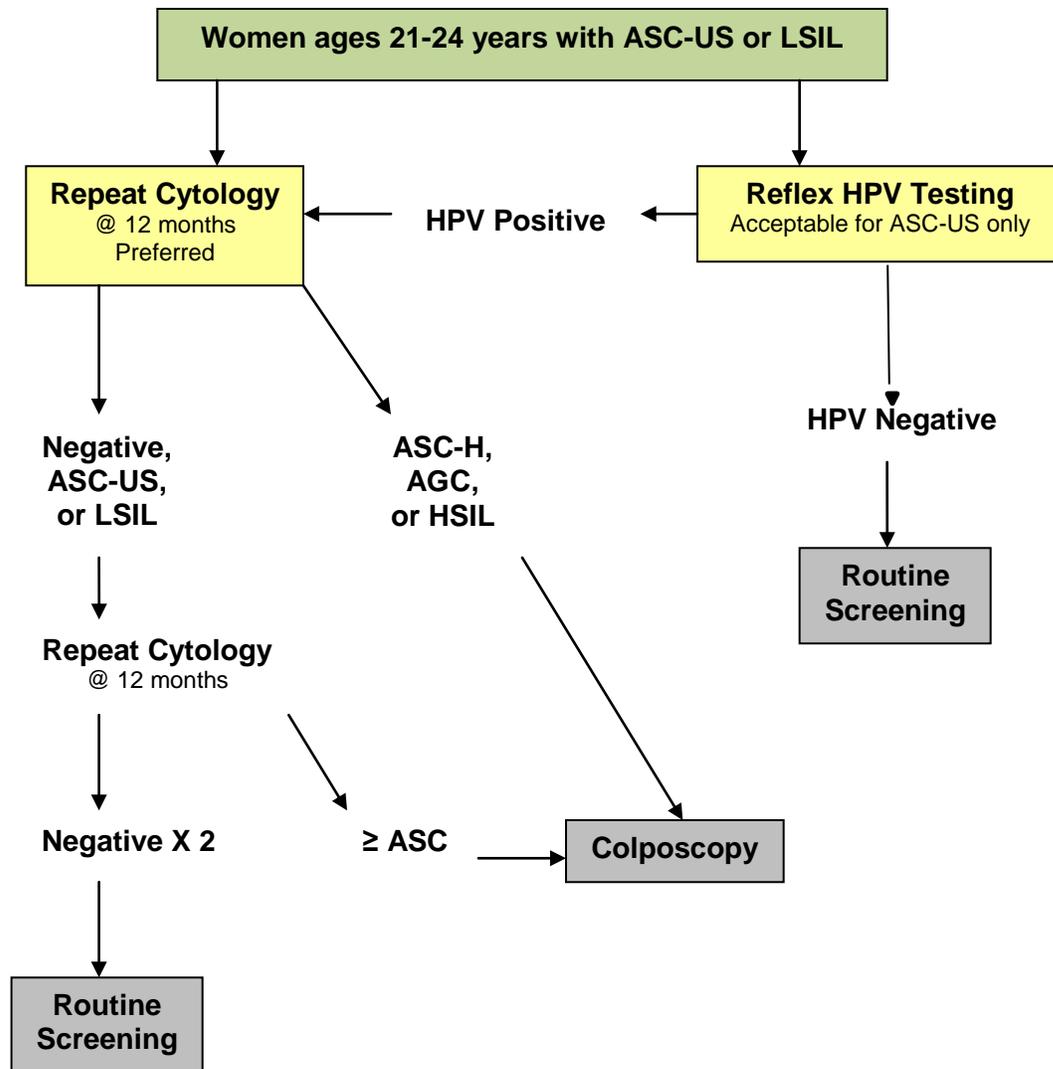
-W-

Wound, Puncture, 1.110

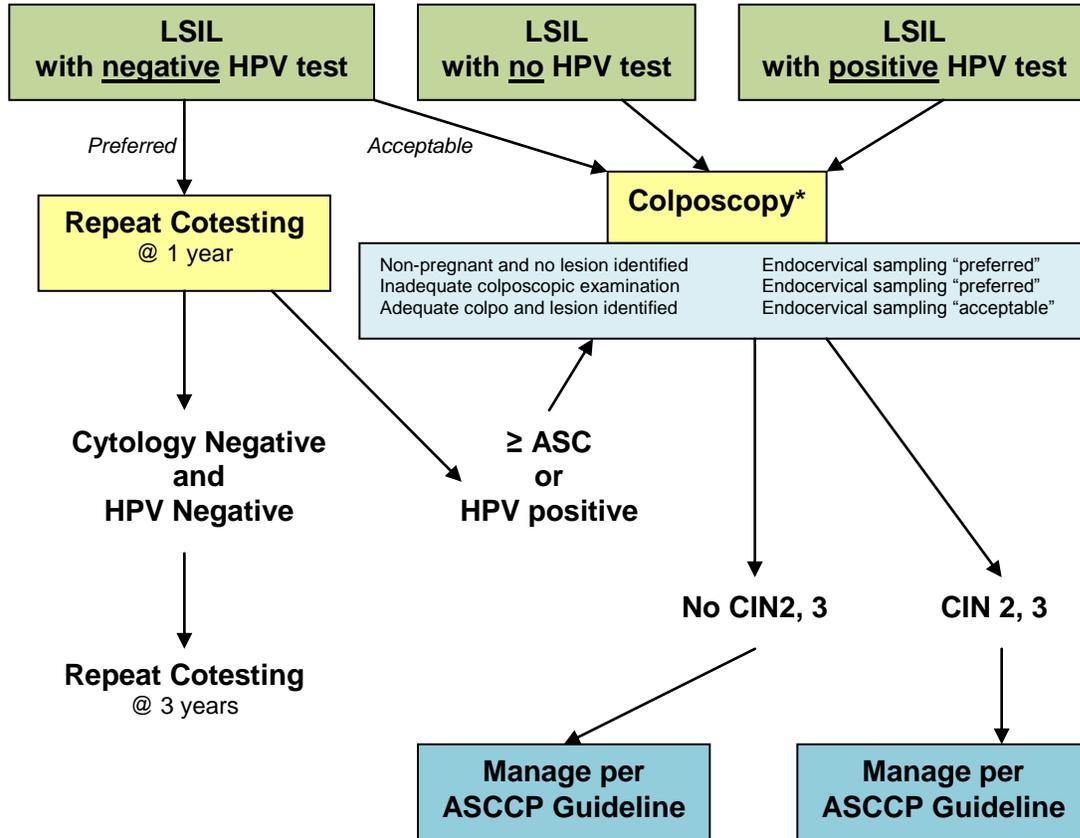
-X-

-Y-

Management of Women Ages 21-24 years with either Atypical Squamous Cells of Undetermined Significance (ASC-US) or Low-grade Squamous Intraepithelial Lesion (LSIL)

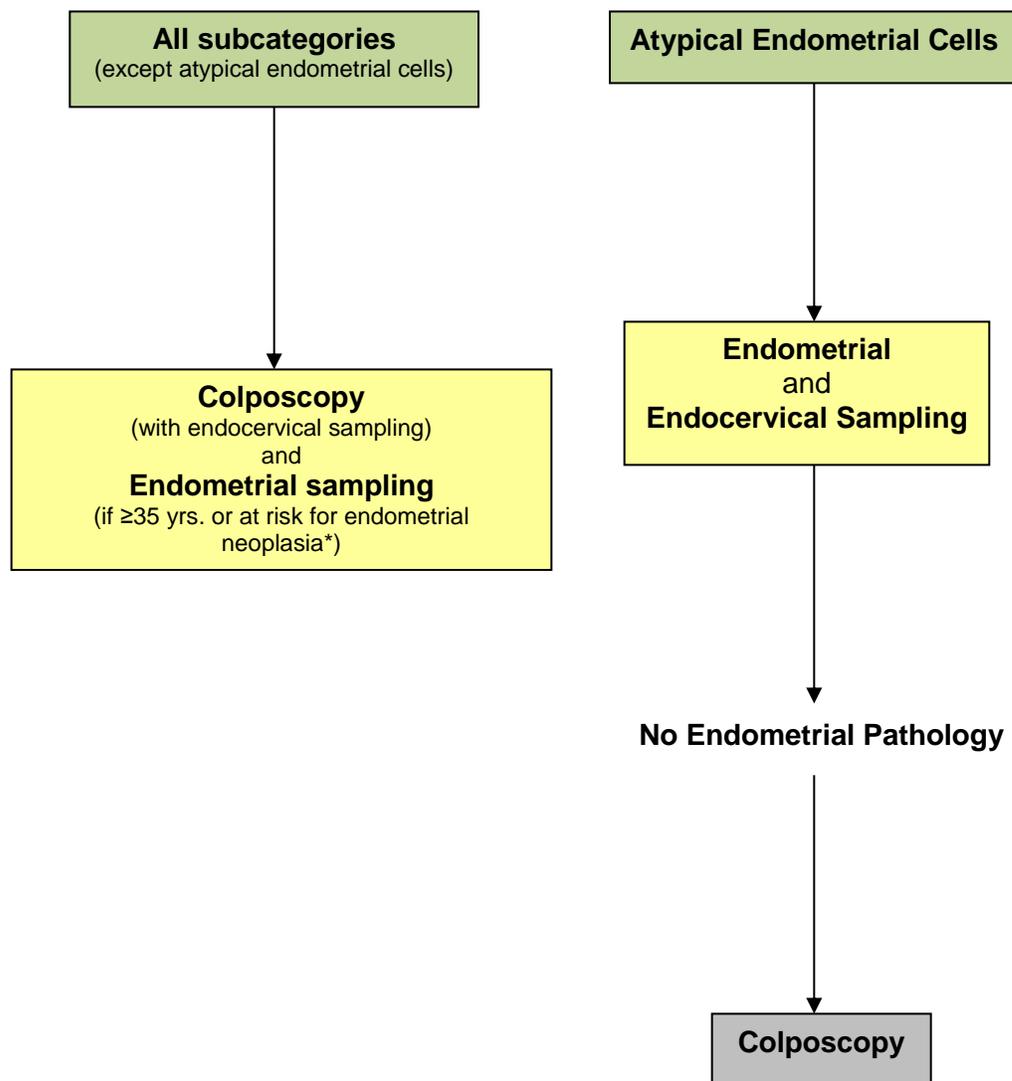


Management of Women >25 years with Low-grade Squamous Intraepithelial Lesions (LSIL)
 (For women between 21-24 years, see previous algorithm.)



***After colposcopy, management is directed by the colposcopist. Refer to the ASCCP algorithm booklet April 2013 for further guidelines.**

Initial Workup of Women with Atypical Glandular Cells (AGC)



*Includes unexplained vaginal bleeding or conditions suggesting chronic anovulation.

After colposcopy, management is directed by the colposcopist. Refer to the ASCCP algorithm booklet April 2013 for further guidelines.

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2. American College of Obstetricians and Gynecologists. (2012). Well-woman visit. Committee Opinion No. 534. *Obstet Gynecol* , 120, 421-424.
3. American Society for Colposcopy and Cervical Pathology. (2013). Algorithms updated consensus guideline for managing abnormal cervical cancer screening tests and cancer precursors.
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5. Moyer, V. A. on behalf of the U.S. Preventive Services Task Force. (2012). Screening for cervical cancer: U.S. Preventive Services Task Force recommendation statement. *Annals of Internal Medicine*, 156 (12), 880-891.
6. Saslow, D., Solomon, D., Lawson, H. W., Killackey, M., Kulasingam, S. L., Cain, J., . . . the ACS-ASCCP-ASCP Cervical Cancer Guideline Committee. (2012). American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. *J Low Genit Tract Dis*, 16 (3), 175-204.
7. Solomon, D., Davey, D., Kurman, R., Moriarty, A., O'Connor, D., Prey, M.,...for the Forum Group Members and Bethesda 2001 Workshop. (2002). The 2001 Bethesda system terminology for reporting results of cervical cytology. *JAMA*, 287(16), 2114-2119.
8. 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.

COMBINED HORMONAL CONTRACEPTION (PILLS, PATCH, RING)

GENERAL INFORMATION

A physical exam is not necessary to begin combined hormonal contraception.

SUBJECTIVE

Screening components for contraceptive services include:

- Reproductive life plan
- Medical history
- Sexual health assessment
- Tobacco use (for clients age 35 and older)

OBJECTIVE

- Blood pressure
- Height, weight, BMI (optional)
- Pregnancy test (if clinically indicated)

ASSESSMENT

A current medical history should be taken for each client. The history must be negative for U.S. Medical Eligibility Criteria categories 3 and 4 to issue combined hormonal contraception.

Refer to the Summary Chart of U. S. Medical Eligibility Criteria for Contraceptive Use in Family Planning Reference section 2.170.

PLAN

PHN follows the ongoing plan of care written by the examiner or RN initiates combine hormonal contraception via Quick Start Protocol.

- Document name, dosage, route, and frequency of the method
- Document number of cycles given
- PHN must consult with health department APN/MD and obtain an order to continue chosen method beyond 6 months.
- Provide necessary health teaching to use method correctly and consistently.
- Provide client with method specific instructions. Resources are available at <http://fpntc.org/training-and-resources/contraceptive-fact-sheets>. A Spanish version is available at <http://www.cardeaservices.org/resourcecenter/contraceptive-fact-sheets-Spanish>. You may also use previously approved instructions.
- Document 3-4 of the Title X Office of Population Affairs required health teaching/counseling topics during each family planning visit until instruction in all required topics is complete.
- Health teaching regarding emergency warning signs:
 - A Abdominal pain – severe (as might be seen with liver disease, gallbladder disease, ectopic pregnancy)
 - C Chest pain - severe, (cough, shortness of breath or sharp pain on inhalation as might be seen with heart attack or pulmonary embolism)

- H** Headache - severe, dizziness, weakness, or numbness, especially if one-sided (as might be seen with migraine or stroke especially with numbness or muscle weakness)
- E** Eye disturbances vision loss or blurring, also speech problems (as might be seen with retinopathy or stroke)
- S** Severe leg pain in calf or thigh (as might be seen with thrombophlebitis)

- Chlamydia and gonorrhea screening
 - Screen all sexually active women aged ≤ 25 years for chlamydia AND gonorrhea annually
 - Screen all sexually active women ≥ 26 years with risk factors for chlamydia AND gonorrhea.
 - Risk factors include; a new partner; more than one sex partner; a partner who has other concurrent partners; or a partner who has a sexually transmitted infection
- Offer condoms for improved STI protection.
- Offer condoms and/or contraceptive foam or film for use as back-up protection against unintended pregnancy.
- Offer ECP as indicated
- Advise client when to return to the clinic for a visit with provider
- Consult APN or physician for complications and warning signs or for side effects that have not responded to standard treatments

Preventative Health Recommendations

Clients are no longer required to have an examination to receive most contraceptive methods. However, the client must be advised of the importance of the recommended related family planning preventative health screening¹ and testing for women including:

Cervical Cytology (pap smear). Refer to PHN Protocol 2.020 for screening guidelines

Genital exam should accompany cervical cancer screening

Clinical Breast Examination:

ACOG recommends annual CBE for women ages 19 and older.

Mammography:

USPSTF recommends screening mammography for women ages 50-74 every other year.

¹If a TennCare child (under the age of 21) receives the major components of a Child Health/EPSTD exam through the health department's family planning clinic, she should also receive developmental screening and vision and hearing risk assessment/screening in order to complete the recommended AAP standards for preventive health care.

REFERENCES

Hatcher, R. et al. Contraceptive Technology, Twentieth Revised Edition. New York: Ardent Media 2011.

A Pocket Guide to Managing Contraception, Hatcher, R.A., Nelson, A.L., Ziemann, M. et. al., Tiger, Georgia: Bridging the Gap Foundation, 2015.

Center for Disease Prevention. “U.S. Medical Eligibility Criteria for Contraceptive Use.” MMWR, Vol. 59, June 18, 2010.

Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs MMWR/ Vol. 63 / No. 4 April 25, 2014

CONDOMS, SPONGE, AND SPERMICIDAL AGENTS

GENERAL INFORMATION

Male Condoms

There are three types of male condoms:

- Latex condom – a barrier to sperm and sexually transmitted infections
- Polyurethane condom – also a barrier to sperm and sexually transmitted infection
- Natural skin condom – a barrier to sperm ONLY

Female Condoms

There is one style of female condom sold under the trade name, FC2 Female Condom® by the Female Health Company (FHC). It is approved for both contraception and STI prevention.

Contraceptive Sponge

The Today Sponge® is the brand name of the contraceptive sponge currently available in the United States. The contraceptive sponge provides a spermicide and a polyurethane physical barrier to cover the cervix. The preservative in the Today Sponge® is metabisulfite. Persons with known allergy to sulfa drugs should not use the Today Sponge®.

Spermicides

Spermicides are also available over the counter and come in different formulations such as foam, gel, cream, film, suppository, or tablet. All are placed inside the vagina prior to sexual intercourse. Nonoxynol-9 is the active ingredient found in spermicides sold in the United States. Spermicides have been associated with vaginal irritation and microscopic ulceration that lead to easier transmission of HIV. **Clients at risk of HIV infection should never use a spermicide.**

SUBJECTIVE

If the client is participating in a visit with a nurse, collect a medical history.

Screening components for contraceptive services include:

- Reproductive life plan
- Medical history
- Sexual health assessment

OBJECTIVE

Male and female clients may receive a supply of male or female condoms and/or spermicide and/or contraceptive sponge without a physical examination or laboratory testing.

ASSESSMENT

Appropriate for condom and/or spermicide use

Contraindications

Male and female clients may receive a supply of condoms and/or spermicide without collecting or reviewing the medical history. However, when possible:

- Inquire about latex, polyurethane or spermicide allergy with condom or spermicide users.
- Sulfa allergy with sponge users.
- History of toxic shock syndrome for sponge users.
- Inquire and counsel about sexual behaviors that increase STI/HIV risks such as multiple partners either consecutively or concurrently, partners who are strangers to the client, a client who has a partner known to have other partners, or a client whose partner has sex with men.

Caution

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

PLAN

- Provide health teaching either face to face or in writing.
- Provide client with method specific instructions. Resources are available at <http://fpntc.org/training-and-resources/contraceptive-fact-sheets>. A Spanish version is available at <http://www.cardeaservices.org/resourcecenter/contraceptive-fact-sheets-Spanish>. You may also use previously approved instructions.
- Provide requested method in adequate amount and include instruction for use and care.
- Re-supply visits are based on the client's request.
- Discuss, and if possible, provide emergency contraception with non-prescriptive barrier methods.
- Encourage consideration of a highly effective method of contraception.
- Discuss the benefits of planned pregnancy and the risks of unintended pregnancy.
- When applicable, document 3-4 of the Title X Office of Population Affairs required health teaching/counseling topics during each family planning visit until instruction in all required topics is complete.

Preventative Health Recommendations

Clients are no longer required to have an examination to receive most contraceptive methods. However, the client must be advised of the importance of the recommended related family planning preventative health screening and testing.

Females:

Cervical Cytology (pap smear) refer to PHN Protocol 2.020 for screening guidelines

Genital exam should accompany cervical cancer screening

Clinical Breast Examination:

ACOG recommends annual CBE for women ages 19 and older.

Mammography:

USPSTF recommends screening mammography for women ages 50-74 every other year.

Males:

Examination of the genitals of adolescent **males** should be conducted to document normal growth and development; exam should include palpation of inguinal nodes, scrotal contents, penis and peri-anal region as well as inspection of skin & hair

REFERENCES

Centers for Disease Control and Prevention, Providing Quality Family Planning Services. Recommendations of CDC and the U.S. Office of Population Affairs. MMWR, April 25, 2014.

Center for Disease Control and Prevention, U.S Medical Eligibility Criteria for Contraceptive Use, 2010, MMWR early release, Volume 59, May 28, 2010.

Hatcher, R. et al. Contraceptive Technology, Twentieth Revised Edition, New York: Ardent Media. 2014.

Zieman M., Hatcher R. A., Allen A. Z. *Managing Contraception 2015-2016*, Tiger, Georgia; Bridging the Gap Foundation, 2015.

CONTRACEPTIVE PATCH

GENERAL INFORMATION

A physical exam is not necessary to begin the contraceptive patch. While deferring the physical examination should not be routine, certain circumstances may exist which make it reasonable. It is essential that the PHN see General Information and Plan of Care for a Deferred Exam found in Protocol 2.010, “All Methods, Initial and/or Annual Family Planning Visit” before dispensing a method without a physical exam.

See Family Planning Clinical Guidelines and the most current edition of Contraceptive Technology for method counseling details.

SUBJECTIVE FINDINGS

For method specific guidelines, including those for a deferred exam, refer to the Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive use in Family Planning reference section 2.170.

