

PUBLIC HEALTH

NURSING PROTOCOL

Tennessee Department of Health
Bureau of Health Services
Patient Care Services
Revised 12/10

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, Regional Nursing Directors, Medical Services Evaluation Committee, 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 health for both adults and children. **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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Staff Support
PHN Practice Committee

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. 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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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 STD 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 FINDINGS

A medical history is not required. If the client is participating in a visit with a nurse, collect a medical history.

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 STD/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 transmission.

OBJECTIVE FINDINGS

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

PLAN

- Provide health teaching either face to face or in writing.
- Women will sign the consent for non-prescriptive method whether they are using a non-prescriptive as their method long term or short term (example, until they return for their implant or IUC).
- 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.

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 record. 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.
- 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.
- Center for Disease Control and Prevention, U.S Medical Eligibility Criteria for Contraceptive Use, 2010, MMWR early release, Volume 59, May 28, 2010.
- "Program Guidelines for Project Grants for Family Planning Services," Office of Population Affairs, U.S. Department of Health and Human Services, January 2001.

DIAPHRAGM

GENERAL INFORMATION

A diaphragm cannot be supplied by deferred exam because a fitting is required. As of August 2008, diaphragms by Ortho-McNeil Pharmaceuticals are made from silicone in the all-flex arcing spring style only. The size range has also changed. It is now available in sizes 65-80.

SUBJECTIVE FINDINGS

Collect medical history

Assess for allergy to spermicides

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
- 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.

PLAN OF CARE

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.

A plan of care will be developed and signed by either the PHN with gyn skills, RN-ES, APN, or Physician (all referred to as “examiner”). The plan of care is developed in accordance with the protocol for the particular examiner. The plan of care written by the examiner must be reviewed and followed by the PHN at each visit.

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 to 4 of the required topics at each visit until instructions on all required topics are 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.

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A Pocket Guide to Managing Contraception, Hatcher, R. A., Nelson, A.L., Ziemann, M., et. al. Tiger, Georgia: Bridging the Gap Foundation, 2010
Contraceptive Technology, Twentieth Edition, Robert A. Hatcher, MD, et. al., 2011.
Family Planning Clinical Guidelines, Tennessee Department of Health, January 2011
Ortho Diaphragm, FDA approved product literature, August 2008.

PRIMARY 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 FINDINGS

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 FINDINGS

- Normal blood pressure
- Normal temperature
- Normal Hgb or Hct
- The client is within 1-2 years of having started her menstrual cycles

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 400 mg every 4 hours until relief not to exceed 3.2 g/day **OR**

- NAPROXEN SODIUM 220 mg tablets, 1-2 tablets as an initial dose, then 1 tablet every 8-12 hours as needed; not to exceed 5 tablets (1100mg) in a 24 hour period.
2. Discuss oral contraceptive use with the client and consult with the 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

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

FERTILITY AWARENESS-BASED METHODS (FAM)

GENERAL INFORMATION

Fertility awareness-based methods can be provided by deferred exam if the nurse is confident in her ability to teach the method. Otherwise she should defer to the NP or physician.

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
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).
Calendar Method	The calendar rhythm method requires that a woman keep a record of the length of 6-12 menstrual cycles. Subtract 11 from the longest cycle to find the last fertile day and 18 from the shortest cycle to find the first fertile day.
Standard Days Method	The standard days method is only for women whose menstrual cycles are 26 to 32 days long. To simplify this method, the client may use a specially designed, color-coded string of beads, brand name CycleBeads®.
Simple Observation 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.

For more detailed information, see Tennessee's Family Planning Clinical Guidelines and the most recent edition of Contraceptive Technology.

SUBJECTIVE FINDINGS

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

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

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 a 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.

- Hemoglobin or Hematocrit as indicated
- Pap smear in accordance with current Pap smear guidelines
- Sickle cell screening
- Syphilis serology
- Mantoux tuberculin test
- 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.