U.S. Medical Eligibility Criteria category system:

- 1 = May provide method with no restrictions
- 2 = May provide method as the advantages generally outweigh the risks. Consult a physician or APN as necessary and document appropriately
- 3 = May not provide method, proven risk usually outweigh the advantages
- 4 = Method may not be used.

OBJECTIVE FINDINGS (Laboratory tests for FP clients are chosen as indicated by the method, or by client need. However, laboratory tests cannot exceed any established department or program screening or testing limits. Limitations on laboratory testing may be established to meet funding or other needs).

- Blood pressure
- Height and weight for BMI
- Physical examination¹ performed annually by examiner
- Hemoglobin or Hematocrit as indicated
- Pap smear in accordance with current Pap smear guidelines
- Sickle cell screening
- Syphilis serology
- Mantoux tuberculin test
- Pregnancy test

¹ If a TennCare child (under the age of 21) receives the major components of a Child Health/EPSTD exam through the health department’s family planning clinic, she should also receive developmental screening and vision and hearing risk assessment/screening in order to complete the recommended AAP standards for preventive health care. REFER TO THE FAMILY PLANNING SECTION OF THE PTBMIS MANUAL FOR CORRECT CODING OF THIS TYPE VISIT.

- Rubella titer
- Wet prep (examiner)
- HIV testing
- Urinalysis
- Gonorrhea and chlamydia screening.

REFER TO SCREENING CRITERIA FOR CHLAMYDIA AND GONORRHEA SECTION 2.170.

ASSESSMENT

Appropriate to begin or continue the contraceptive patch either with or without the physical examination.

PLAN OF CARE FOR DEFERRED EXAM VISIT

The plan of care for a deferred exam visit is considered preliminary or temporary and can be established by the PHN. This preliminary or temporary plan of care must address the following:

- An explanation for the deferral.
- The medical history for the initial client, an updated medical history for the annual client who is deferring the exam, and an updated history for the supply client who is changing her method by deferred exam. The history must be negative for U.S. Medical Eligibility Criteria categories 3 and 4 to dispense without an exam. Consider a physician or APN consult for any category 2 findings and document appropriately.
- For annual visits (or re-supply visits), consult for side effects that have not responded to standard treatments (i.e., take COC pill at bedtime for nausea), complications, or warning signs. Record consult instruction in chart.
- Blood pressure measurement, weight, hemoglobin or hematocrit as indicated.
- Height for initial visit or annually for adolescents.
- Name, dosage, route, and frequency of the contraceptive chosen.
- The number of cycles given (up to 3 cycles).
- Informed consent form for an initial client or if giving the return client a new method.
- Document necessary health teaching to start and use method correctly and consistently. (See Client Instruction Sheet found in Appendix of Family Planning Clinical Guidelines available in English and Spanish).
- Document necessary health teaching regarding emergency warning signs:
 - A** Abdominal pain – severe (as might be seen with liver disease, gallbladder disease, ectopic pregnancy)
 - C** Chest pain - severe, (cough, shortness of breath or sharp pain on inhalation as might be seen with heart attack or pulmonary embolism)
 - H** Headache - severe, dizziness, weakness, or numbness, especially if one-sided (as might be seen with migraine or stroke especially with numbness or muscle weakness)
 - E** Eye disturbances vision loss or blurring, also speech problems (as might be seen with retinopathy or stroke)
 - S** Severe leg pain in calf or thigh (as might be seen with thrombophlebitis)

- Offer condoms for improved STD protection.
- Offer condoms and/or contraceptive foam or film for use as back-up protection against unintended pregnancy.
- Date of the exam appointment. In clinics with open access systems, chart the date the client is expected to return

PLAN OF CARE FOR AN EXAM VISIT OR RESUPPLY VISIT

An **ongoing plan of care** will be developed and signed at the exam visit by either the PHN with gyn skills, RN-ES, APN or Physician (all referred to as “examiner”). The ongoing plan of care is developed in accordance with the protocol for the particular examiner. The ongoing plan of care written by the examiner must be reviewed and followed by the PHN at each visit. For re-supply visits, consult APN or physician for complications and warning signs. Also consult for side effects that have not responded to standard treatments. Record consultant instructions in chart

HEALTH TEACHING

Through the Title X Program Guidelines, the federal Office of Population Affairs requires that counseling about certain topics occur with family planning clients. These required topics must be discussed with the client at least once during the time the client is under the care of the Family Planning Program. Ideally, the client will receive instruction on 3 or 4 of the required topics at each visit until instruction in all required topics is completed. Topics do not need to be repeated unless the client request a review or the provider assesses that a review is needed. **Address client counseling at each visit and base counseling/education on client needs and program requirements.**

For contraceptive method education and counseling, use the Client Instruction Sheet found in the current version of the Tennessee’s Family Planning Clinical Guidelines. Also use the teaching tool on the reverse side of the method-specific consent form.

All providers must document education and counseling provided during each family planning visit on the table found on the history form in the medical chart. The expression, “counseling per protocol” is not adequate documentation for Title X education and counseling that should occur during initial, annual, supply and medical visits.

There is a detailed list of the REQUIRED counseling/education topics in the Family Planning Program Clinical Guidelines, under Visit Guidelines. Other counseling topics are also detailed. A brief list of counseling/education topics is provided in the All Methods, Initial and/or Annual Family Planning Visit section of the PHN Protocol.

REFERENCES

- Contraceptive Technology, Twentieth Revised Edition, Robert A. Hatcher, M.D., et al, 2011.
- Contraceptive Technology Reports, A supplement to Contraceptive Technology Update, BB#S02103, May 2002.
- Contraceptive Technology Update, “FDA Revises Evra Safety Labeling Due To Increased Estrogen Levels”, Volume 27, Number 1, January 2006.
- A Pocket Guide to Managing Contraception, Hatcher, R.A., Nelson, A.L., Ziemann, M. et. al., Tiger, Georgia: Bridging the Gap Foundation, 2010.
- "Family Planning Program Clinical Guidelines," Tennessee Department of Health, 2011.
- Ortho Evra Package Insert, Ortho McNeil Pharmaceutical, Inc., November 2001.
- “Program Guidelines for Project Grants for Family Planning Services,” Office of Population Affairs, U.S. Department of Health and Human Services, January 2001.
- Center for Disease Control and Prevention, US Medical Eligibility Criteria for Contraceptive Use, MMWR, Vol. 59, June 18, 2010.

DIAPHRAGM

GENERAL INFORMATION

A diaphragm cannot be supplied by deferred exam because a fitting is required.

SUBJECTIVE

Screening components for contraceptive services include:

- Reproductive life plan
- Medical history
- Sexual health assessment
- Assess for allergy to spermicides

OBJECTIVE

Height, Weight, BMI (Optional)

ASSESSMENT

Patient request diaphragm for birth control

PLAN

The ongoing plan of care written by the examiner must be reviewed and followed by the PHN at each visit. For re-supply visits, consult APN or physician for complications and warning signs. Also consult for side effects that have not responded to standard treatments.

- Provide necessary health teaching to use method correctly and consistently
- Provide client with method specific instructions. Resources are available at <http://fpntc.org/training-and-resources/contraceptive-fact-sheets>. A Spanish version is available at <http://www.cardeaservices.org/resourcecenter/contraceptive-fact-sheets-Spanish>. You may also use previously approved instructions.
- Refer to APN or MD for bimanual examination, cervical inspection and fitting.
- Document 3-4 of the Title X Office of Population Affairs required health teaching/counseling topics during each family planning visit until instruction in all required topics is complete.
- Chlamydia and gonorrhea screening
 - Screen all sexually active women aged ≤ 25 years for chlamydia AND gonorrhea annually
 - Screen all sexually active women ≥ 26 years with risk factors for chlamydia AND gonorrhea.
 - Risk factors include; a new partner; more than one sex partner; a partner who has other concurrent partners; or a partner who has a sexually transmitted infection
- Offer condoms for improved STI protection.
- Offer ECP as indicated

- Advise client when to return to the clinic for visit with provider

Preventative Health Recommendations

Clients are no longer required to have an examination to receive most contraceptive methods. However, the client must be advised of the importance of the recommended related family planning preventative health screening and testing.

Females:

Cervical Cytology (pap smear) refer to PHN Protocol 2.020 for screening guidelines

Genital exam should accompany cervical cancer screening

Clinical Breast Examination:

ACOG recommends annual CBE for women ages 19 and older.

Mammography:

USPSTF recommends screening mammography for women ages 50-74 every other year.

REFERENCES

Centers for Disease Control and Prevention. Providing Quality Family Planning Services. Recommendations of CDC and the U.S. Office of Population Affairs. MMWR. April 25, 2014

Zieman M., Hatcher R. A., Allen A. Z., *Managing Contraception 2015-2016*, Tiger, Georgia; Bridging the Gap Foundation, 2015.

Hatcher, R. et al. Contraceptive Technology, Twentieth Revised Edition. New York: Ardent Media 2011.

DYSMENORRHEA

GENERAL INFORMATION

Primary dysmenorrhea is defined as painful menstruation that begins with or shortly after menarche. It is physiologic in nature due to either excessive secretion of prostaglandin by the endometrium or structural abnormality of the uterus. Studies of uterine contractions with primary dysmenorrhea reveal uterine pressures that are similar to those found during the second stage of labor.

Secondary dysmenorrhea begins later in life and is the result of having developed other physical factors. Endometriosis is an example of secondary dysmenorrhea. Both primary and secondary dysmenorrhea can be debilitating.

SUBJECTIVE

The client complains of one or more of the following symptoms just before and/or as her menstrual period begins:

- Lower abdominal cramping pain with onset of menstrual flow
- Pain radiating to the lower back or down inner thigh
- Nausea, vomiting, urinary frequency, and/or diarrhea during first 48 hours of menses
- Headache, dizziness, chills
- Weakness or fainting (symptoms of vasomotor instability)

OBJECTIVE

- Normal blood pressure
- Normal temperature
- Normal Hgb or Hct
- The client is, typically, within 1-2 years of having started her menstrual cycles (menarche).

ASSESSMENT

Primary Dysmenorrhea

PLAN

1. At the earliest sign or symptom of menstruation or 1-2 days before the onset of menses begin the following:
 - **IBUPROFEN (MOTRIN) OR NAPROXEN SODIUM (ALEVE)**
Per manufacturer's instructions
2. Discuss oral contraceptive use with the client and consult with the health department APN or MD if the client would like to begin COC to treat her primary dysmenorrhea. DMPA and the levonorgestrel-releasing IUD also decrease menstrual pain and menstrual flow. A consult would be necessary for these as well.

3. Other comfort measures:
 - Apply a warm heating pad to lower abdomen
 - Avoid constipation
 - Exercise regularly between menstrual cycles

Health Teaching:

Review the signs and symptoms of toxic shock syndrome for tampon users.

Young women who are menstruating are of reproductive age and will benefit from information regarding reproductive health and human sexuality. These can be offered at time convenient for the client and the staff.

Referral Indicators:

Severe cramping unrelieved by OTC analgesics that persists beyond the first 2 days and/or increases in severity throughout menses.

Dysmenorrhea with fever.

Tampon users who develop sudden onset of high fever, chills, sunburn-like rash, hypertension, vomiting, and diarrhea should immediately remove the tampon and be referred for emergency medical treatment.

Dysmenorrhea that begins later in life (years after menarche).

Follow-up:

Patient will be asked to contact a health provider if no improvement in 48 hours.

REFERENCES

Hatcher, R. et al, Contraceptive Technology, Twentieth Revised Edition, New York: Ardent Media. 2011.

Kelsey, B. & Nagtalon-Ramos, J. Midwifery & Women's Health Nurse Practitioner Certification Review Guide. Burlington, MA: Jones & Bartlett. 2016

EMERGENCY CONTRACEPTIVE PILLS (ECPs)

GENERAL INFORMATION

All clinics must have plans in place to provide ECPs on site to clients who request them. All clinics must have plans in place to educate clients regarding the availability of ECPs.

The package label for ECPs *recommends* starting treatment within 72 hours of unprotected sexual intercourse, but they may be effective for up to 120 hours.

ECPs following rape and sexual abuse

If a victim of rape or sexual abuse is underage, refer to Community Health Services (CHS) Policy 3.06 for direction regarding child abuse reporting. All citizens of Tennessee, including health care professionals, are required to report any suspicion of 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. Refer to the DCS website: at www.tennessee.gov/youth for further information on the process for reporting suspected child abuse or child sexual abuse is described. The Child Protective Services section of the website provides the required reporting information. Clinics are discouraged from deciphering what is or is not child abuse or child sexual abuse. It is the responsibility of DCS to decide whether or not the reported suspicion warrants investigation under Tennessee's child abuse/child sexual abuse laws.

SUBJECTIVE

Client reports unprotected sexual intercourse sometime within the previous 120 hours (5 days). Record last menstrual period if known.

Contraindications:

- A known established pregnancy (not that it is dangerous for the woman or the pregnancy, but because ECPs cannot prevent an established pregnancy)
- Undiagnosed abnormal vaginal bleeding
- Allergy to the product

OBJECTIVE

Client is already late for her menstrual period; advise a pregnancy test
 Client is not late for her menstrual period; no pregnancy test needed **UNLESS**
If issuing or prescribing Ella, a pregnancy test is required

ASSESSMENT

Client requests ECPs and has no contraindications

PLAN

- Physical examination is not required
- Provide ECPs and document in chart.
- Consult health department physician or APN before providing ECPs if unprotected sexual intercourse greater than 120 hours prior to visit.
- Because hormonal ECP is not 100% effective, check urine pregnancy test 3 weeks after ECP use.
- Offer Family Planning clinic services on same day or offer an appointment.
- Provide literature and counseling on contraceptive methods and the benefits of consistent use of a regular contraceptive method. Most methods can be supplied at time of ECP visit. Refer to Quick Start Protocol 2.010
- Document 3-4 of the Title X Office of Population Affairs required health teaching/counseling topics during each family planning visit until instruction in all required topics is complete.

Provide ECPs from one of the following regimens:

Dedicated Emergency Contraception products

Ella®	One tablet as soon as possible	Ulipristal acetate 30 mg	<ul style="list-style-type: none"> • REQUIRES NEGATIVE PREGNANCY TEST • Recommended for clients over 170 lbs
Next Choice®	Both tablets taken at once as soon as possible	Levonorgestrel 0.75mg each tablet	
Plan B One-step® Or Opicon One-Step	One tablet as soon as possible	Levonorgestrel 1.5 mg	

Caution:

Instruct client to watch for **DANGER SIGNS** (“ACHES”) during the two weeks following the administration of ECPs:

- A** Abdominal pain – severe (as might be seen with liver disease, gallbladder disease, ectopic pregnancy)
- C** Chest pain - severe, (cough, shortness of breath or sharp pain on inhalation as might be seen with heart attack or pulmonary embolism)
- H** Headache - severe, dizziness, weakness, or numbness, especially if one-sided (as might be seen with migraine or stroke especially with numbness or muscle weakness)

- E** Eye disturbances vision loss or blurring, speech problems
(as might be seen with retinopathy or stroke)
- S** Severe leg pain in calf or thigh (as might be seen with thrombophlebitis)

REFERENCES:

American College of Obstetricians and Gynecologists (ACOG), "Emergency Contraception", ACOG Technical Bulletin, 69, December 2005.

Hatcher, RA, Trussell, J, Nelson al, et al. Contraceptive Technology. Twentieth edition. New York: Ardent Media 2011.

Center for Disease Control and Prevention. "U.S. Medical Eligibility Criteria for Contraceptive Use." MMWR, Vol. 59, June 18, 2010.

Zieman M., Hatcher R. A., Allen A. Z. *Managing Contraception 2015-2016*, Tiger, Georgia; Bridging the Gap Foundation, 2015

FERTILITY AWARENESS-BASED METHODS (FAM)

GENERAL INFORMATION

Fertility awareness-based methods can be provided by deferred exam.

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:

Fertility Awareness-based Method	Synopsis
Calendar Method	The calendar rhythm method requires that a woman keep a record of the length of 6-12 menstrual cycles. Find the longest and shortest of your past menstrual cycles. Subtract 18 from the number of days in the shortest cycle to find the first fertile day. Subtract 11 from the number of days in the longest cycle to find the last fertile day. To prevent pregnancy, avoid unprotected intercourse from the first through the last days identified as fertile.
Standard Days Method	The standard days method is only for women whose menstrual cycles are 26 to 32 days long. On days 8 to 19, avoid unprotected intercourse. To simplify this method, the client may use a specially designed, color-coded string of beads, brand name CycleBeads®.
Two Day Method	Until a woman can say, "I do not have vaginal secretions today and I did not have secretions yesterday", she must consider herself fertile.
Billings Ovulation Method	This ovulation method relies on assessment of the cervical mucus by look, touch, and by the feeling of wetness at the vulva.
Symptothermal Method	The symptothermal method is a method that combines observation of cervical mucous with basal body temperature (BBT).

SUBJECTIVE

Collect and review medical history including obstetric and gynecologic history with emphasis on the menstrual cycle preferable for the previous 6-12 months.

Screening components for contraceptive services include:

- Medical history
- Reproductive life plan
- Sexual health assessment

OBJECTIVE

- Pregnancy test (if clinically indicated)
- Height, Weight, BMI (optional)

PLAN

- Provide necessary health teaching to use method correctly and consistently
- Provide client with method specific instructions. Resources are available at <http://fpntc.org/training-and-resources/contraceptive-fact-sheets>. A Spanish version is available at <http://www.cardeaservices.org/resourcecenter/contraceptive-fact-sheets-Spanish>. You may also use previously approved instructions.
- Document 3-4 of the Title X Office of Population Affairs required health teaching/counseling topics during each family planning visit until instruction in all required topics is complete.
- Chlamydia and gonorrhea screening
 - Screen all sexually active women aged ≤ 25 years for chlamydia AND gonorrhea annually
 - Screen all sexually active women ≥ 26 years with risk factors for chlamydia AND gonorrhea.
 - Risk factors include; a new partner; more than one sex partner; a partner who has other concurrent partners; or a partner who has a sexually transmitted infection
- Offer condoms for improved STI protection
- Offer ECP as indicated
- Advise client when to return to the clinic for visit with provider

Preventative Health Recommendations

Clients are no longer required to have an examination to receive most contraceptive methods. However, the client must be advised of the importance of the recommended related family planning preventative health screening and testing.

Females:

Cervical Cytology (pap smear) refer to PHN Protocol 2.020 for screening guidelines

Genital exam should accompany cervical cancer screening

Clinical Breast Examination:

ACOG recommends annual CBE for women ages 19 and older.

Mammography:

USPSTF recommends screening mammography for women ages 50-74 every other year.

Males:

Examination of the genitals of adolescent **males** should be conducted to document normal growth and development; exam should include palpation of inguinal nodes, scrotal contents, penis and peri-anal region as well as inspection of skin & hair

REFERENCES

Contraceptive Technology, Robert A. Hatcher, M.D., et al., Twentieth Revised Edition, 2011.

"Family Planning Clinical Guidelines" Tennessee Department of Health, January 2011

A Pocket Guide to Managing Contraception, Hatcher, R.A., Nelson, A.L., Ziemann, M. et. al., Tiger, Georgia: Bridging the Gap Foundation, 2010.

www.cyclebeads.com

Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs MMWR/ Vol. 63 / No. 4 April 25, 2014

INTRAUTERINE CONTRACEPTIVES (IUC)

GENERAL INFORMATION

IUC's include the Copper T-380A (Paragard), the Levonorgestrel IUS (Mirena and Skyla). IUC's are not abortifacients. Paragard is indicated for contraception for up to 10 years while Mirena is reliable for up to 5 years and Skyla up to 3 years. Paragard and Mirena are being investigated for extended use.

Each device has a unique insertion procedure and must be placed by a clinician who has been trained regarding the nuances of insertion of the specific IUC.

All PHNs must be able to discuss the intrauterine contraceptives (IUC) option with clients, provide the client with written information on the safety and effectiveness of IUCs, and answer any questions the client may have. Refer client to APN/MD for consultation.

SUBJECTIVE

- Medical history
- Reproductive life plan
- Sexual health assessment

OBJECTIVE

Pregnancy test is **required** day of insertion

ASSESSMENT

An IUC can be inserted under any of the following circumstances:

- Ideally, at time of menses
- When pregnancy can be ruled out
- Within 48 hours after delivery (vaginal or C/S)
- Immediately following first/second trimester abortion

A current medical history should be taken for each client. The history must be negative for U.S. Medical Eligibility Criteria categories 3 and 4 to issue without an exam.

Refer to the Summary Chart of U. S. Medical Eligibility Criteria for Contraceptive Use in Family Planning Reference section 2.170.

Contraindications for IUCs:

- Active pelvic infection (PID, endometritis, mucopurulent cervicitis)
- Known or suspected pregnancy
- Cervical or endometrial cancer
- Severe cervical stenosis
- Abnormal vaginal bleeding that has not been evaluated
- Severe uterine distortion (bicornuate uterus, fibroids)

- Gestational trophoblastic neoplasia
- Wilson's disease or copper allergy (Paragard only)

PLAN

- Perform pregnancy test
- Document 3-4 of the Title X Office of Population Affairs required health teaching/counseling topics during each family planning visit until instruction in all required topics is complete.
- Chlamydia and gonorrhea screening
 - Screen all sexually active women aged ≤ 25 years for chlamydia AND gonorrhea annually
 - Screen all sexually active women ≥ 26 years with risk factors for chlamydia AND gonorrhea.
 - Risk factors include; a new partner; more than one sex partner; a partner who has other concurrent partners; or a partner who has a sexually transmitted infection
- Offer condoms for improved STI protection
- Advise client when to return to the clinic for visit with provider

Teach IUC Warning Signs

- ✓ All IUC clients must be counseled to report the signs of pelvic infection. These include:
 - Malodorous vaginal discharge
 - Fever (101 F or more without obvious cause)
 - Sudden severe abdominal or suprapubic pain
 - Dyspareunia
- ✓ Other **WARNING SIGNS** that IUC clients must be instructed to report immediately include:
 - Abdominal or pelvic pain (ectopic pregnancy)
 - Prolonged or heavy bleeding/discharge/odor (infection)
 - Painful sexual intercourse
 - Fever or chills (infection)
 - Any signs of pregnancy
 - Known exposure to gonorrhea/chlamydia
 - Cannot feel strings or can feel plastic (expelled/perforated IUC)
 - Missed period or abnormal spotting or bleeding (infection or ectopic pregnancy)
 - Flu-like illness (infection)
- ✓ The following is a useful acronym for remember the IUC warning signs:
 - P** Period late (pregnancy), abnormal spotting or bleeding
 - A** Abdominal pain, pain with intercourse
 - I** Infection exposure (any STI), abnormal discharge
 - N** Not feeling well, fever, chills
 - S** String missing, shorter or longer

Preventative Health Recommendations

Clients are no longer required to have an examination to receive most contraceptive methods. However, the client must be advised of the importance of the recommended related family planning preventative health screening and testing.

Females:

Cervical Cytology (pap smear) refer to PHN Protocol 2.020 for screening guidelines

Genital exam should accompany cervical cancer screening

Clinical Breast Examination:

ACOG recommends annual CBE for women ages 19 and older.

Mammography:

USPSTF recommends screening mammography for women ages 50-74 every other year.

REFERENCES

Kelsey, B. & Nagtalon-Ramos, J. Midwifery & Women's Health Nurse Practitioner Certification Review Guide. Burlington, MA: Jones & Bartlett. 2016

Hatcher, R. et al. Contraceptive Technology, Twentieth Revised Edition. New York: Ardent Media 2011.

Center for Disease Control and Prevention, U.S Medical Eligibility Criteria for Contraceptive Use, 2010, MMWR, Volume 59, June 18, 2010.

ParaGard T 380A, Intrauterine Copper Contraceptive, Prescribing Information, Duramed Pharmaceuticals, Inc., May 2006.

Mirena Intrauterine System, Prescribing Information, Bayer HealthCare Pharmaceuticals, July 2008.

A Pocket Guide to Managing Contraception, Hatcher, R. A., Nelson, A. L., Ziemann, A., et al, . Tiger, Georgia: Bridging the Gap Foundation, 2010-2012.

PRECONCEPTION HEALTH SERVICES

GENERAL INFORMATION

Preconception describes any time that a woman of reproductive potential is at risk of becoming pregnant or when a man is at risk for impregnating his female partner. Preconception health-care services aim to identify and modify biomedical, behavioral, and social risks to a woman's health or pregnancy outcomes through prevention and management.

SUBJECTIVE

Medical history

Female client	Male client	Female and Male
<ul style="list-style-type: none"> - history of poor birth outcomes - preterm or cesarean delivery - miscarriage and stillbirth - medicines that are known teratogens 	<ul style="list-style-type: none"> - medical/surgical history that might impair reproductive health - history of reproductive failures - conditions that can reduce sperm quality (i.e.obesity, diabetes,varicocele) 	<ul style="list-style-type: none"> - Reproductive life plan - Sexual health assessment - Environmental exposures, hazard and toxins - Genetic conditions - Immunization history - Depression - Intimate partner violence

OBJECTIVE

Height, weight, BMI (optional)

Blood pressure

For female and male clients with a sustained BP > 135/80 (treated or untreated), refer client to primary care physician for diabetes screen

ASSESSMENT

Preconception care/counseling

PLAN

For women: Folic acid 0.4 to 0.8 mg daily

Management/referral as indicated for:

Hypertension

Diabetes

Depression

Intimate partner violence

Tobacco/ETOH/drug use

Immunizations

REFERENCES:

Center for Disease Prevention. "U.S. Medical Eligibility Criteria for Contraceptive Use." MMWR, Vol. 59, June 18, 2010.

MMWR, Providing Quality Family Planning Services, Recommendations of CDC and the U.S. Office of Population Affairs, April 25, 2014/63(04)

PREGNANCY TEST

GENERAL INFORMATION

Patients requesting pregnancy tests at the Health Department should be tested on that day and only deferred if absolutely necessary.

SUBJECTIVE

Screening components for pregnancy testing and counseling includes:

Appropriate history

Date of LMP

History of unprotected coitus since LMP

Symptoms of pregnancy and date symptoms appeared:

Breast tenderness

Fatigue

Nausea

Urinary frequency

OBJECTIVE

Positive or negative urine pregnancy test

ASSESSMENT

Pregnancy test positive, pregnancy intended

Pregnancy test positive, pregnancy unintended

Pregnancy test negative, pregnancy desired

Pregnancy test negative, pregnancy not desired

PLAN

- Discuss test results clearly and objectively.
- Refer to health department APN or MD for pelvic exam as indicated
- Chlamydia and gonorrhea screening
 - Screen all sexually active women aged ≤ 25 years for chlamydia AND gonorrhea annually
 - Screen all sexually active women ≥ 26 years with risk factors for chlamydia AND gonorrhea.
 - Risk factors include; a new partner; more than one sex partner; a partner who has other concurrent partners; or a partner who has a sexually transmitted infection

If pregnancy test is positive and pregnancy is desired

- Provide an estimation of gestational age
- Inform client about normal signs/symptoms of pregnancy
- Provide initial prenatal counseling including
 - Importance of early prenatal care
 - Importance of nutrition, prenatal vitamins, and folic acid
- Stress importance of good dental care during pregnancy and refer if applicable

- Discuss appropriate vaccinations and offer if available
- Enroll or refer eligible clients to WIC, HUGS, and Presumptive TennCare
- If patient is not eligible for Presumptive TennCare, refer patient to other prenatal care resources
- Advise patient to avoid
 - Drugs, both prescription and OTC
 - Smoking including e-cigarettes
 - Alcohol and substance use
 - Fish containing high mercury (shark, swordfish, king mackerel, or tilefish)
- Discuss impact of STI on pregnancy, offer STI screening including HIV
- Review signs/symptoms of ectopic pregnancy or threatened abortion including bleeding, spotting, or acute lower abdominal pain
- Provide infant care information/counseling
 - ✓ Discuss prevention of sleep related deaths and SIDS. Discuss and provide “ABC’s of Safe Sleep” handout included at the end of this protocol. Encourage parents to share ABC’s with all other caregivers of the newborn.

If the pregnancy test is positive and the pregnancy is not desired:

- Provide factual non-biased counseling and referral for the following patient requested options
 - Parenting
 - Adoption
 - Termination
- Provide a list of area and community resources for those options requested by the patient.
- Discuss the timetable for decision-making (obtaining pregnancy termination during the first trimester).
- Consider whether or not a mental health referral is needed.

If pregnancy test is **negative** and pregnancy is **not desired**

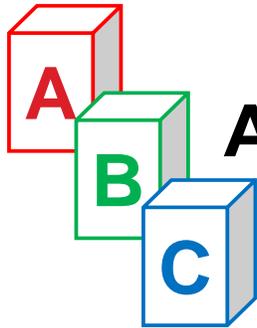
- Offer contraceptive services/counseling

If pregnancy test is **negative** and pregnancy is **desired**:

- Discuss reproductive life plan
- Refer to preconception health services protocol 2.105
- Offer basic infertility services (if indicated)

REFERENCES

- U.S. Department of Health and Human Services, Public Health Service, Health Service Administration, Bureau of Community Health Services Program, *Program Guidelines For Project Grants For Family Planning*, 2001.
- U.S. Department of Health and Human Services, Public Health Service, Standards of Compliance for Abortion-Related Services in Family Planning Service Projects, *Federal Register* 58(23), February 5, 1993.
- Centers for Disease Control and Prevention. MMWR. Providing Quality Family Planning Services. Vol. 63, No. 4. April 25, 2014.



ABC's of Safe Sleep

Babies should sleep...

Alone

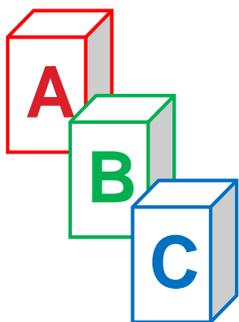
- Not with an adult, another child, or pets
- Not with pillows or stuffed toys
- Not with crib bumpers
- Room-sharing* is recommended

On their Back

- Not on their side
- Not on their stomach

In a Crib

- Not in an adult bed
- Not on a couch or sofa
- Not in a chair



El ABC del sueño seguro

Los bebés deben dormir...

A solas

- No con un adulto, ni con otro niño, ni con una mascota
- Sin cojines ni muñecos de peluche
- Sin protectores en la cuna
- Se recomienda compartir la habitación*

Boca arriba

- No de lado
- No boca abajo

En una Cuna

- No en la cama de un adulto
- No en un diván, ni en un sofá
- No en una silla

PROGESTIN-ONLY IMPLANT(S)

GENERAL INFORMATION

Nexplanon® is a subdermal progestin only implants placed in the non-dominant upper arm that provide up to 3 years of highly reliable contraception. Nexplanon® does not contain silicone or latex and can only be inserted/removed by a trained provider.

PHNs must be able to discuss progestin-only implant(s) option with clients, provide the client with written information on the safety and effectiveness of implants, and answer any questions the client may have. Refer client to APN/MD for consultation.

Candidates for implant contraceptives include, but are not limited to:

- Women who want a 3 year contraceptive effect
- Women who are accepting of irregular menstruation
- Women who have no contraindications to the method

SUBJECTIVE

Medical history
Reproductive life plan
Sexual health assessment

OBJECTIVE

Pregnancy test day of insertion
Height, Weight, BMI (optional)

ASSESSMENT

A current medical history should be taken for each client. The history must be negative for U.S. Medical Eligibility Criteria categories 3 and 4 to dispense without an exam

Refer to the Summary Chart of U. S. Medical Eligibility Criteria for Contraceptive Use in Family Planning Reference section 2.170.

PLAN

- Provide necessary health teaching to use method correctly and consistently
- Document 3-4 of the Title X Office of Population Affairs required health teaching/counseling topics during each family planning visit until instruction in all required topics is complete.
- Chlamydia and gonorrhea screening
 - Screen all sexually active women aged ≤ 25 years for chlamydia AND gonorrhea annually
 - Screen all sexually active women ≥ 26 years with risk factors for chlamydia AND gonorrhea.
 - Risk factors include; a new partner; more than one sex partner; a partner who has other concurrent partners; or a partner who has a sexually transmitted infection
- Implants do not protect against STI's and HIV. Advise clients to use latex or polyurethane condoms to decrease the risks of STIs.

- Also counsel the client to avoid high risk sexual behaviors including multiple partners and having a sexual partner with multiple partners.
- Offer condoms for improved STI protection
- Advise client when to return to the clinic for visit with provider

Document necessary health teaching regarding the following emergency warning signs:

Warning signs: The following 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

Preventative Health Recommendations

Clients are no longer required to have an examination to receive most contraceptive methods.

However, the client must be advised of the importance of the recommended related family planning preventative health screening¹ and testing.

Females:

Cervical Cytology (pap smear) refer to PHN Protocol 2.020 for screening guidelines

Genital exam should accompany cervical cancer screening

Clinical Breast Examination:

ACOG recommends annual CBE for women ages 19 and older.

Mammography:

USPSTF recommends screening mammography for women ages 50-74 every other year.

¹ If a TennCare child (under the age of 21) receives the major components of a Child Health/EPSTD exam through the health department's family planning clinic, she should also receive developmental screening and vision and hearing risk assessment/screening in order to complete the recommended AAP standards for preventive health care.

REFERENCES

Nexplanon® Physician and Patient Package insert, 2011

Hatcher, R. et al. Contraceptive Technology Twentieth Revised Edition, 2011, New York, : Ardent Media

Pocket Guide To Managing Contraception, Hatcher, R. A., Nelson, A. L., Zieman, M., et. al., Tiger, Georgia: Bridging the Gap Foundation, 2010-2012.

Center for Disease Control and Prevention, US Medical Eligibility Criteria for Contraceptive Use, MMWR early release, Vol. 59, May 28, 2010.

Contraceptive Technology Update, “Bulletin: Single-rod contraceptive Implant Implanon gets Food & Drug Administration’s OK”, Vol. 27, No. 9, September 2006.
www.nexplanon-usa.com

PROGESTIN-ONLY INJECTABLE CONTRACEPTION

GENERAL INFORMATION

Depo-medroxyprogesterone (DMPA) is an injectable contraceptive.

SUBJECTIVE

Screening components for contraceptive services include:

- Reproductive life plan
- Medical history
- Sexual health assessment

OBJECTIVE

- Blood Pressure
- Pregnancy test (if clinically indicated)
- Height, Weight, BMI (optional)

ASSESSMENT

A current medical history should be taken for each client. The history must be negative for U.S. Medical Eligibility Criteria categories 3 and 4 to dispense without an exam.

Refer to the Summary Chart of U. S. Medical Eligibility Criteria for Contraceptive Use in Family Planning Reference section 2.170.

Appropriate to begin or continue progestin-only injectable contraception

PLAN

PHN follows the ongoing plan of care written by the examiner or RN initiates combine hormonal contraception via Quick Start Protocol.

Administration of DMPA:

DMPA product must be shaken vigorously immediately prior to administration or the crystals will leave suspension and clump in the needle. Also the nurse and client must **not** rub the injection site after administration as this will disrupt the crystals and can lead to method failure (pregnancy). Note the package insert instructions for the particular progestin-only injectable product.

Administer progestin-only injectable contraception according to the following guidelines:

Initial injection

Follow Quick Start Protocol 2.010

Subsequent injection

The package insert for Depo Provera 150 IM® advises repeating injections every 11-13 weeks.

It is not harmful to a client to receive a re-injection as early as 10 weeks. However, some third party health insurance payors have restrictions regarding early re-injections. Therefore, clients who need early re-injection and who have third party payors, need to find out what their health insurance plan requires by asking at their pharmacy. Early re-injection is not harmful, but it is not cost effective.

If greater than the 13-week interval, assess the client regarding unprotected intercourse. If the client has had unprotected intercourse, perform a pregnancy test. Refer to Quick Start Protocol 2.010

A two week wait and a second pregnancy test is **NOT** the preferred approach UNLESS the client so chooses.

- Document anatomical location of injection
- PHN must consult with health department APN/MD and obtain an order to continue chosen method beyond 6 months
- Provide necessary health teaching to use method correctly and consistently
- Provide client with method specific instructions. Resources are available at <http://fpntc.org/training-and-resources/contraceptive-fact-sheets>. A Spanish version is available at <http://www.cardeaservices.org/resourcecenter/contraceptive-fact-sheets-Spanish>. You may also use previously approved instructions.
- Document 3-4 of the Title X Office of Population Affairs required health teaching/counseling topics during each family planning visit until instruction in all required topics is complete.
- Chlamydia and gonorrhea screening
 - Screen all sexually active women aged ≤ 25 years for chlamydia AND gonorrhea annually
 - Screen all sexually active women ≥ 26 years with risk factors for chlamydia AND gonorrhea.
 - Risk factors include; a new partner; more than one sex partner; a partner who has other concurrent partners; or a partner who has a sexually transmitted infection
- Offer condoms for improved STI protection.
- Offer condoms and/or contraceptive foam or film for use as back-up protection against unintended pregnancy.
- Offer ECP as indicated
- Advise client when to return to the clinic for next injection and/or visit with provider
- Consult APN or physician for complications and warning signs and for side effects that have not responded to standard treatments
- Instruct on 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)
- Instruct on importance of folic acid supplementation (400 mcg daily)

- Provide client health teaching regarding emergency warning signs:
 - A** Abdominal pain – severe (as might be seen with liver disease, gallbladder disease, ectopic pregnancy)
 - C** Chest pain - severe, (cough, shortness of breath or sharp pain on inhalation as might be seen with heart attack or pulmonary embolism)
 - H** Headache - severe, dizziness, weakness, or numbness, especially if one sided (as might be seen with migraine or stroke especially with numbness or muscle weakness)
 - E** Eye disturbances vision loss or blurring, also speech problem (as might be seen with retinopathy or stroke)
 - S** Severe leg pain in calf or thigh (as might be seen with thrombophlebitis)

Preventative Health Recommendations

Clients are no longer required to have an examination to receive most contraceptive methods. However, the client must be advised of the importance of the recommended related family planning preventative health screening and testing.

Females:

Cervical Cytology (pap smear) refer to PHN Protocol 2.020 for screening guidelines

Genital exam should accompany cervical cancer screening

Clinical Breast Examination:

ACOG recommends annual CBE for women ages 19 and older.

Mammography:

USPSTF recommends screening mammography for women ages 50-74 every other year.

REFERENCES

Hatcher, R. et al. Contraceptive Technology, Twentieth Revised Edition. New York: Ardent Media 2011.

Depo-Provera package Insert, Pfizer Pharmaceutical Company

Pocket Guide To Managing Contraception, Hatcher, R. A., Nelson, A. L., Ziemann, M., et. al., Tiger, Georgia: Bridging the Gap Foundation, 2015.

Center for Disease Control and Prevention, US Medical Eligibility Criteria for Contraceptive Use, MMWR Vol. 59, June 18, 2010.

Centers for Disease Control and Prevention. Providing Quality Family Planning Services. Recommendations of CDC and the U.S. Office of Population Affairs. MMWR. April 25, 2014.

PROGESTIN-ONLY PILLS

GENERAL INFORMATION

Progestin only pills are taken daily without a pill/hormone free interval.

SUBJECT

Medical history
Reproductive life plan
Sexual health assessment

OBJECTIVE

Pregnancy test (if clinically indicated)
Height, weight, BMI (optional)

ASSESSMENT

A current medical history should be taken for each client. The history must be negative for U.S. Medical Eligibility Criteria categories 3 and 4 to dispense without an exam.

Refer to the Summary Chart of U. S. Medical Eligibility Criteria for Contraceptive Use in Family Planning Reference section 2.170.

Appropriate to being or continue progestin-only oral contraceptive.

PLAN

PHN follows the ongoing plan of care written by the examiner or RN initiates combine hormonal contraception via Quick Start Protocol.

- Document name, dosage, route, and frequency of the progestin-only oral contraceptive chosen.
- Document number of cycles given
- PHN must consult with health department APN/MD to obtain an order to continue chosen method beyond 6 months
- Provide necessary health teaching to use method correctly and consistently.
- Provide client with method specific instructions. Resources are available at <http://fpntc.org/training-and-resources/contraceptive-fact-sheets>. A Spanish version is available at <http://www.cardeaservices.org/resourcecenter/contraceptive-fact-sheets-Spanish>. You may also use previously approved instructions.
- Document 3-4 of the Title X Office of Population Affairs required health teaching/counseling topics during each family planning visit until instruction in all required topics is complete.
- Chlamydia and gonorrhea screening
 - Screen all sexually active women aged ≤ 25 years for chlamydia AND gonorrhea annually
 - Screen all sexually active women ≥ 26 years with risk factors for chlamydia AND gonorrhea.

- Risk factors include; a new partner; more than one sex partner; a partner who has other concurrent partners; or a partner who has a sexually transmitted infection
- Offer condoms for improved STI protection.
- Offer condoms and/or contraceptive foam or film for use as back-up protection against unintended pregnancy
- Offer ECP as indicated
- Advise client when to return to the clinic for a visit with provider

Health Teaching

Document necessary health teaching regarding emergency warning signs:

- A** Abdominal pain – severe (as might be seen with liver disease, gallbladder disease, ectopic pregnancy)
 - C** Chest pain - severe, (cough, shortness of breath or sharp pain on inhalation as might be seen with heart attack or pulmonary embolism)
 - H** Headache - severe, dizziness, weakness, or numbness, especially if one-sided (as might be seen with migraine or stroke especially with numbness, muscle weakness, or visual changes)
 - E** Eye disturbances vision loss or blurring, also speech problems (as might be seen with retinopathy or stroke)
 - S** Severe leg pain in calf or thigh (as might be seen with thrombophlebitis)
- Consult APN or physician for complications and warning signs and for side effects that have not responded to standard treatments

Preventative Health Recommendations

Clients are no longer required to have an examination to receive most contraceptive methods. However, the client must be advised of the importance of the recommended related family planning preventative health screening and testing.

Females:

Cervical Cytology (pap smear) refer to PHN Protocol 2.020 for screening guidelines

Genital exam should accompany cervical cancer screening

Clinical Breast Examination:

ACOG recommends annual CBE for women ages 19 and older.

Mammography:

USPSTF recommends screening mammography for women ages 50-74 every other year.

REFERENCES

Hatcher, R. et al. Contraceptive Technology, Twentieth Revised Edition. New York: Ardent Media 2011.

“Family Planning Clinical Guidelines”, Tennessee Department of Health, January 2011.

Hatcher, R. A., Nelson, A. L., Ziemann, M., et. al., A Pocket Guide to Managing Contraception, Tiger, Georgia: Bridging the Gap Foundation 2015.

Center for Disease Control and Prevention, US Medical Eligibility Criteria for Contraceptive Use, MMWR, Vol. 59, June 18, 2010.

STERILIZATION

GENERAL INFORMATION

Sterilization is the surgical interruption, or closure, of pathways for sperm or ova, preventing fertilization. The method should be considered a permanent means 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 methods of birth control for both sexes.

For detailed information on policy, federal sterilization requirements, selection criteria, sterilization consent forms, and general instructions access the Office of Population Affairs web site at <http://www.hhs.gov/opa/pdfs/42-cfr-50-c.pdf>
For a complete list of approved resources serving as the Family Planning Clinical Guidelines, see Attachment F, Tennessee Department of Health Family Planning Clinical Guidelines.

Sterilization is a service that may be provided or arranged for with government funding. When Family Planning Program funds are used to provide sterilization, federal sterilization consent guidelines must be followed. Medicaid and TennCare also have the same requirements as Title X. In Tennessee, program funding for sterilization is limited. Clinic sites should keep a list of clients requesting sterilization through the state sterilization program, and prioritize applicants when funds for sterilization are available.

Indications include: Client desires permanent, low risk, highly effective contraceptive method.

ADVANTAGES of *female* sterilization (tubal ligation) include:

- ✓ One-time decision provides permanent fertility control
- ✓ Highly effective, convenient
- ✓ Cost effective
- ✓ Nothing to buy or remember
- ✓ Lack of significant long-term side effects
- ✓ No need for partner compliance
- ✓ No need to interrupt sexual activity
- ✓ Considered safe with low complication and morbidity rates
- ✓ Certain techniques can be performed immediately after pregnancy
- ✓ Can be performed while client is lactating
- ✓ Bilateral tubal ligation (BTL) is immediately effective
- ✓ Low long term risks and costs
- ✓ Privacy

ADVANTAGES of *male* sterilization (vasectomy) include:

- ✓ One-time decision provides permanent fertility control
- ✓ Highly effective, convenient

- ✓ Considered safe with low complication and morbidity rates
- ✓ Cost effective (most cost effective of all contraceptive methods)
- ✓ Removal of contraceptive burden from the woman
- ✓ No need for partner compliance after post vasectomy sperm check is done to prove that no sperm remain in the reproductive tract
- ✓ No need to interrupt sexual activity
- ✓ Short recovery time
- ✓ Vasectomy is equally effective, simpler, safer, and much less expensive than BTL
- ✓ Privacy

DISADVANTAGES of *female* sterilization include:

- Inherent risks associated with any surgery: infection, injury to other organs, hemorrhage, and complications of anesthesia
- Initial cost may be high
- Procedure to reverse sterilization is difficult, has limited success rates, is expensive, and not covered by insurance
- Title X and Medicaid funding require a 30-day waiting period between the date of signature on consent form and day of surgery
- Provides no protection against HIV and other sexually transmitted infections
- Some clients may have regrets following the procedure
- Menstrual irregularities, increased dysmenorrhea, and premenstrual syndrome are reported by some women following BTL (not supported by research)
- Possibility of ectopic pregnancy if method fails

DISADVANTAGES of *male* sterilization include:

- Inherent risks associated with any surgery: infection, injury to other organs, hemorrhage, and complications of anesthesia
- Initial cost may be high
- Some clients may have regrets following the procedure
- Procedure to reverse sterilization is difficult, has limited success rates, is expensive, and not covered by insurance
- Vasectomy is not immediately effective
- Title X funding requires a 30-day waiting period between the date of signature on consent form and day of surgery
- Possible post vasectomy complications can include hematoma formation, congestive epididymitis, and sperm granuloma

PLAN

- Discuss all available options of contraception
- Offer condoms, foam, or film for protection against STIs
- Provide written and oral instructions regarding various components of sterilization
- Obtain informed consent
- Obtain approval for sterilization via the appropriate process for region/agency
- Schedule appointment with provider for sterilization procedure

- Provide appropriate follow-up
- Return for recheck and/or for resolution of any complications

Health Teaching:

Communicate the importance of following instructions and keeping all appointments as directed to complete the sterilization process

Instruct client that sterilization does not protect against STIs and HIV

Provide verbal and written information regarding possible danger signs following sterilization and the necessary steps in follow-up

Instruct on 30 day waiting period

Referral Indicators after procedure:

Side effects or complications to the sterilization procedure

Pregnancy

Client verbalizing feelings of regret about sterilization

Client verbalizing sexual adjustment issues/problems

REFERENCES

Providing Quality Family Planning Services Recommendations of CDC and the U.S.

Office of Population Affairs MMWR/ Vol. 63 / No. 4 April 25, 2014

QUICK REFERENCE TO STERILIZATIONS

Providing Quality Family Planning Services. Recommendations of CDC and the U.S. Office of Population Affairs, 2014

1. Family Planning Clinical Guidelines under Sterilization

Federal Guidelines:

- Minimum age is 21
- Mentally incompetent/institutionalized individual may **not** be sterilized
- Waiting period: 30 days between date of consent signed to date of surgery. Consent valid for up to 180 days only after date consent is signed
- Decision not to be sterilized at any time will not result in withdrawal or withholding of state or federal benefits
- Under no circumstances may a hysterectomy be performed using Title X dollars or as a part of Family Planning Program solely for purpose of rendering the individual unable to reproduce

Selection Criteria

- Family Planning Program client or partner of Family Planning client
- Low income client
- No clients with TennCare or insurance that covers sterilization: instead, refer client
- Clients
 - with method failure
 - medical contraindication to use of temporary methods
 - who have had multiple pregnancies
 - other high risks
- Older client
- For female sterilization, priority should be given to those who will have an outpatient procedure, so that more clients can be served

Possible contraindications

Client:

- has mental/emotional conditions negating informed consent
- or couple feels they are not *yet* ready to assume the responsibility of parenthood
- believes reversal is possible in case of situational changes such as remarriage or death of child(ren).

2. Federal Sterilization Forms: Forms must be completed in compliance with regulations.

VAGINAL CONTRACEPTIVE RING

GENERAL INFORMATION

A physical exam is not necessary to begin the vaginal contraceptive ring. While deferring the physical examination should not be routine, certain circumstances may exist which make it reasonable. It is essential that the PHN see General Information and Plan of Care for a Deferred Exam found in Protocol 2.010, "All Methods, Initial and/or Annual Family Planning Visit" before dispensing a method without a physical exam.

See Family Planning Clinical Guidelines and the most current edition of Contraceptive Technology for method counseling details.

SUBJECTIVE FINDINGS

For method specific guidelines, including those for a deferred exam, refer to the Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive use found in Family Planning Reference section 2.170.

U.S. Medical Eligibility Criteria category system:

- 1 = May provide method with no restrictions
- 2 = May provide method, as the advantages generally outweigh the risk. Consult with a physician or APN as needed and document appropriately
- 3 = May not provide method, proven risk usually outweigh the advantages
- 4 = Method may not be used.

OBJECTIVE FINDINGS (Laboratory tests for FP clients are chosen as indicated by the method, or by client need. However, laboratory tests cannot exceed any established department or program screening or testing limits. Limitations on laboratory testing may be established to meet funding or other needs.)

- Blood pressure
- Height and weight for BMI
- Physical examination¹ performed annually by examiner
- Hemoglobin or Hematocrit as indicated
- Pap smear in accordance with current Pap smear guidelines
- Sickle cell screening
- Syphilis serology
- Mantoux tuberculin test

¹ If a TennCare child (under the age of 21) receives the major components of a Child Health/EPSDT exam through the health department's family planning clinic, she should also receive developmental screening and vision and hearing risk assessment/screening in order to complete the recommended AAP standards for preventive health care. REFER TO THE FAMILY PLANNING SECTION OF PTBMIS MANUAL FOR CORRECT CODING OF THIS TYPE VISIT.

- Pregnancy test
- Rubella titer
- Wet prep (examiner)
- HIV testing
- Urinalysis
- Gonorrhea and chlamydia screening

REFER TO SCREENING CRITERIA FOR CHLAMYDIA AND GONORRHEA FOUND IN SECTION 2.170.

ASSESSMENT

Appropriate to begin or continue the vaginal contraceptive ring either with or without the physical examination.

PLAN OF CARE FOR DEFERRED EXAM

The plan of care for a deferred exam visit is considered preliminary or temporary and can be established by the PHN. This preliminary or temporary plan of care must address the following:

- An explanation for the deferral.
- The medical history for the initial client, an updated medical history for the annual client who is deferring the exam, and an updated history for the supply client who is changing her method by deferred exam. The history must be negative for U.S. Medical Eligibility Criteria categories 3 and 4 to dispense without an exam. Consider a physician or APN consult for any category 2 findings and document appropriately.
- For annual visits (or re-supply visits), consult for side effects that have not responded to standard treatments (i.e., take COC pill at bedtime for nausea), complications, or warning signs. Record consult instruction in chart.
- Blood pressure measurement, weight, hemoglobin or hematocrit as indicated.
- Height for initial visit or annually for adolescents.
- Name, dosage, route, and frequency of the contraceptive chosen.
- The number of cycles given (up to 3 cycles).
- Informed consent form for an initial client or if giving the return client a new method.
- Document necessary health teaching to start and to use method correctly and consistently. (See Client Instruction Sheet available in English and Spanish found in the Appendix of the Family Planning Clinical Guidelines).
- Document necessary health teaching regarding emergency warning signs:
 - A** Abdominal pain – severe (as might be seen with liver disease, gallbladder disease, ectopic pregnancy)
 - C** Chest pain - severe, (cough, shortness of breath or sharp pain on inhalation as might be seen with heart attack or pulmonary embolism)
 - H** Headache – severe, dizziness, weakness, or numbness, especially if one-sided (as might be seen with migraine or stroke especially with numbness or muscle weakness)

- E** Eye disturbances vision loss or blurring, also speech problems (as might be seen with retinopathy or stroke)
- S** Severe leg pain in calf or thigh (as might be seen with thrombophlebitis)
- Offer condoms for improved STD protection.
- Offer condoms and/or contraceptive foam or film for use as back-up protection against unintended pregnancy.
- Date of the exam appointment. In clinics with open access systems, chart the date the client is expected to return

PLAN OF CARE FOR AN EXAM VISIT OR RESUPPLY VISIT

An **ongoing plan of care** will be developed and signed at the **exam visit** by either the PHN with gyn skills, RN-ES, APN or Physician (all referred to as “examiner”). The ongoing plan of care is developed in accordance with the protocol for the particular examiner. The ongoing plan of care written by the examiner must be reviewed and followed by the PHN at each visit. For re-supply visits, consult APN or physician for complications and warning signs. Also consult for side effects that have not responded to standard treatments. Record consultant instructions in chart

HEALTH TEACHING

Through the Title X Program Guidelines, the federal Office of Population Affairs requires that counseling about certain topics occur with family planning clients. These required topics must be discussed with the client at least once during the time the client is under the care of the Family Planning Program. Ideally, the client will receive instruction on 3 or 4 of the required topics at each visit until instruction in all required topics is completed. Topics do not need to be repeated unless the client request a review or the provider assesses that a review is needed. **Address client counseling at each visit and base counseling/education on client needs and program requirements.**

For contraceptive method education and counseling, use the Client Instruction Sheet found in the current version of the Tennessee’s Family Planning Clinical Guidelines. Also use the teaching tool on the reverse side of the method-specific consent form.

All providers must document education and counseling provided during each family planning visit on the table found on the history form in the medical chart. The expression, “counseling per protocol” is not adequate documentation for Title X education and counseling that should occur during initial, annual, supply and medical visits.

There is a detailed list of the REQUIRED counseling/education topics in the Family Planning Program Clinical Guidelines, under Visit Guidelines. Other counseling topics are also detailed. A brief list of counseling/education topics is provided in the All Methods, Initial and/or Annual Family Planning Visit section of the PHN Protocol.

REFERENCES

- Contraceptive Technology, Twentieth Revised Edition, Robert A. Hatcher, M.D., et al, 2011.
- Contraceptive Technology Update, "Draw the Circle Wide to Add Contraceptive Ring", Volume 26, Number 6, June 2005.
- A Pocket Guide to Managing Contraception, Hatcher, R.A., Nelson, A.L., Ziemann, M. et. al., Tiger, Georgia: Bridging the Gap Foundation, 2010-12.
- "Family Planning Program Clinical Guidelines," Tennessee Department of Health, January 2011.
- NuvaRing Package Insert, Organon, Inc., 2005.
- "Program Guidelines for Project Grants for Family Planning Services," Office of Population Affairs, U.S. Department of Health and Human Services, January 2001.
- Center for Disease Control and Prevention, US Medical Eligibility Criteria for Contraceptive Use, MMWR, Vol. 59, June 18, 2010.

RESCINDED JUNE 2015

FAMILY PLANNING REFERENCE MATERIAL

Screening Criteria for Chlamydia and Gonorrhea

Effective September 1, 2010

The screening criteria for chlamydia and gonorrhea are established by the Tennessee STD Program. The screening criteria for chlamydia and gonorrhea have been revised based on risk criteria, national recommendations, and availability of funds. The screening criteria for Family Planning in Tennessee are:

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 counties with positivity rates of 3 percent or higher 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

Knoxville/Knox

Jackson/Madison

ASCARIASIS (ROUNDWORMS)

SUBJECTIVE

History of passage of adult worm, round and pinkish-white, often no symptoms

May have symptoms of:

- Abdominal pain
- Nausea and vomiting
- Anorexia
- Weight loss
- Pica
- Persistent cough, fever, blood tinged sputum
- Choking

OBJECTIVE

Laboratory confirmation of roundworm infestation from stool specimen, OR visual observation of roundworm in stool or vomitus; There is no useful blood test.

ASSESSMENT

Ascariasis (Roundworms)

PLAN

Pyrantel Pamoate, 11mg base/kg, once daily for 3 consecutive days.

Pyrantel Dosing - Single Dose			
Weight		Chewable Tablets (250mg Pyrantel base/chewable tablet)	Suspension (50mg Pyrantel base/ml)
25 to 37 lbs	11 to 16 kg	<u>1/2</u>	2.5 ml
38 to 62 lbs	17 to 28 kg	1	5 ml
63 to 87 lbs	29 to 39 kg	1 & 1/2	7.5 ml
88 to 112 lbs	40 to 50 kg	2	10 ml
113 to 137 lbs	51 to 62 kg	2 & 1/2	12.5 ml
138 to 162 lbs	63 to 73 kg	3	15 ml
163 to 187 lbs	74 to 84 kg	3 & 1/2	17.5 ml
188 lbs or more	85 kg or more	4	20 ml

NOTE: DO NOT GIVE TO CHILDREN UNDER TWO YEARS OLD, PREGNANT OR POSSIBLY PREGNANT, OR BREAST-FEEDING WOMEN WITHOUT SPECIFIC AUTHORIZATION OF A HEALTH DEPARTMENT PHYSICIAN

Family members submit specimen and treat as indicated

Health Teaching

Avoid contacting soil that may be contaminated
Sanitary disposal of diapers and feces; cleaning of toilet seat; attention to children's play areas
Wash hands before eating, preparing food, and after elimination; keep nails short
Discourage eating food that has been dropped on the floor, or is unwashed from the garden; wash, peel or cook raw fruits and vegetables before eating.

Referral Indicators

No response to treatment
Children under two years of age
Pregnant or breast-feeding women
Pulmonary involvement
Abdominal pain

Follow-Up

Patient/parent will be asked to contact health provider if reoccurrence of symptoms after second treatment

Reference

CDC.gov; Ascarius Infection; September 2012.
UpToDate.com; Pyrantel Pamoate: pediatric drug information; September 2012.
Quartzpharmaceuticals.com; Pin-x-overview; September 2012.

CONSTIPATION, ACUTE, CHILD

SUBJECTIVE

Malaise, headache, abdominal cramping
 History of hard, dry, stools; may be history of fecal soiling in older child
 History of infrequent passage of stools relative to the individual's usual habit
 Pain and/or straining at defecation; reluctance to sit on toilet
 Stool streaked with blood
 Diet and medication history

OBJECTIVE

Signs of dehydration
 Anal fissure or evidence of irritation
 Mild abdominal distention with or without palpable firm mass
 Stool streaked with bright blood

ASSESSMENT

Acute childhood constipation

PLAN

Encourage defecation when urge presents
 Adjust diet to allow for adequate fluid and carbohydrate intake:
Young infants - Offer water 1-3 times daily between feedings; reduce intake of formula, if excessive
Older infants - increase fluid intake; increase amounts of pureed fruits in the diet, especially prunes and plums; the amount needed will vary with individual infants
Older children - Increase fluid intake; add prunes, apricots, and figs to the daily diet; include high-residue substances such as bran, whole wheat, oatmeal, and green leafy vegetables in daily diet
 Discourage use of suppositories, laxatives, or enemas unless specifically ordered by health department physician or APN.
 For minor anal irritation, advise warm sitz baths and use of petroleum jelly or ointment
 For older child, support for feet when toileting

NOTE: HONEY SHOULD NOT BE USED AS OSMOTIC AGENT DUE TO DANGER OF BOTULISM

Referral Indicators:

Persistent, severe, or recurrent abdominal pain
 Persistent fecal soiling
 Persistent constipation despite adequate dietary intake
 Vomiting, dehydration, fever
 Severe breakdown of skin around anus
 Blood streaked stool

Follow-Up:

Patient/parent will be asked to contact health provider if not resolved in 48-72 hours

Reference

Mayo Clinic, Guide To Self-Care, Fifth Edition 2006

FLUORIDE VARNISH

General Information

- The bacteria associated with dental caries have been identified as *Streptococcus Mutans*. The presence of these bacteria along with food and saliva allow the process of decay to begin on the tooth surface. Untreated decay progresses through stages of tooth destruction. As the decay progresses, the affected area becomes larger.
- There has been a well-documented decline in dental caries in children in the United States, which has been attributed to widespread use of various forms of fluoride. With the use of fluoride varnish, a high-concentration of fluoride in a small amount is painted directly onto the teeth.
- Even people living in communities where water supplies are fluoridated benefit from exposure to fluorides found in toothpaste, mouth rinses, professionally applied fluorides, and in foods processed in cities where water supplies are fluoridated (i.e., the “halo” phenomenon).
- The use of topical fluoride supplements is one alternative means of providing protection to the teeth of children 0 months old to 21¹ years of age who are at risk for dental caries.
- Proper application technique reduces the possibility that a patient will swallow varnish during its application and limits the total amount of fluoride swallowed as the varnish wears off the teeth over several hours.
- A combination of various types of fluoride use (e.g. optimally fluoridated water, prescription fluoride supplements, and professionally applied topical fluoride) reduces dental caries significantly more than any one method alone.
- No published evidence indicates that professionally applied fluoride varnish is a risk factor for enamel fluorosis, even among children aged <6 years.
- Applying the fluoride varnish to any and all tooth surfaces reduces the risk of decay.
- A helpful tip for applying fluoride varnish to the teeth of young children is to sit knee-to-knee with parent or caregiver, and have child lay in the health care provider’s lap.

¹ Topical application of fluoride varnish is safe for the prenatal patient

SUBJECTIVE

Age 0 – 21 years of age
Target population age 0 - 5 years
Mother requests application of dental varnish for child
Health care provider recommends application of dental varnish

OBJECTIVE

White spot lesions may or may not be present on any teeth in the child’s oral cavity

ASSESSMENT

Need for dental varnish application

PLAN

Public Health Nurse to apply dental fluoride varnish application according to package instructions

Health Teaching:

- Instruct parent/guardian on the correct care of child’s teeth until the next day
- Provide parent/guardian with appropriate information sheet for care of child’s teeth following fluoride varnish application
- Instruct parent or guardian on the need for additional applications of fluoride varnish
- Counsel parent/guardian to closely supervise tooth brushing by young children in order to prevent their ingestion of fluoride toothpaste and to ensure that only very small quantities (pea-sized amounts) are used (so as to reduce the risk of dental fluorosis)
- Counsel parent/guardian regarding the risks that contributes to dental decay
- Instruct parent/guardian about proper diet and feeding habits, as well as the daily care of the child’s teeth to contribute to the prevention of dental decay

Follow-Up:

Fluoride varnish should be applied two times annually or according to package instructions.

REFERENCE

Morbidity and Mortality Weekly Report, Recommendations and Reports, August 17, 2001, Vol. 50 No. RR-14; pages 18–19

Tenn. Code Ann. § 63-5-109

TUBERCULOSIS, Treatment of Tuberculosis Infection (TBI)

Tuberculosis Infection (TBI) is an asymptomatic state in persons who are infected with Mycobacterium tuberculosis and have future risk of developing active TB, but is not currently infectious to others.

SUBJECTIVE:

History of positive Mantoux skin test or positive IGRA
 Physician referral
 History of positive HIV status
 Previous treatment for TBI
 Contact to TB case or suspect
 Risk factor(s) for TB on TB/TBI Risk Assessment Tool (RAT)
 Clinical information from other providers if applicable

OBJECTIVE:

Positive tuberculin skin test
 Positive IGRA
 Normal chest x-ray
 No symptoms of TB

ASSESSMENT:

Positive tuberculin skin test
 Positive IGRA
 Immunosuppressed with known contact to TB case/suspect regardless of TST results
 Child <5 years and contact to TB case/suspect regardless of TST results
 Pregnant and contact to TB case/suspect regardless of TST results
 Diabetic patients with a documented positive test or positive IGRA who cannot prove that they have completed adequate TBI treatment should be assessed for new risk factors

PLAN:

Provide Screening Evaluation:

Complete TB/TBI Risk Assessment Tool (TB RAT)
 Provide TB testing, if appropriate
 Make appointment for patient with the regional TB clinic for evaluation if not previously done and/or consult with TB clinic staff
 Notify TB clinician of any patient with TB symptoms
 Patient will be evaluated by clinician in TB clinic. Evaluation will include focused physical exam, chest x-ray (including PA and lateral for children), and appropriate lab tests, if indicated by clinician
 Obtain records from other providers
 Obtain medical history
 Record any allergies or previous adverse reactions to medications

Assess and document all current medications (prescription, OTCs, or home remedies)

Assess and document history of substance abuse (alcohol or drugs)

Treatment:

Obtain written medical order by clinician for appropriate anti-tuberculosis medication

- Obtain written medical order by clinician for appropriate laboratory monitoring (as indicated). Laboratory testing should be considered on an individual basis for those taking other medications for chronic medical conditions

Obtain copy of last office visit progress note if seen by private provider

Consult with regional TB clinic regarding special circumstances (obtain approval from Regional TB clinician to adhere to medication orders from private providers; review chart to assure appropriateness)

Monitor for possible contraindications prior to initiating drug therapy, especially liver disease or factors that may contribute to liver disease (i.e., liver toxic medications, and alcohol abuse) and document on drug monitoring form (notify TB clinic of any contraindications)

If patient is a child, notify regional clinic for recommendations and/or specific orders

- All children <5 years of age who are contacts to TB cases/suspects are to receive TBI therapy until 10 week follow-up skin test is negative (window therapy)
- Children (≤ 18 years of age) are to receive directly observed preventive therapy (DOPT) throughout TBI treatment
- All patients receiving 3HP therapy regardless of age are to receive DOPT weekly therapy throughout TBI treatment

	Daily Regimen (INH or RIF)	Weekly Regimen (INH/RPT“3HP”)
	See 2015 TB manual Table III-3 Drug Regimens for the Treatment of TBI for more information	All patients receiving the 3HP regimen will receive DOPT DOPT will only be issued in the local health department clinic
LABS	Perform baseline CMP and CBC with platelets & without differential; HIV (if not already drawn) for patients with: chronic liver disease suspected liver disorder immunosuppressed pregnant or within 3 mos. postpartum Regular alcohol use	For adults ≥ 18 years of age perform baseline CMP and CBC with platelets & without differential; HIV (if not already drawn); urine pregnancy test for women of childbearing age (if applicable) <u>hold DOPT</u> if pregnancy test is positive

	Daily Regimen (INH or RIF)	Weekly Regimen (INH/RPT “3HP”)
Issuing medication	<p>Issue only one (1) month supply of ordered medication</p> <p>If patient is going out of town for an extended period, consult with TB clinic regarding dispensing more than a one-month supply of medications</p> <p>If patient buying medication, obtain name of pharmacy and monitor monthly pick-up</p>	<p>Issue only one (1) weekly dose of ordered medication</p> <p>Ideally, doses should be spaced 7 days apart with a minimum of 5 days between doses</p> <p>No less than three (3) doses or more than five (5) doses should be given in any 28 day period</p>
What to do if treatment gets behind schedule or is deferred	<p>If patient has stopped medication or not picked up a resupply for:</p> <p><u>Less than 2 months</u> Carefully assess for signs/symptoms of active TB; if assessment is negative, the nurse may restart the medication</p> <p>If there are signs/symptoms of TB disease, the PHN notifies the TB clinician for further orders</p> <p><u>Greater than 2 months</u> IF patient stopped TB medication; has not picked up medication re-supply OR TBI therapy is deferred for any reason (e.g., until after pregnancy, after completion of rehab, patient returns from travel, etc.), the patient must be reevaluated by the TB clinician in TB clinic (including a clinical exam and CXR) before restarting medication</p>	<p>If the patient misses three (3) doses within any 28 day period, the regimen should be discontinued and <u>not</u> restarted</p>

Provide Health Teaching:

Discuss specific drug dosage, the anticipated benefits and possible side effects (especially liver toxicity)

Educate patient on whom to contact (give name and number) if side effects develop, including contact for holidays and weekends (emergency room, etc.)

Provide “*Patient Medication Instruction Sheet*”

Advise patient to stop the drug if adverse reactions occur. Provide name and number of person to contact for instructions.

Educate patient about the importance of disclosing any other medications (prescription, over-the-counter, or home remedies) including use of alcohol or drugs

Educate patient about adverse effects of alcohol use with TBI medications
 Educate women of child-bearing age need barrier method (e.g., condom, diaphragm, etc.) even if using a hormonal family planning (FP) method (rifampin daily regimen and 3HP weekly regimen only)
 Educate patient about the importance of keeping appointments and date of next clinic visit

Provide Documentation:

Send a copy of medical record, prescriptions and test results to regional TB clinic
 Document patient's verbalized understanding of risks/benefits and willingness to take TBI treatment
 Document TB/TBI education materials given
 Document treatment completion or reasons not completed

Provide Follow up:

Issue only one (1) month supply of drugs as ordered by clinician (daily regimen only)
 Issue only one (1) weekly dose of drugs as ordered by clinician (3HP weekly regimen only)
 At each clinic visit:

- Monitor for contraindications and signs/symptoms of adverse reactions while on therapy and notify TB clinic of any signs/symptoms
- Ask patient about new medications (prescription, over-the-counter, home remedies)
- Provide laboratory monitoring as ordered by clinician
 - If any test exceeds the upper limit of normal (ULN), send results to TB clinic or private physician for review; if liver enzymes (SGOT/SGPT) exceed ULN by three (3) times with symptoms, or by five (5) times without symptoms, or bilirubin is over the ULN at any level, notify TB clinic immediately for special orders
- Perform urine pregnancy test upon suspicion of possible pregnancy (3HP weekly regimen only)
 - If positive, hold DOT

Contact patient if appointment not kept
 Provide all other follow-up according to current TB Manual

Provide Referral:

Refer patient to private physician or tuberculosis clinic:
 SGOT/SGPT > 3x ULN with symptoms, or > 5x ULN even without symptoms, or any abnormal bilirubin
 Symptoms of adverse reactions or drug toxicity (fill out the FDA 3500 voluntary form and send to the State TB Medical Director for review)
 Patient develops symptoms of active tuberculosis

REFERENCES:

American Academy of Pediatrics, 2012:736-759.
 American Academy of Pediatrics. Tuberculosis. In: Pickering LK, Baker C, Kimberlin DW, Long SS, eds. 2012 Red Book
 CDC. Core curriculum on TB: What the Clinician Should Know, 5th Ed., 2011

- CDC. Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC
MMWR 2005; 54 (No. RR-15, 1-37)
- CDC. Guidelines for Using the QuantiFERON-TB Gold Test for Detecting *Mycobacterium tuberculosis* Infection, United States MMWR 2005; 54 (No. RR-15,1-37)
- CDC. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection. MMWR 2000;49:1-51
- CDC. Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection—United States, 2010. MMWR 2010;59(RR-5);1-25
- Tennessee Department of Health, Tuberculosis Program Manual, 2015

HUMAN PAPILOMAVIRUS (HPV) VACCINE: HPV4 and HPV9 (GARDASIL[®] or GARDASIL[®]9 by Merck)

GENERAL INFORMATION

Human Papillomavirus (HPV) is the most common sexually-transmitted virus in the United States, with over 40 known strains infecting the genital areas of men and women. It is transmitted through intimate skin to skin contact: about 80% of sexually-active men and women are infected with HPV at some point in their lives. Most HPV infections are undetectable and go away on their own without causing problems; however, certain HPV types can cause head and neck cancers and cancers of the cervix and anogenital areas. Each year in the US, HPV causes about 360,000 cases of genital warts, about 17,600 cancers in women and 7,300 cancers in men.

HPV vaccine is an inactivated vaccine, administered intramuscularly. There are two types made by Merck. Gardasil[®] (HPV4) is licensed by the Food and Drug Administration (FDA) for administration to males and females aged 9 years through 26 years; it protects against HPV 6 and 11 (causes of 90% of genital warts) and HPV 16 and 18 (causes of 65% of HPV-associated invasive cancers in men and women). Gardasil[®] 9 (HPV9) is currently licensed for females 9 through 26 years and males 9 through 15; however, the Advisory Committee on Immunization Practices (ACIP) recommends either brand in males through 26 for whom HPV vaccination is indicated. TDH protocols follow ACIP recommendations. HPV9 protects against 5 additional strains, protecting against an *additional* 14% of HPV cancers in females and 4% of HPV cancers in males. Both vaccines are given in a three-dose series. HPV vaccine has no effect on pre-existing infections; however, sexually active and HPV-infected patients for whom vaccination is recommended will benefit from protection against strains not yet acquired and should be vaccinated.

GlaxoSmithKline produces the HPV vaccine Cervarix[®], which targets HPV 16 and 18. It is licensed for females 9-25 only, on the same schedule as HPV4 and HPV9. It is not widely used in the US and not typically stocked in health departments. If a woman has started the vaccine series with Cervarix[®], any available HPV vaccine may be used to complete the series.

HPV vaccine may be simultaneously administered with other vaccines, including live virus vaccines. It is stored in standard refrigerated conditions at 2-8°C (35-46°F).

To determine if a patient in an ACIP recommended group is eligible for free federal vaccine, refer to the current Tennessee Immunization Program Policy on the use of federal vaccine.

Contraindications to giving the vaccine include the following:

Severe allergic (anaphylactic) reaction to a previous dose of HPV4 or HPV9 or any component (including yeast). The vaccine contains no preservatives.

Precautions:

Moderate to severe acute illness (defer until recovery) [Note: Low grade fever <100.5°F or mild illnesses are not reasons for deferring immunization]

Pregnancy: the vaccine has not been associated with adverse events when given during pregnancy; however it is not recommended if recipient is known to be pregnant.

Special Situations (per ACIP):

Breastfeeding is not a precaution or contraindication to immunization

A history of abnormal Pap smears, genital warts or other HPV infection is not a precaution or contraindication to vaccination. Such persons can benefit from protection against strains they have not yet acquired. Recipients should be advised that the vaccine does not protect against any strains they have already acquired.

Adverse Reactions:

Soreness, swelling or redness around the injection site is common
Syncope (especially common in adolescents)

PLAN

ACIP Recommendations for Use of either HPV9 or HPV4:

Females

- Routine Recommendation: Give first dose to all pre-teens at age 11 or 12 years (may begin at 9 years).
- Catch-up vaccination of all females age 13 through 26 years who have not completed the series.
- Females who have initiated the series before turning 27 may complete the series even if past age 26.

Males

- Routine Recommendation: Give first dose to all pre-teens at age 11 or 12 years (may begin at 9 years).
- Catch-up vaccination of all males 13 through 21 years who have not completed the series.
- The vaccine *may* be given to older males 22-26 who have not completed the series.
- It is *recommended* for previously unvaccinated older males 22-26 who have sex with men or whose immune system is weakened by HIV infection, other illness or medication.
- Males who have initiated the series before turning 27 may complete the series even if past age 26.

If a person has already started a vaccine series with HPV4, continue to use HPV4 if available unless HPV9 is requested or HPV4 supplies have run out. Either HPV4 or HPV9 may be used to complete the series as health department clinics transition to HPV9.

	Recommended Interval	Minimum Interval
Dose 2	1 to 2 months after dose 1	4 weeks after dose 1
Dose 3	6 months after dose 1	12 weeks after dose 2 and 24 weeks after dose 1

- ✓ Counsel regarding HPV benefits, side effects, and management
- ✓ Ask parent/guardian or recipient about contraindications, precautions
- ✓ Have parent/guardian or recipient read Vaccine Information Statement
- ✓ Administer the 0.5 mL dose of vaccine intramuscularly according to manufacturer instructions
- ✓ Advise parent/guardian or recipient to return for the next dose at the appropriate interval
- ✓ Advise to wait in clinic for 20 minutes after administration of vaccine
- ✓ Record manufacturer and lot number of the vaccine administered, date vaccine and VIS given, address of facility, and name and title of person administering vaccine
- ✓ Instruct patient/guardian to contact Health Department if adverse reaction occurs

REFERENCES

Use of 9-Valent Human Papillomavirus (HPV) Vaccine: Updated HPV Vaccination Recommendations of the Advisory Committee on Immunization Practices, MMWR March 27, 2015; pp. 300-304. <http://www.cdc.gov/mmwr/pdf/wk/mm6411.pdf>

GARDASIL®9 [Human Papillomavirus 9-valent Recombinant Vaccine] Vaccine package insert, Merck, copyright 2014, Revised February 2015.

GARDASIL® [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine] Vaccine package insert, Merck, copyright 2006, Revised June 2014.

Cervarix [Bivalent Human Papillomavirus (Types 16, 18) Vaccine, Recombinant] Prescribing Information, GlaxoSmithKline, copyright 2009. Revised February 2015.
http://us.gsk.com/products/assets/us_cervarix.pdf

COMVAX

(Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant Vaccine))

GENERAL INFORMATION:

Hepatitis B vaccine is available in combination with *Haemophilus influenzae* type b (Hib) vaccine as Comvax® (by Merck). It is licensed for use when either or both antigens are indicated and the other antigen is not contraindicated. Because premature Hib vaccination can cause non-response to subsequent doses (“immunotolerance”) of Hib vaccine, instead of immunity, no Hib-containing vaccine should ever be administered before 6 weeks of age. Comvax may be used to complete the hepatitis B vaccine series in all infants, including those whose mothers are or may be infected with hepatitis B virus (HBsAg positive or HBsAg status unknown). (For additional information, see HIB and Hepatitis protocols)

Contraindications and precautions

Severe allergic reaction to vaccine component or following a prior dose
 Moderate or severe acute illness
 Age younger than 6 weeks

Adverse events may include:

Swelling, redness and/or pain
 Systemic reactions infrequent, serious adverse reactions rare

PLAN

Have accompanying adult read “Vaccine Information Statement”/“Vaccine Information Materials”

Counsel regarding benefits, side effects, and management

Administration of Vaccine:

RECOMMENDED SCHEDULE

Age		Volume and Route	Minimum	Minimum interval
2 months	Primary dose	0.5ml IM	6 weeks	
4 months	Primary dose	0.5ml IM		4 weeks after dose 1
12-15 months	Booster dose	0.5ml IM	12 months	8 weeks after dose 2

OFF SCHEDULE AND MIXING WITH OTHER HIB AND HEPATITIS B VACCINE

Children who have started the vaccine with Comvax or PedvaxHIB may complete the series with PedvaxHIB and/or Comvax following the 2 –dose primary series with a third dose as a booster after the first birthday (remember to administer Hepatitis B with PedvaxHIB)

If it is necessary to change vaccine type (by switching to a different type of Hib vaccine, such as ActHIB® or Pentacel® by Sanofi Pasteur), then three (3) doses of any combination constitute the primary series. In such cases, either vaccine may be used for the booster (4th dose), regardless of what was administered in the primary series (remember to administer a hepatitis B vaccine, if necessary, when using a Hib vaccine other than Comvax)

DELAYED VACCINE SCHEDULES

VACCINE	AGE STARTING HIB AND HEP B SERIES	RECOMMENDED CATCH-UP FOR OLDER CHILDREN
Hepatitis B	Birth (no Hib given)	Follow routine Comvax schedule above. Final valid Hep B dose is the booster dose (a 4-month dose is too early to be a valid 3 rd Hep B).
Comvax	Starting at 12-14 months	Give 2 doses of Comvax two (2) months apart and the third hepatitis B vaccine six (6) months after first Comvax
Comvax	Starting at 15-59 months	Give one dose of Comvax; give second hepatitis B at least 4 weeks later, and 3 rd (final) dose at least 8 weeks after the second dose and at least 16 weeks after the Comvax dose;* only one dose of Hib vaccine is required at this age

*The accelerated catch up schedule is recommended whenever children are behind on their shots.

NOTE

- If a child is **greater than 59 months of age**, Hib-containing vaccine is not normally indicated
- Older children, if at **high risk** (e.g., sickle cell, post splenectomy, immunodeficient), may receive Hib-containing vaccine with a health department physician or APN order
- Comvax may be given **simultaneously with all other vaccines**
- Comvax may be **interchangeable** with other Hib and Hepatitis B vaccine, but the total number of doses changes if switching brands of Hib vaccines (see schedule above)
- Advise to wait in clinic 20 minutes after injection
- Record manufacturer and lot number of the vaccine administered, date, name, address, and title of person administering vaccine
- Instruct parent to contact Health Department if adverse reaction occurs (complete VAERS form)

Referral Indicators:

Severe allergic (anaphylactic) hypersensitivity to any component of the vaccine

Follow-up:

Return for next Comvax at appropriate intervals

REFERENCES:

"Epidemiology and Prevention of Vaccine-Preventable Diseases, Department of Health and Human Services, Centers for Disease Control and Prevention, 10th Edition, February 2008

DIPHTHERIA, TETANUS TOXOID, ACELLULAR PERTUSSIS, INACTIVATED POLIO VACCINE (DTaP-IPV) (Kinrix®, by GSK)

GENERAL INFORMATION

Kinrix® (DTaP-IPV booster), by GSK, is licensed as a single dose by the FDA as the fifth dose in the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine series and the fourth dose in the inactivated poliovirus vaccine (IPV) series in children 4 through 6 years of age. Kinrix may be used in children who have already received 4 or more doses of IPV prior to the 4th birthday.

Kinrix® may be used once as the DTaP-IPV booster dose routinely administered between ages 4 and 6 years. If inadvertently administered as part of the primary series before age 4, it may still be used as the single 4-6 year old booster.

Contraindications to giving the vaccine include the following:

Kinrix® is not licensed for use before the 4th birthday or after the 7th birthday

An immediate anaphylactic reaction following a previous dose of vaccine containing any of the components of DTaP or IPV (diphtheria, tetanus, pertussis or poliomyelitis) or any vaccine components, including neomycin and polymixin B.

Encephalopathy within 7 days of administration of previous dose of DTP or DTaP

An unstable, progressive neurologic disorder (see note)

Children with a severe (anaphylactic) allergy to latex should not receive Kinrix® in the pre-filled vaccine formulation. The single dose vial preparation is latex free.

The following precautions, although not considered contraindications, should be carefully evaluated concerning the risks and benefits of vaccination for individuals who experienced any one of the following adverse reactions:

Temperature of 105°F or higher within 48 hours (with no other identifiable cause) after vaccination with DTaP/DTP

Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours after vaccination with DTaP/DTP

Persistent, inconsolable crying lasting 3 hours or more, occurring within 48 hours after vaccination with DTaP/DTP

Convulsions, with or without fever, within 3 days after vaccination with DTaP/DTP

Guillain-Barre Syndrome occurring within 6 weeks of a previous dose of a tetanus toxoid- containing vaccine.

Defer vaccination of children with moderate to severe acute illness until they are well

NOTE: Stable/resolved neurologic condition (i.e., controlled epilepsy, cerebral palsy, or developmental delay), or a family history of convulsions in first-degree family members (parents or siblings) is not a contraindication for DTaP. If a child has any of the following conditions, vaccination should be delayed until the child has been evaluated, treatment initiated, and the condition stabilized: (1) an evolving neurologic disorder (uncontrolled epilepsy, infantile spasms, progressive encephalopathy); (2) a history of seizures which has not been evaluated; or, (3) a neurologic event which occurs between doses of pertussis containing vaccine.

Adverse events include the following:

Local reactions (injection site pain, swelling or redness)

Nodule at injection site

Hypersensitivity reactions (Arthus-type)

Fever

Drowsiness, loss of appetite

Severe systemic reactions are rare

PLAN

- Ask parent or guardian about the medical history and recent health status of the child to determine the existence of any contraindications
- Ask parent or guardian about adverse reaction after previous dose
- Counsel regarding benefits, side effects, and management; recommend that parent may administer acetaminophen if a fever develops and the child is uncomfortable. If the child does not show signs of discomfort, medication is not necessary.
- Have accompanying adult read “Vaccine Information Statement” (VIS)
- Administer vaccine INTRAMUSCULARLY
- Advise to wait in clinic for 20 minutes after injection
- Record manufacturer and lot number of the vaccine administered, date that vaccine and VIS were given, name, address, and title of person administering vaccine
- Instruct parent to contact Health Department if adverse reaction occurs (complete VAERS form)

Referral Indicators:

Unstable neurological conditions

Allergic hypersensitivity to any component of the vaccine

Severe reaction to previous DTaP/DTP or IPV

If severe reaction is reported as occurring within 30 days following vaccine administered by health department personnel, VAERS Report form must be completed

Refer for Tdap at 11-12 years

Follow-up:

After completion of series, refer for Tdap at 11-12 years

REFERENCES:

KINRIX™ (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine) by GSK. Package Insert, last revised July 2014.

“Epidemiology and Prevention of Vaccine-Preventable Diseases”, Centers for Disease Control and Prevention, DHHS, 13th edition.

<http://www.cdc.gov/vaccines/pubs/pinkbook/index.html#toc#toc>. Last accessed May 21, 2015.

HAEMOPHILUS *INFLUENZAE* type b CONJUGATE VACCINE (Hib)

GENERAL INFORMATION

Contraindications and Precautions include the following:

- Anaphylactic reaction to a vaccine component or following a prior dose of that vaccine
- Moderate or severe acute illness
- Children younger than 6 weeks of age

Adverse events include the following:

- Swelling, redness and/or pain
- Systemic reactions infrequent, serious adverse reactions rare

ACIP Recommended Population

- All infants, including those born premature should receive a primary series conjugate Hib vaccine (separate or in combination), beginning at 2 months of age.
- The number of doses in the primary series depends on the type of vaccine used.
 - A primary series of PRP-OMP (PedvaxHIB) vaccine is two doses;
 - PRP-T (ActHIB) requires a three-dose primary series (see table).

A booster is recommended at 12-15 months regardless of which vaccine is used for the primary series.

One dose of Hib vaccine should be administered to persons who have functional or anatomic asplenia or sickle cell disease or are undergoing elective splenectomy if they have not previously received Hib vaccine. Hib vaccination 14 or more days before splenectomy is suggested. Recipients of a hematopoietic stem cell transplant should be vaccinated with a 3-dose regimen 6 to 12 months after a successful transplant, regardless of vaccination history; at least 4 weeks should separate doses. Administer with health department MD or APN order. (See **Table 2**)

Federally-purchased Hib vaccine is available only to children eligible for the Vaccines for Children (VFC) Program.

Administration of Vaccine:

Appropriate age for Hib: at least 2 months old, but less than 5 years (minimum age 6 weeks)

Appropriate time interval since last Hib

Children who have started the 3 dose primary series of vaccinations with ActHib vaccine may complete the primary series with Pedvax HIB but will still need a total of 3 doses in the primary series. The dose administered routinely after age 12 months is a booster dose.

PLAN

Ask patient/guardian about contraindications

Have patient/guardian read Vaccine Information Statement

Counsel regarding benefits, side effects, and management

NOTE: This vaccine is lyophilized and must be reconstituted with the diluent that is provided with the vaccine; NO OTHER DILUENT CAN BE USED; reconstitute with entire content of diluent vial and inject the entire amount of the reconstituted vial; this is a single unit dose and must be administered within 24 hours of reconstitution

Advise to wait in clinic for 20 minutes after injection

Document vaccine administration on the immunization clinic record

Instruct patient/guardian to contact Health Department if adverse reaction occurs

Vaccine	Age beginning primary series	Primary series	Booster	Minimum interval
PRP-T (ActHib) 0.5cc IM	2-6 months	3 doses, 2 months apart	12-15 months	4 weeks between dose 1 and dose 2, 4 weeks between dose 2 and dose 3, 8 weeks between dose 3 and booster dose
	7-11 months	2 doses 2 months apart	12-15 months	
	12-14 months	1 dose	2 months later	
	15-59 months	1 dose	----	
PRP-OMP (Pedvax HIB) 0.5 cc IM	2-6 months	2 doses, 2 months apart	12-15 months	4 weeks between dose 1 and dose 2 8 weeks between dose 2 and booster dose
	7-11 months	2 doses, 2 months apart	12-15 months	
	12-14 months	1 dose	2 months later	
	15-59 months	1 dose	---	

NOTE:

- If child is greater than 59 months of age, Hib vaccine is not routinely indicated
- Ideally, the same brand of vaccine should be used throughout the entire vaccination series; however, where it is necessary to change the types of vaccine, a child 2-6 months of age seen for the primary series should receive three doses of Hib vaccine (i.e., child receives 1 dose ActHIB should then receive 2 doses of Pedvax HIB or if child receives 2 doses of ActHIB should then receive 1 dose of Pedvax HIB for primary series; child would then get booster at 12-15 months)
- Hib vaccines may be given simultaneously at different injection sites with all other vaccines.
- Hiberix brand PRP-T vaccine is approved only for the booster dose of the Hib series among children 12 months of age and older

Referral Indicators:

Allergic hypersensitivity to any component of the vaccine

Follow-up:

If severe reaction is reported as occurring within 30 days following vaccine administered by health department personnel, VAERS Report form must be completed

Return at appropriate interval according to schedule

TABLE 2. Guidance for *Haemophilus influenzae* type b (Hib) vaccination in high-risk groups

High-risk group*	Hib vaccine guidance
Patients aged <12 mos	Follow routine Hib vaccination recommendations
Patients aged 12–59 mos	If unimmunized or received 0 or 1 dose before age 12 mos: 2 doses, 8 wks apart If received ≥2 doses before age 12 mos: 1 dose 8 wks after last dose If completed a primary series and received a booster dose at age ≥12 mos: no additional doses
Patients aged <60 months undergoing chemotherapy or radiation therapy†	If routine Hib doses administered ≥14 days before starting therapy: revaccination not required If dose administered within 14 days of starting therapy or given during therapy: repeat doses starting at least 3 mos following therapy completion
Patients aged ≥15 mos undergoing elective splenectomy	If unimmunized:‡ 1 dose prior to procedure§
Asplenic patients aged >59 mos and adults	If unimmunized:§ 1 dose
HIV-infected children aged ≥60 mos	If unimmunized:§ 1 dose
HIV-infected adults	Hib vaccination is not recommended
Recipients of hematopoietic stem cell transplant, all ages	Regardless of Hib vaccination history: 3 doses (at least 4 wks apart) beginning 6–12 mos after transplant

* Persons with functional or anatomic asplenia, HIV infection, immunoglobulin deficiency including immunoglobulin G2 subclass deficiency, or early component complement deficiency, recipients of a hematopoietic stem cell transplant, and those receiving chemotherapy or radiation therapy for malignant neoplasms.

† Some experts suggest conducting serologic testing for these patients (Source: Rubin LG, Levin MJ, Ljungman P, et al. 2013 IDSA clinical practice guideline for vaccination of the immunocompromised host. Clin Infect Dis 2013;[Epub ahead of print] doi: 10.1093/cid/cit684).

‡ Patients who have not received a primary series and booster dose or at least 1 dose of Hib vaccine after 14 months are considered unimmunized.

§ Some experts suggest vaccination at least 14 days before the procedure (Sources: CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 2011;60[No. RR-2]; CDC. Recommendations of the Advisory Committee on Immunization Practices

REFERENCES

“Epidemiology and Prevention of Vaccine - Preventable Diseases”, 12th Edition, Centers for Disease Control and Prevention, Department of Health and Human Services, May 2011

ACIP Adult Immunization Schedule footnote, 2014

HEPATITIS A VACCINE

GENERAL INFORMATION

Hepatitis A disease is a serious liver infection caused by the Hepatitis A virus (HAV). HAV is found in the stool of persons with Hepatitis A. It is not often fatal, but is highly contagious with transmission occurring primarily by the fecal-oral route.

Hepatitis A vaccine is inactivated and contains no live organisms; Hepatitis A vaccine is not licensed for children younger than 1 year of age. Hepatitis A vaccine may be administered simultaneously with other vaccines.

To determine if a patient in an ACIP-recommended group is eligible for free, Federal vaccine, please see the current Tennessee Immunization Program Policy on the use of Federal vaccine.

Recommended Populations who should be vaccinated include:

- All children 12-23 months
- Previously unvaccinated children 23 months through 18 years of age
- Any person requesting protection from Hepatitis A virus infection
- Members of households planning to adopt a child, or care for a newly arriving adopted child, from a country where hepatitis A is common (see www.cdc.gov/travel).
- People who use street drugs.
- Men who have sex with men

- International travelers (refer)
- Persons working with hepatitis A-infected non-human primates (refer)
- Persons who work with hepatitis A in research laboratories (refer)

- ❖ Persons who have blood clotting-factor disorders or chronic liver disease (health department MD or APN order)

Contraindications to giving the vaccine include the following:

Persons with a history of severe reaction to a prior dose of hepatitis A vaccine or to any hepatitis A vaccine component

Precautions (risks and benefits of vaccination should be carefully evaluated for individuals under the following circumstances):

Moderate to severe acute illness (defer until illness resolves)

Adverse Reactions:

Severe allergic reaction to vaccine (rare)
 Injection site soreness, tenderness, redness, swelling (common)
 Fatigue, fever, malaise, anorexia, nausea, headache (systemic)

PLAN

1. Ask patient/guardian about contraindications
2. Have patient/guardian read Vaccine Information Statement
3. Administer the appropriate pediatric or adult formulation of the vaccine according to manufacturer instructions
4. Counsel regarding side effects of vaccine
5. Advise patient or parent/guardian to return for the second dose in 6-12 months
6. Advise to wait in clinic for 20 minutes after injection
7. Document vaccine administration on the immunization clinic record
8. Instruct patient/guardian to contact Health Department if adverse reaction occurs

Dosage:

VAQTA (Merck) **or** HAVRIX (GlaxoSmithKline) hepatitis A vaccines:

Pediatric Formulation (ages 12 mos. to 19 years), 2 doses required

Administer 0.5 cc IM

Administer second dose 6-12 months later.

Adult Formulation (≥ 19 years), 2 doses required

Administer 1.0 cc IM

Administer second dose 6-12 months later.

TWINRIX Combination Hepatitis A and B vaccine (GlaxoSmithKline):

(Licensed for adults ≥ 18 years only, 3 doses required)

Administer 1.0 cc IM,

Administer second dose 1 month after the first dose.

Administer third dose 6 months after the first dose.

Referral Indicators:

If vaccine is indicated for liver disease or blood clotting factor disorder¹, written order from health department MD or APN is needed

Severe reaction to previous vaccine (consult MD)

REFERENCES

CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. 12th edition, May 2012: pp 101-114.

<http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hep-a.html#who>

CDC. Advisory Committee on Immunizations Practices (ACIP) Recommended Immunization Schedule for Adults Aged 19 years and older - United States, 2013. MMWR, February 1, 2013/62(01);9-19.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/su6201a3.htm>

¹ Per Advisory Committee on Immunization Practices (ACIP) guidelines, hemophilia is not a contraindication for any vaccination, but administration should be done in consultation with a health department physician to minimize the risk of hematoma formation

MENINGOCOCCAL VACCINE MENINGOCOCCAL CONJUGATE VACCINE (MENACTRA™, MENVEO™)

GENERAL INFORMATION

Meningococcal disease is caused by bacteria (*Neisseria meningitidis*) that infect the bloodstream and the linings of the brain and spinal cord, causing serious illness. Meningococcal disease is rare in the United States, but is now the leading cause of bacterial meningitis in children. Of people with meningococcal disease, 10% die and 11-19% of survivors have permanent disabilities (such as mental retardation, hearing loss, and loss of limbs). Meningococcal disease is most likely to occur in infants and toddlers, although the type (serogroup B) that causes most disease in this age group is not preventable by vaccine. After infancy, the next period of increased risk is from 16-21 years. Infection is spread by direct contact with infected individuals (e.g., sharing a glass or cigarette, or kissing), or via droplets of respiratory secretions (e.g., coughing or sneezing). Symptoms include the sudden onset of fever, chills, severe headache, stiff neck, rash, nausea, vomiting and lethargy.

Meningococcal vaccine is inactivated and contains no live organisms. The vaccine is designed to prevent infections from serogroups A, C, Y and W-135. Protective antibody levels may be achieved within 7-10 days after vaccination. Meningococcal vaccine may be given at the same time as other immunizations, if needed.

Meningococcal Conjugate Vaccine (MCV4)

There are 2 MCV4 vaccines: Menactra™ by Sanofi Pasteur (licensed age 9 months through 55 years) and Menveo™ by Novartis (licensed age 24 months through 55 years)

Immunity is expected to last 3-5 years following a single dose.

MCV4 is recommended for routine use in preteens and certain individuals who are at elevated risk for meningococcal disease and are between 2 and 55 years of age

Where MCV4 is not available, Meningococcal Polysaccharide Vaccine (MPSV4, Menomune™) is an acceptable substitute for some, not all, persons for whom MCV4 is recommended; refer to Meningococcal Polysaccharide vaccine (MPSV4, Menomune) protocol as needed for additional information. MCV4 is always preferred to MPSV4.

ACIP Recommended Populations include the following:

Adolescents (First dose routinely for children 11 through 12 years and as catch up for any children 13 through 18 years not previously vaccinated with MCV4)

College freshmen in dormitories, including those through age 21 who enroll in college and present for vaccine before moving on campus, if not previously vaccinated or booster indicated

Persons age 2 through 55 years who have anatomic or functional asplenia or terminal complement component deficiencies, including such persons who had received one dose of MPSV4 three (3) or more years earlier (with health department physician order)

Persons age 2 through 55 years who travel to, or reside in, countries in which *N. meningitidis* is hyperendemic or epidemic, particularly if contact with local populations is prolonged

Military recruits (Health departments should refer)

Microbiologists routinely exposed to isolates to *N. meningitidis* (Health departments refer)

To determine if a patient in an ACIP-recommended group is eligible for free, Federal vaccine, please see the current Tennessee Immunization Program Policy on the use of Federal vaccine.

Contraindications to giving the vaccine include the following:

Persons under 2 years or over 55 years of age

If known to be pregnant, consult with health officer or refer to medical provider

Hypersensitivity to any component of the vaccine, including diphtheria toxoid

Menactra only: hypersensitivity to dry natural latex (contained in vaccine vial stopper)

Note: Menveo packaging does not contain latex.

Precautions include the following:

Immunization should be deferred during the course of any moderate to severe illness

Anyone who has ever had Guillain-Barre Syndrome

Adverse Reactions include the following:

COMMON

Mild injection site pain and redness (within 1 -2 days of vaccination)

Mild systemic reactions such as headache and malaise (within 7 days of vaccination)

RARE

Fever (within 7 days of vaccination) or severe systemic reaction

PLAN

Vaccinate according to the following table [Use federally-funded vaccine, in accordance with current guidance for its use (see cover letter). If state or locally-purchased vaccine is available, persons ineligible for federally-funded vaccine may be vaccinated in accordance with local policy]:

Risk group	First dose (age in years)	Booster dose (age in years)§
Persons aged 11 through 18 years	11 through 12	16 (catch up dose through age 18)*
	13 through 15	16 through 18*
	16 or older	-none-
HIV-infected persons age 11 through 18 years	11 through 12 (primary 2-dose series, at least 8 weeks apart*)	16 (catch up dose through age 18)* ‡
	13 through 15 (primary 2-dose series, at least 8 weeks apart*)	16 through 18*‡
	≥16 (primary 2-dose series, at least 8 weeks apart*)	-none-
Persons aged 2 through 55 years with persistent complement component deficiency (such as C5-C9, properdin or factor D) or asplenia (functional or anatomic)	At earliest opportunity (primary 2-dose series, at least 8 weeks apart)	Every 5 years following the second primary series dose.

Risk group	First dose (age in years)	Booster dose (age in years)§
Persons age 2-55 years with prolonged increased risk for exposure to N. meningitidis**	1 dose	If aged 2 through 6 years, after 3 years, <i>if still at increased risk</i> If aged 7 years or older, after 5 years <i>if still at increased risk</i>
§ <i>Minimum interval between primary and booster doses of vaccine is 8 weeks</i>		
* <u>To determine if a patient in an ACIP-recommended group is eligible for free, Federal vaccine, please see the current Tennessee Immunization Program Policy on the use of Federal vaccine.</u>		
‡ <i>Calculate need for booster dose based upon age at receipt of the second dose in the primary 2-dose series.</i>		
** <i>Microbiologists routinely working with Neisseria meningitidis and travelers or residents of countries where meningococcal disease is hyperendemic or epidemic.</i>		

If using Menveo, reconstitute product according to manufacturer package insert prior to administration.

Administer a single dose of vaccine, 0.5 ml **INTRAMUSCULARLY**

Ask patient/guardian about contraindications

Have patient/guardian read Vaccine Information Statement

Document vaccine administration on the immunization clinic record

Advise to wait in clinic for 20 minutes after injection

Instruct patient/guardian to contact Health Department if adverse reaction occurs

Health Teaching:

Provide current Vaccine Information Sheet (VIS) about meningococcal disease and the benefits of vaccination

If the vaccine is used in persons receiving immunosuppressive therapy, the expected immune response may not be obtained

Educate recipients for whom a booster dose is recommended about the timing and importance of the booster dose

Referral:

Pregnancy

Military recruits

Microbiologists occupationally exposed to isolates of N. meningitidis

Travelers (to a travel clinic)

REFERENCES

Menactra® [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine] package insert, Sanofi Pasteur (Aventis Pasteur), April 2008

MENVEO® [Meningococcal (Groups A, C, Y and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine] package insert, Novartis, January 2011

MMWR, Prevention and Control of Meningococcal Disease, Recommendations of the Advisory Committee on Immunization Practices (ACIP), U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Atlanta, GA 30333, May 27, 2005/Vol.54/No. RR-7

MMWR, Notice to Readers: Recommendation from the Advisory Committee on Immunization Practices (ACIP) for Use of Quadrivalent Meningococcal Conjugate Vaccine (MCV4) in Children Aged 2--10 Years at Increased Risk for Invasive Meningococcal Disease. December 7, 2007 / 56(48):1265-1266

MMWR, Updated Recommendations for the Use of Meningococcal Conjugate Vaccines – Advisory Committee on Immunization Practices (ACIP) 2010, January 28, 2011.
<http://www.cdc.gov/mmwr/pdf/wk/mm6003.pdf>

POLIO VACCINE, INACTIVATED

GENERAL INFORMATION

IPV is the only poliovirus vaccine recommended for all persons

The all-IPV routine schedule requires 4 doses of vaccine to be given at ages 2 months, 4 months, 6-18 months, and 4-6 years

If primary series was started after age 4 years, only 3 doses are required.

A 4th dose is not necessary if the 3rd dose was administered \geq 4 years or older and at least 6 months after the previous dose.

IPV can be administered simultaneously with all other vaccines recommended for the same visit

Contraindications and precautions to IPV include:

Anaphylactic hypersensitivity

Severe febrile illness (a precaution; delay until resolved)

Allergic to streptomycin, neomycin, or polymixin B

Pregnancy (a precaution; however, if required because immediate protection needed for traveling outside of country, obtain a health department physician order)

Adverse Reactions to IPV include:

Possibility of hypersensitivity reactions in individuals sensitive to streptomycin, polymixin B, or neomycin

PLAN

Have accompanying adult read Vaccine Information Statement/Vaccine Information Material

Counsel regarding benefits, side effects, and management

Administer appropriate vaccine, as specified by manufacturer, in accordance with Schedule

Recommended Vaccine Schedule:

2 months, 4 months, 6-18 months, and 4-6 years

The minimum age for dose 1 is 6 weeks.

A minimum interval of 4 weeks is required from dose 1 to dose 2 and from dose 2 to dose 3. A minimum interval of 6 months is required between doses 3 and 4.

Use of minimum intervals during the first 6 months of life is recommended only if the recipient is at risk for exposure (during an outbreak or for travel to a polioendemic area). History shots administered using minimum intervals do not need to be repeated.

The final dose of IPV is recommended routinely at 4-6 years of age, regardless of the number of previous doses.

Children immunized with the DTaP/IPV-Hib combination vaccine (Pentacel) will receive 4 doses of IPV by 18 months of age and are recommended to receive

a 5th dose at 4-6 years. If a 5-dose schedule is used, a minimum interval of 6 months is recommended between doses 4 and 5.

If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.

See table below for details of approved use for various IPV-containing vaccines.

TABLE. Currently licensed vaccines containing inactivated poliovirus vaccine (IPV) — United States, 2009*

Vaccine composition	Trade name	Manufacturer	Approved use in ACIP [†] routine schedule	Comments
IPV	Ipol (Poliovax [§])	Sanofi Pasteur	2, 4, 6–18 mos, and 4–6 yrs	Approved for use in infants, children, and adults [¶]
DTaP-HepB-IPV**	Perdiarix	GlaxoSmithKline	2, 4, and 6 mos	Approved for first 3 doses of IPV through age 6 yrs ^{††}
DTaP-IPV/Hib ^{§§}	Pentacel	Sanofi Pasteur	2, 4, 6, and 15–18 mos	Approved for 4 doses of IPV through age 4 yrs ^{¶¶}
DTaP-IPV***	Kinrix	GlaxoSmithKline	4–6 yrs	Approved for booster dose at age 4–6 yrs ^{†††}

* As of August 5, 2009.

† Advisory Committee on Immunization Practices. Full schedule available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5751a5.htm>.

§ Not currently distributed in the United States.

¶ Package insert available at <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm133479.pdf>.

** Diphtheria and tetanus toxoids and acellular pertussis adsorbed, hepatitis B (recombinant), and inactivated poliovirus vaccine combined.

†† Package insert available at <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm168055.pdf>.

§§ Diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus, and *Haemophilus b* conjugate (tetanus toxoid conjugate) vaccine.

¶¶ Package insert available at <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm109810.pdf>.

*** Diphtheria and tetanus toxoids and acellular pertussis adsorbed, and inactivated poliovirus vaccine.

††† Package insert available at <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm107220.pdf>.

Advise to wait in clinic 20 minutes after injection

Record manufacturer and lot number of the vaccine administered, date, name, address and title of person administering vaccine (National Childhood Vaccine Injury Act)

Instruct patient to contact Health Department if adverse reaction occurs (complete appropriate form)

Referral Indicators:

Allergic hypersensitivity to any component of the vaccine

History of severe reaction to previous dose

Follow-up:

Return at appropriate interval according to schedule

References

MMWR, August 7, 2009/58 (30): 829. Updated Recommendations of the Advisory Committee on Immunization Practices Regarding Routine Poliovirus Vaccination.

<http://www.cdc.gov/mmwr/PDF/wk/mm5830.pdf>

Centers for Disease Control and Prevention. Poliomyelitis prevention in the United States: updated recommendations of the Advisory Committee on Immunization Practices (AICP). MMWR 2000;49(No. RR-5). <http://www.cdc.gov/mmwr/PDF/rr/rr4905.pdf>

“Epidemiology and Prevention of Vaccine-Preventable Diseases”, Centers for Disease Control and Prevention, DHHS, 13th edition.

<http://www.cdc.gov/vaccines/pubs/pinkbook/index.html#toc#toc>. Last accessed May 21, 2015.

ROTAVIRUS VACCINE **(RotaTeq[®] “RV5” by Merck, Rotarix[®] “RV1” by GSK)**

GENERAL INFORMATION

Rotavirus causes severe diarrhea and is usually accompanied by fever and vomiting. It is the most common cause of severe gastroenteritis in infants and young children in the U.S. Rotavirus is seasonal, with peak numbers of cases occurring in the winter and early spring. Before the introduction of vaccine in 2006, rotavirus diarrhea resulted in about 200,000 emergency room visits and 55,000 hospitalizations in the US annually. Transmission occurs through the fecal-oral route.

Rotavirus vaccines are live vaccines administered by mouth, between the age of 6 weeks zero days and 8 months zero days of age. They may be administered simultaneously with other vaccines. Two rotavirus vaccines are licensed in the U.S.: Rotateq[®] by Merck (abbreviated “RV5” by CDC) and Rotarix[®] by GSK (abbreviated “RV1” by CDC). RV5(Rotateq) is a three-dose series and RV1 (Rotarix) is a two-dose series: the ACIP/CDC expresses no preference between the two vaccines. Please note: this protocol follows ACIP/CDC recommendations for a harmonized schedule of the two brands, which differs from product package inserts.

Special situations:

Infants in contact with pregnant women or persons with compromised immune systems **may** be vaccinated.

Infants who have received or will receive blood or antibody-containing products may receive the vaccine *at any time*. Previously, it was recommended that such infants wait 42 days before vaccination.

Re-administration of a dose to an infant who spits up or vomits during or after administration of the vaccine is not generally recommended. If this occurs, continue series at normal interval.

If *any* dose in the series is RV5, or if the brand of any dose is unknown, a total of 3 doses must be administered to complete the series. Although preferable to use one brand for the entire series, vaccination should not be deferred because the product previously used is unknown or unavailable.

3-Dose Immunization Schedule: If any dose is Rotateq® (RV5) or unknown brand

Dose	Product	Recommended age	Minimum interval to next dose	Special Notes
Dose 1	RotaTeq (RV5) or Rotarix (RV1)	2 months: Administer between age 6 weeks and 14 weeks 6 days (42-104 days)	4 weeks	If dose 1 was given at ≥ 15 weeks, the series may be continued
Dose 2	RotaTeq (RV5) or Rotarix (RV1)	4 months	4 weeks	
Dose 3 Final dose	RotaTeq (RV5) or Rotarix (RV1)	6 months		Do not administer after age 8 months 0 days

2-Dose Immunization Schedule: If Using Rotarix® (RV1) Only

Dose Number	Recommended age at administration	Minimum interval to next dose	Special Notes
Dose 1	2 months: Administer between age 6 weeks and 14 weeks 6 days (42-104 days)	4 weeks	If dose 1 was given at ≥ 15 weeks, the series should be completed
Dose 2 Final dose	4 months		Do not administer after 8 months 0 days of age.

Contraindications to giving the vaccine include the following:

- Infants <6 weeks (42 days) or >8 months 0 days (precise age in days not specified)
- Infants with a history of severe allergic reaction to a prior dose of rotavirus vaccine or to any rotavirus vaccine component
- Infants with a severe (anaphylactic) reaction to latex should not receive Rotarix (RV1). RotaTeq (RV5) should be used because it is latex free.
- Previous history of intussusception
- Infants diagnosed with Severe Combined Immunodeficiency (SCID)

Precautions (risks and benefits of vaccination should be carefully evaluated under the following circumstances):

- Moderate to severe acute illness (defer until illness resolves) [Note: Low grade fever <100.5°F or mild upper respiratory infections are not reasons for deferring]
- Preexisting chronic gastrointestinal disease (e.g., chronic diarrhea, congenital abdominal disorders)

Altered immunocompetence including:

- Blood disorders or cancers involving the bone marrow or lymph system
- Infants on high dose systemic corticosteroids
- Infants with an immunodeficiency other than SCID

Adverse Reactions:

- Severe allergic reaction to vaccine (rare)
- High fever

PLAN

- Ask parent/guardian about contraindications, precautions
- Have parent/guardian read Vaccine Information Statement
- If using Rotarix (RV1), reconstitute vaccine according to manufacturer's instructions
- Administer the vaccine by mouth according to the manufacturer instructions [if an incomplete dose is administered or the infant vomits, repeating the dose is not recommended]
- Counsel regarding side effects of vaccine
- Advise parent/guardian to return for the next dose in a minimum of 4 weeks
- Advise to wait in clinic for 20 minutes after administration of vaccine
- Record manufacturer and lot number of the vaccine administered, date vaccine and VIS given, address of facility, and name and title of person administering vaccine
- Instruct patient/guardian to contact Health Department if adverse reaction occurs (complete VAERS)

Referral Indicators:

- Infants with precautions to vaccination other than an acute moderate to severe illness should be referred for a health department physician order.

REFERENCES

- CDC. Cortese MM, Parashar UD. Prevention of rotavirus gastroenteritis among infants and children: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2009;58(No. RR-2).
- RotaTeq (Rotavirus Vaccine, Live, Oral, Pentavalent) Vaccine package insert, Merck, Revised September 2011.
- Rotarix (Rotavirus Vaccine, Live Attenuated) Vaccine package insert, GSK, Revised February 2011.
- CDC. Prevention of Rotavirus Gastroenteritis among Infants and Children. Recommendations of the Advisory Committee on Immunization Practices, MMWR. August 11, 2006. <http://www.cdc.gov/mmwr/PDF/rr/rr5512.pdf>. Last accessed August 12, 2008.
- CDC. Addition of Severe Combined Immunodeficiency as a Contraindication for Administration of Rotavirus Vaccine, June 11, 2010. MMWR. <http://www.cdc.gov/mmwr/pdf/wk/mm5922.pdf>. Last accessed February 15, 2012.

CHLAMYDIA TRACHOMATIS, Case or Contact

SUBJECTIVE

Symptoms may include:

FEMALES-

Vaginal discharge
Dysuria, pelvic pain
Changes in menses
Intermenstrual spotting
Postcoital bleeding
Commonly asymptomatic

MALES -

Dysuria
Penile discharge
Commonly asymptomatic

“A friend told me to come in”

Sexual contact to confirmed or suspected case of chlamydia, gonorrhea, NGU, or non-specific cervicitis

Private physician or other health care provider referral

OBJECTIVE

Muco-purulent discharge from urethra or cervix

Laboratory positive for *Chlamydia trachomatis*

ASSESSMENT

Confirmed or suspected case of *Chlamydia trachomatis*

Contact to confirmed or suspected case of *Chlamydia trachomatis*

Last menstrual period

Test all exposed sites (vaginal, oral, rectal, and urethral)

PLAN

Screen¹ for chlamydia and gonorrhea using currently available test; refer to “*Laboratory Policies and Procedures Manual for Local Health Departments*” for information on specimen storage and mailing.

Draw blood for syphilis serology.

Consider need for hepatitis B vaccination and provide (if available) or refer as indicated

Offer HIV counseling and literature for all clients; offer testing for high-risk individuals or those requesting service.

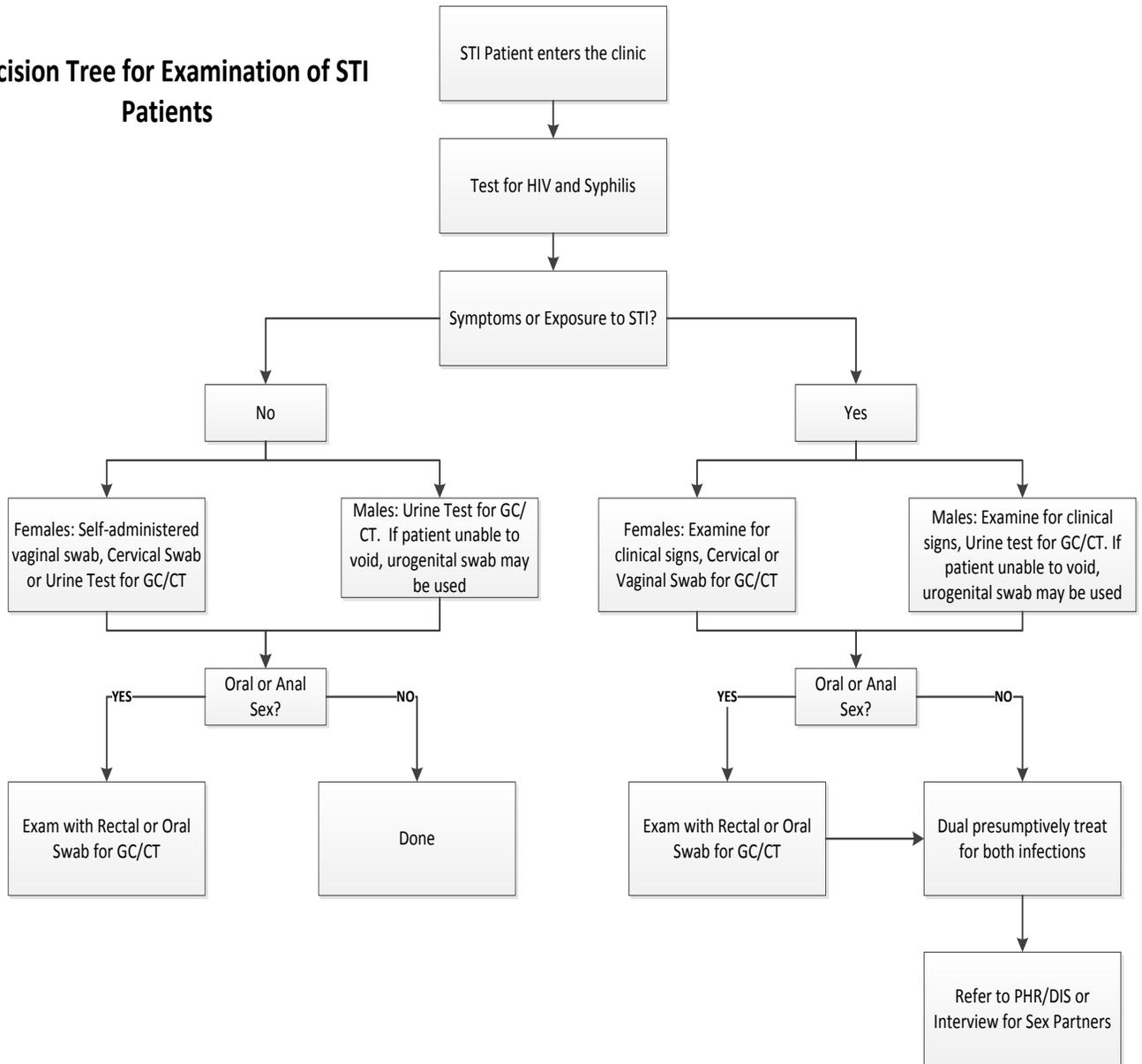
Interview patient for sexual contacts and encourage all contacts to obtain treatment:

Obtain name, address, phone number, age, sex, race, and date of exposure of all contacts within the last 60 days; do not write the information in the patient’s record; if a contact to confirmed case, do not write the original case name in the contact’s chart.

Notify the public health representative of the original positive case name and contact information
Counsel, examine, and test all persons exposed.

¹ Several studies of different test technologies have shown various post-treatment intervals wherein a false positive test result may occur. Therefore, repeat testing should not be performed within 3 weeks of appropriate treatment. Patients that have been exposed to an infected person within 3 weeks of treatment should be retreated, but not retested.

Decision Tree for Examination of STI Patients



TREATMENT

Use dual treatment on the person to be treated, unless you have a confirmed negative test for gonorrhea (see protocol for gonorrhea).

If the chlamydia test is positive, refer to the treatment guidelines found in the PHN Protocol for **Chlamydia Partner Delivered Treatment**.

AZITHROMYCIN is the drug of choice for chlamydia.

Treatment for Chlamydia Only²**Adult/Adolescent:**

Azithromycin 1 gm orally as a single dose

OR

Doxycycline 100 mg orally BID x 7 days³

Pregnant Adult/Adolescent or Nursing Mothers:

(if unprotected coitus since LMP, suspect pregnancy and treat accordingly):

Azithromycin 1 gm orally as a single dose

OR

Amoxicillin 500 mg orally TID x 7 days

Allergic Pregnant Individuals:

Consult with health department physician regarding choice of above antibiotics

Dual Treatment for Chlamydia and Gonorrhea (regardless of site of exposure)⁴**Non-Allergic Adult/Adolescent:**

Ceftriaxone 250 mg IM as a single dose

PLUS ONE OF THE FOLLOWING:

Azithromycin 1 gm orally as a single dose

OR

Doxycycline 100 mg orally BID x 7 days⁵

² Patients and/or sex partners presenting for treatment of laboratory confirmed chlamydia, and are **known to have a negative gonorrhea test**, are to be treated for chlamydia only.

³ Doxycycline is contraindicated in pregnancy and nursing mothers.

⁴ When the laboratory results for both diseases are not available on the person being treated, dual treatment (for chlamydia and gonorrhea) should be administered. Do not refer for desensitization treatment in absence of lab confirmed gonorrhea.

⁵ Doxycycline is contraindicated in pregnancy and nursing mothers.

Non-Allergic Pregnant Adult/ Adolescent/ Nursing Mothers:

Ceftriaxone 250 mg as a single dose

PLUS ONE OF THE FOLLOWING:

Azithromycin 1 gm orally as a single dose

OR

Amoxicillin 500 mg orally TID x 7 days

Allergic Adult/Adolescent:

Azithromycin 2 grams (tablets only) orally as a single dose⁶

Allergic Pregnant Adult/Adolescent/Nursing Mothers :

Azithromycin 2 grams (tablets only) orally as a single dose

OR

Azithromycin 1 gm orally as a single dose for chlamydia and refer preferably to infectious disease physician experienced in the procedure for cephalosporin desensitization and treatment

DILUENT- Use 1% lidocaine solution, sterile water for injection, or 0.9% sodium chloride solution and document accordingly (if allergic to lidocaine, mix with sterile water or normal saline). Lidocaine allergy includes allergies to local anesthesia such as Nupercaine[®], Xylocaine[®], Carbocaine[®], Marcaine[®] or Atanert[®]. There has been no cross sensitivity shown to para-aminobenzoic derivatives such as procaine, tetracaine, and benzocaine.

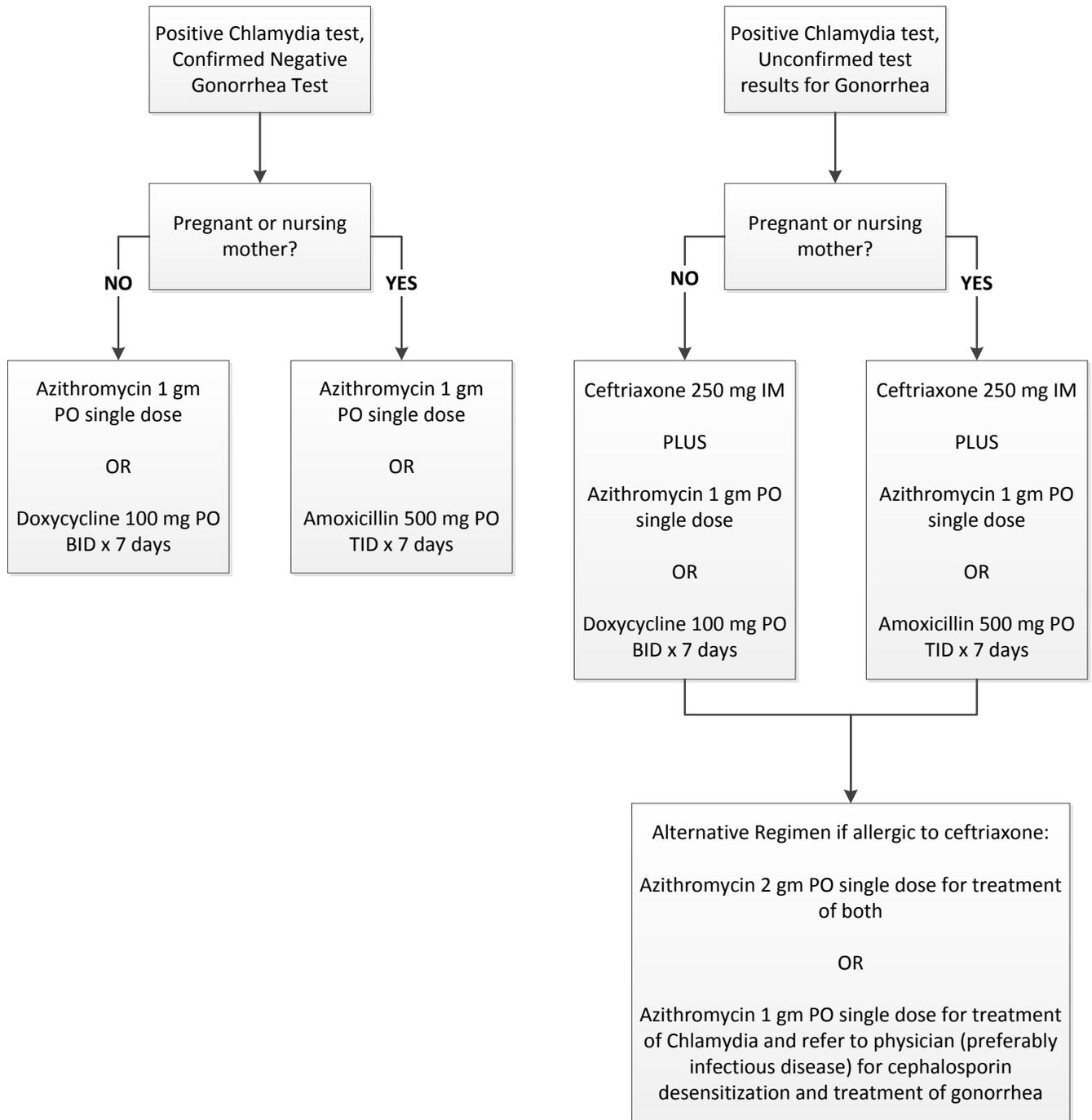
Penicillin or Cephalosporin Allergies: Ceftriaxone is the drug of choice for gonorrhea. If the patient alleges an allergy to penicillin or cephalosporins, the nurse should take a thorough history of allergic response to determine if there is a history of severe allergic reaction such as anaphylaxis or Stevens Johnson syndrome. If the history indicates a non-anaphylactic reaction, (i.e. mild to moderate rash, itching, etc.), the patient should be treated with ceftriaxone. If history indicates a severe reaction such as anaphylaxis, or nurse is unable to gain a history consistent with a non-anaphylactic reaction the patient should be treated with 2 grams azithromycin.⁷ Since there is little to no incidence of ceftriaxone resistant gonorrhea reported in the United States, all patients returning with gonorrhea and persistent or recurring symptoms should be considered reinfected and retreated with ceftriaxone.⁸

⁶ Studies have indicated increase frequency of gastrointestinal problems with a 2 gram dose of azithromycin. According to the PDR, azithromycin tablets can be taken with food to lessen the occurrence of GI symptoms. Patients should be advised to return for repeat treatment if vomiting occurs.

⁷ Studies indicate that 10% of patients alleging an allergy to PCN are actually allergic when testing is done. Only 5-10% of patients allergic to PCN will have a cross reaction/sensitivity to cephalosporins. Therefore, only 0.5-1% of patients that allege an allergy to PCN would actually be allergic to a cephalosporin. With a thorough history taken on those patients alleging PCN allergy, a risk of an allergic reaction to ceftriaxone will be extremely rare.

⁸ There is no need for the laboratory to perform sensitivity testing on isolates unless the CDC begins reporting an increased incidence of ceftriaxone-resistant gonorrhea from their Gonorrhea Isolate Surveillance Program GISP).

Chlamydia and Gonorrhea Treatment Decision Tree



Health Teaching

- Offer condoms and encourage use during any sexual activity.
- Encourage all sexual contacts to obtain care.
- Stress completion of all medicines and advise to avoid intercourse until patient and their sex partner(s) have completed treatment including 7 days after single-dose therapy or completion of 7 or 14-day treatment regimen.
- Warn patient that until medication is completed and all sex partners are treated, chlamydial infection may be transmitted and reinfection is likely.
- If using oral contraceptive, encourage use of barrier method until two weeks following completion of treatment. Offer condoms.
- Discuss HIV and STD prevention.
- Encourage voiding before and after intercourse.
- Increase water intake with medications.
- Avoid antacids and exposure to sun when taking doxycycline.
- Stress hygiene, including wearing cotton underwear, loose clothing, avoidance of underpants while sleeping, wiping front to back, and avoid feminine hygiene sprays and deodorants.
- Stress need for follow-up exam if symptoms persist, recur, or exacerbate.

Referral Indicators

- Pregnant individuals with **significant** medical issues (consultation with private physician or Health Officer prior to treatment)
- Prepubertal children as indicated (refer to CHS Child Abuse Policy)
- No response to treatment
- Dyspareunia and/or moderate to severe abdominal pain
- Complications (i.e., PID, postpartum infection, abnormal Pap)

Follow-Up

- Return if no improvement after treatment.
- Counsel infected patient to return for retesting 3 months after completion of treatment. If this does not occur, retest all persons treated for chlamydia infection if they present for care within 12 months following treatment.
- In cases of treatment failure, consult with health department physician or APN
- Report all cases to Sexually Transmitted Disease Program representative.
- Test of cure is not appropriate except in pregnant women who should be tested 4-6 weeks after completing therapy.

REFERENCE

Centers for Disease Control and Prevention Sexually Transmitted Diseases Treatment Guidelines, 2010. MMWR 2010; 59(No. RR-12).

GONORRHEA

SUBJECTIVE

Symptoms may include:

FEMALES-(a large percentage of infected women are asymptomatic in the early stages of disease)

Early Symptoms

Dysuria
Leukorrhea, change in vaginal discharge
Unilateral labial pain and swelling
Lower abdominal discomfort
Pharyngitis

Later Symptoms

Purulent, irritating vaginal discharge
Fever (possibly high)
Rectal pain and discharge
Abnormal menstrual bleeding
Increased dysmenorrhea
Nausea, vomiting
Lesions in genital area
Joint pain and swelling
Upper abdominal pain

“A friend told me to come in”

Pain, tenderness in pelvic organs
Sexual contact to confirmed or suspected case of gonorrhea
Private physician or other health care provider referral

MALES -

Early Symptoms

Dysuria with increased frequency
Whitish discharge from penis
Pharyngitis

Later Symptoms

Yellowish/greenish discharge from penis
Epididymitis
Proctitis

OBJECTIVE

Purulent discharge from urethra or cervix noted on exam
Laboratory positive for *Neisseria gonorrhoeae*

ASSESSMENT

Confirmed or suspected case of *Neisseria gonorrhoeae*
Contact to confirmed or suspected case of *Neisseria gonorrhoeae*
Last menstrual period
Assess sites exposed (vaginal, oral, rectal, and urethra)

PLAN

Screen¹ for chlamydia and gonorrhea using currently available test; refer to “*Laboratory Policies and Procedures Manual for Local Health Departments*” for information on specimen storage and mailing.

¹ Several studies of different test technologies have shown various post-treatment intervals wherein a false positive test result may occur. Repeat testing for *N. gonorrhoeae* should not be performed less than 1 week after appropriate treatment, and repeat testing for *C. trachomatis* should not be performed less than 3 weeks after appropriate treatment. Patients that have been exposed to an infected person within these intervals treatment should be re- treated, but not re-tested.

Draw blood for syphilis serology.

Consider need for hepatitis B vaccination and provide (if available) or refer as indicated

Offer HIV counseling and literature for all clients; offer testing for high-risk individuals or those requesting service.

Interview patient for sexual contacts and encourage all contacts to obtain treatment:

Obtain name, address, phone number, age, sex, race, and date of exposure of all contacts within the last 60 days; do not write the information in the patient's record; if a contact to confirmed case, **do not write the original case name in the contact's chart.**

Notify the public health representative of the original positive case name and contact information Counsel, examine, and test all persons exposed.

TREATMENT

It is recommended that all patients being treated for gonorrhea receive dual treatment for both gonorrhea and chlamydia regardless of Chlamydia testing or results.²

Dual therapy, administered concurrently, is considered the only adequate therapy, regardless of the chlamydia results.

Treatment for Gonorrhea and Chlamydia **(regardless of site of infection OR Chlamydia results)**

Non-Allergic Adult/Adolescent:

Ceftriaxone 250 mg IM as a single dose

PLUS ONE OF THE FOLLOWING:

Azithromycin 1 gm orally as a single dose

OR

Doxycycline 100 mg orally BID x 7 days^{3,4}

Non-allergic Pregnant Adult/Adolescent or Breastfeeding Mothers:

(if unprotected coitus since LMP, suspect pregnancy and treat accordingly):

Ceftriaxone 250 mg IM as a single dose

PLUS ONE OF THE FOLLOWING:

Azithromycin 1 gm orally as a single dose

OR

Amoxicillin 500 mg orally TID x 7 days⁴

² Dual treatment is recommended because patients infected with *N. gonorrhoeae* frequently are co-infected with *C. trachomatis*. Additionally, the use of a second antimicrobial is recommended for use with ceftriaxone to theoretically improve treatment efficacy and delay emergence and spread of resistance to *N. gonorrhoeae* to cephalosporins.

³ Doxycycline is contraindicated in pregnancy and nursing mothers

⁴ Because of resistance concerns among Gonococcal Isolate Surveillance Project isolates, the use of azithromycin as the second antimicrobial is preferred to doxycycline (and, among pregnant or nursing mothers, to amoxicillin).

Allergic Adult/Adolescent (regardless of pregnancy or breastfeeding status):

Azithromycin 2 grams (tablet only) orally as a single dose

PLUS

Test-of-cure in 1 week

If the patient has no clinical symptoms of persistent infection, the DNA-Probe specimen collection may be used for testing.

OR

If the patient has persistent symptoms, a culture plate with antimicrobial susceptibility should be performed.

The decision to re-treat at the test-of-cure visit will be based on nursing judgment and/or consultation with the health department physician or APN

DILUENT- Use 1% lidocaine solution, sterile water for injection, or 0.9% sodium chloride solution and document accordingly (if allergic to lidocaine, mix with sterile water or normal saline). Lidocaine allergy includes allergies to local anesthesia such as Nupercaine®, Xylocaine®, Carbocaine®, Marcaine® or Atanert®; there has been no cross sensitivity shown to para-aminobenzoic derivatives such as procaine, tetracaine, and benzocaine.

Penicillin or Cephalosporin Allergies: Ceftriaxone is the drug of choice for gonorrhea. If the patient alleges an allergy to penicillin or cephalosporins, the nurse should take a thorough history of allergic response to determine if there is a history of a severe reaction such as anaphylaxis or Stevens Johnson syndrome. If the history indicates a non-anaphylactic reaction, (i.e. mild to moderate rash, itching, etc.), the patient should be treated with ceftriaxone.⁵ If history indicates a severe reaction such as anaphylaxis, or the nurse is unable to gain a reliable history consistent with a non-anaphylactic reaction, the patient should be treated with azithromycin 2 grams followed by a test-of-cure 1 week after treatment.

Health Teaching

Offer condoms and encourage use during any sexual activity.

Encourage all sexual contacts to obtain care.

Stress completion of all medicines and advise to avoid intercourse until patient and their sex partner(s) have completed treatment including 7 days after single-dose therapy or completion of 7 or 14-day treatment regimen.

Warn patient that until medication is completed and all sex partners are treated, gonococcal infection may be transmitted and reinfection is likely.

If using oral contraceptive, encourage use of barrier method until two weeks following completion of treatment. Offer condoms. Discuss HIV and STD prevention.

⁵ Studies indicate that only 10% of patients alleging an allergy to PCN are actually allergic when testing is done. Only 5-10% of patients allergic to PCN will have a cross reaction/sensitivity to cephalosporins; therefore, only 0.5-1% of patients that allege an allergy to PCN would actually be allergic to a cephalosporin. With a thorough history taken on those patients alleging PCN allergy, a risk of an allergic reaction to ceftriaxone will be extremely rare.

Encourage voiding before and after intercourse. Increase water intake with medications.
 Avoid antacids and exposure to sun when taking doxycycline.
 Stress hygiene, including wearing cotton underwear, loose clothing, avoidance of underpants while sleeping, wiping from front to back and avoid feminine hygiene sprays and deodorants.
 Stress need for follow-up exam if symptoms persist, recur, or exacerbate.

Referral Indicators

Pregnant individuals with **significant** medical issues (consultation with private physician or Health Officer prior to treatment)
 Prepubertal children as indicated (refer to HSA Child Abuse Policy)
 No response to treatment
 Dyspareunia and/or moderate to severe abdominal pain
 Complications (i.e. PID, postpartum infection, abnormal Pap)

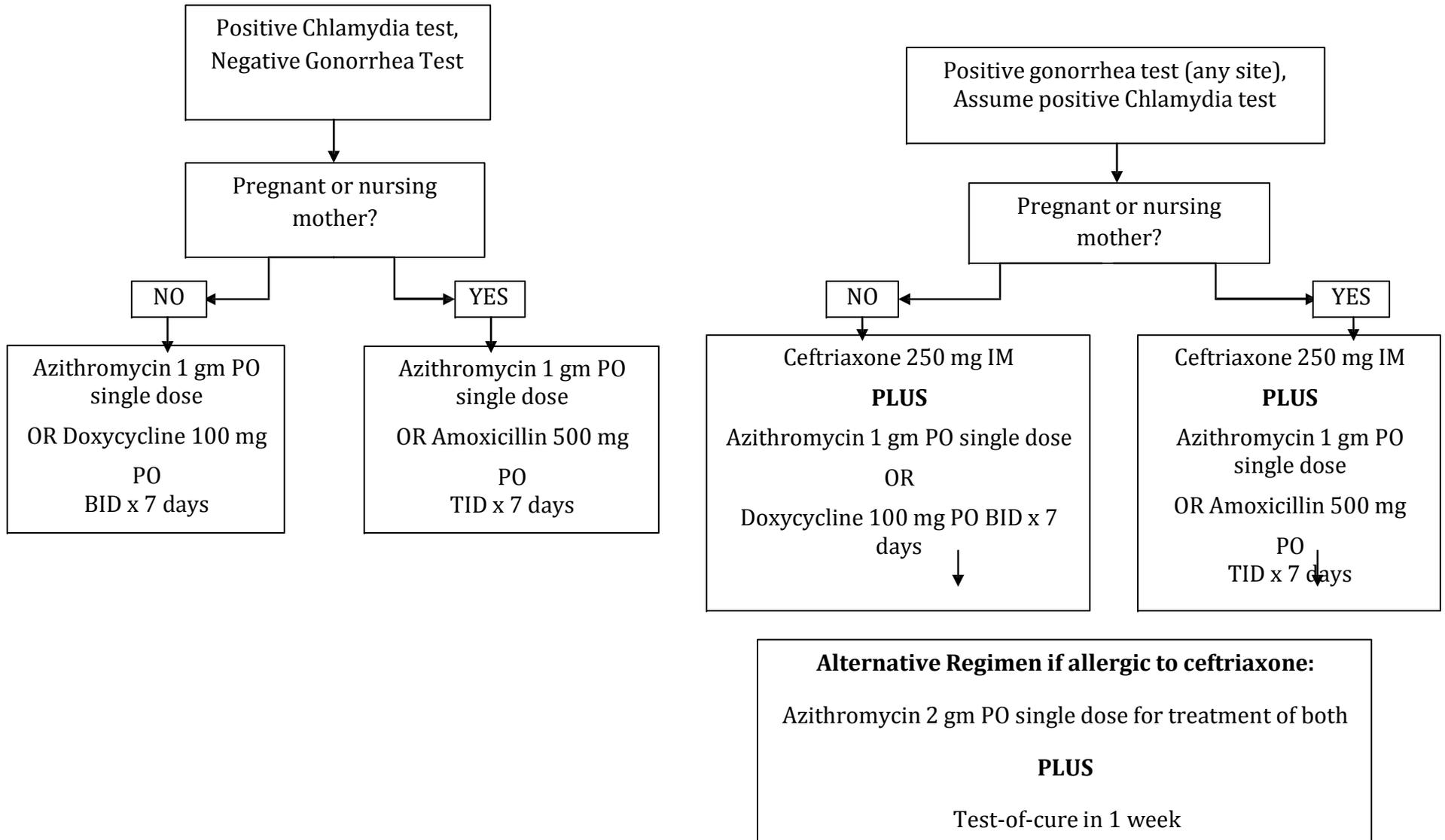
Follow-Up

Counsel all infected clients, regardless of treatment regimen, to return 1 week after treatment **if they experience persistent clinical symptoms**.
 In the absence of persistent clinical symptoms, counsel all infected patients to return for retesting of gonorrhea 3 months after completion of treatment or 1 week after treatment if not treated with ceftriaxone. If this does not occur, retest all persons treated for infection if they present for care within 12 months following treatment.
 Treatment failure should be considered in all patients with clinical or laboratory evidence of persistent infection after treatment. In all cases of suspected treatment failure, consult with health department physician /APN and obtain a culture with antimicrobial susceptibility testing on specimens from relevant anatomic sites.
 Suspected treatment failures should be reported within 24 hours.
 Report all cases to Sexually Transmitted Disease Program representative

REFERENCE

- Centers for Disease Control and Prevention Update to CDC's Sexually Transmitted Diseases Treatment Guidelines, 2010: Oral Cephalosporins No Longer a Recommended Treatment for Gonococcal Infections. *MMWR* 2012; 61(31):590-594.
- Centers for Disease Control and Prevention Sexually Transmitted Diseases Treatment Guidelines, 2010. *MMWR* 2010; 59 (No. RR-12).
- Lyss SB, Kamb ML, Peterman TA, et al. *Chlamydia trachomatis* among patients infected with and treated for *Neisseria gonorrhoeae* in sexually transmitted disease clinics in the United States. *Ann Intern Med* 2003;139:178–85.
- Sathia L, Ellis B, Phillip S, et al. Pharyngeal gonorrhoea—is dual therapy the way forward? *Int J STD AIDS* 2007;18:647–8.
- Golden M, Kerani R, Shafii T, Whittington W, Holmes K. Does azithromycin co-treatment enhance the efficacy of oral cephalosporins for pharyngeal gonorrhea? Presented at: 18th International Society for STD Research (ISSTD) Conference, London, UK, June 2009.

Gonorrhea and Chlamydia Treatment Decision Tree



HERPES SIMPLEX (GENITAL HERPES)

BACKGROUND

Genital Herpes is a common sexually transmitted disease caused by the herpes simplex virus, usually type 2 (HSV-2). While HSV-2 causes mainly genital infections, HSV-1 is associated primarily with oral infection, however either type can infect any site. It is a life-long viral infection that can be transmitted through anal, vaginal, or oral sex.

The majority of genital herpes infections are transmitted by persons unaware that they have the infection or who are asymptomatic when transmission occurs. The average incubation period after exposure is 4 days with a range of 2 to 12 days.

SUBJECTIVE

Primary infection:

Symptoms occur from 3 to 7 days after contact

Uniform shaped blisters that become painful ulcers. New lesions may develop for up to 5 – 7 days after the first group appears. Symptoms tend to resolve within 2-3 weeks.

Local pain, itching, and burning may be present at the affected site.

Dysuria (may lead to urinary retention)

May experience flu like symptoms including headache, low grade fever, muscle aches and swollen inguinal lymph nodes

Recurrent infection:

Common, particularly during the first year of infection.

May be brought on by alteration in the immune system, fatigue, stress, and local skin trauma.

Symptoms are typically shorter in duration and less severe than the first outbreak

OBJECTIVE

Multiple vesicular or ulcerative lesions that are uniform in size

Lesions may appear anywhere on genitalia, mouth, throat or anus

Tender enlarged nodes may be palpated in groin

Patient may have an elevated temperature and flu-like symptoms

ASSESSMENT

Possible genital herpes

PLAN

- Collect culture for herpes
- Refer/consult health department physician or APN for prescription or medication order
- Provide STD counseling, screen for gonorrhea and chlamydia, offer testing for HIV and syphilis as indicated

Palliative measures:

- Tepid water sitz bath 2-4 times daily while lesions are present (do not allow anyone else to use same towel). Urinating while sitting in a tub of tepid water may relieve the burning associated with voiding.
- Keep genital area clean and dry. A hair dryer on cool setting may be used
- May take Ibuprofen or Acetaminophen q 4 hrs/PRN for pain
- Over the counter creams and ointments are generally not recommended
- Increase consumption of water to keep urine dilute
- Avoid tight or irritating underwear and clothing

Health Teaching:

Counsel patients regarding the natural history of the disease, with emphasis on the potential for recurrent episodes, asymptomatic viral shedding, and the risk for sexual transmission

Recurrent outbreaks are common but tend to become less frequent and severe after the first year. Recurrences may be triggered by emotional stress, illness, sunlight and fatigue. Many patients experience mild symptoms called prodromal symptoms before ulcers develop. These may include itching, tingling or pain. Effective episodic treatment requires initiation of therapy within 1 day of lesion onset or during the prodromal period that precedes some outbreaks.

Encourage patient to inform their current sex partners that they have genital herpes and to inform future partners before initiating a sexual relationship

Advise to abstain from sexual activity when lesions or prodromal symptoms are present

Oral sex should be avoided if there are ulcers or blister around the mouth because a person with the oral form can give a partner genital herpes by performing oral sex.

Condoms used consistently and correctly may reduce the risk of herpes transmission

Do not touch the lesions or fluid from the lesions in order to avoid transfer of virus to other parts of the body, e.g., the eyes

Instruct patient in immediate and thorough hand washing after any genital contact or use disposable gloves

Assess and/or encourage Hepatitis B vaccination

Pregnant women should inform their doctor if they have ever experienced any symptoms of, been exposed to, or been diagnosed with genital herpes. HSV is of particular concern in pregnant women because the infection can be passed from mother to child during delivery resulting in a potentially fatal infection in the neonate.

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