PLAN

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 and an updated medical history for the annual client.
- For annual visits (or re-supply visits), consult APN or physician for problems that have not responded to standard FAM counseling. Record consultant instructions in chart.
- Blood pressure measurement, hemoglobin or hematocrit as indicated.
- Name of the fertility awareness-based method chosen with summary of the instructions given for the particular method.
- Informed consent form for an initial client or if giving the return client a new method.
- Necessary health teaching to use method correctly and consistently.
- Document health teaching/counseling in chart.
- 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

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 record. 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.

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 "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

INTRAUTERINE CONTRACEPTIVES (IUC)

GENERAL INFORMATION

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. All PHNs must know how to make IUC referrals. IUCs cannot be provided by deferred exam.

Patient package inserts for either product is available on line at www.paraguard.com (scroll down and select Patient Information on the left side of the screen, only need to print pages 4-5) or www.mirena-us.com (scroll to the bottom of the page and select Patient Information, 4 page document.) Before making an IUC referral, review the patient package insert with the patient and provide her a copy. Advise her to take the patient package insert with her to the IUC referral visit. Document in the chart that the patient package insert was reviewed and given to the client.

Contraindications for IUCs:

- Active pelvic infection (including PID, endometritis, mucopurulent cervicitis, and pelvic tuberculosis)
- Known or suspected pregnancy
- Cervical or endometrial cancer
- Abnormal vaginal bleeding that has not been evaluated
- Severe uterine distortion (bicornuate uterus, cervical stenosis, or fibroids the severely distort the uterine cavity)
- Gestational trophoblastic neoplasia
- Wilson's disease or copper allergy (Paragard only)

SUBJECTIVE FINDINGS

Collect medical history for the APN or physician to review with the client.

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

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.

- Sickle cell screening
- Syphilis serology
- Mantoux tuberculin test
- Pregnancy test
- Rubella titer
- Wet prep (examiner)
- HIV testing
- Urinalysis
- Gonorrhea and chlamydia screening

REFER TO SCREENING CRITERIA FOR CHLAMYDIA AND GONORRHEA SECTION 2.170.

ASSESSMENT

Possible candidate for IUC insertion/Candidate for IUC referral

PLAN

A **plan of care** will be developed and signed by either the PHN with gyn skills, the RN who graduated from a certificate program, the APN or Physician (all referred to as “examiner”). The plan of care is developed in accordance with the protocol for the particular examiner. The plan of care written by the examiner must be reviewed and followed by the PHN at each visit. The suggested components of the examiner’s plan of care can be found in The Family Planning Clinical Guidelines. The most current edition of Contraceptive Technology is also a good resource for the examiner’s plan of care.

PHN with gyn skills will not insert either type of IUC. PHNs with gyn skills could perform the pre-insertion examination and collect the pre-insertion labs if requested to do so by the inserter.

INSTRUCTIONS

IUC insertion day instructions

- Provide written and oral instructions on the use of the IUC including name of the IUC, date of insertion, number of years the device is effective.
- Perform pregnancy test
- Obtain informed consent prior to insertion. Use the patient package insert provided with the device (or online as noted above) and the teaching tool found on the reverse side of the method specific consent form.
- Oral NSAIDs may be recommended one hour prior to insertion and repeated as directed following insertion to minimize cramping and pain at the discretion of the provider.
- Advise client to bring someone with her to the clinic to provide a ride home in case she experiences pain or nausea immediately after insertion.
- Paragard is effective against pregnancy immediately. If Mirena is not inserted within 7 days after the start of her menstrual cycle, then instruct the patient to use another contraceptive method for 7 days.

- Do not insert anything into the vagina or have intercourse for 24 hours following insertion of the IUC.
- IUCs do not protect against STDs and HIV. Advise clients to use latex or polyurethane condoms to decrease the risks of STDs. Also, counsel the client to avoid high risk sexual behaviors including multiple partners and having a sexual partner with multiple partners.
- IUC users will need to check for the IUC string at the end of each menstrual cycle. After insertion, give the client the trimmed IUC strings to help her learn how they feel. She should report the absence of or any changes in the length of the strings. She should report the presence of the plastic portion of the IUC if it is palpable at the cervical os.
- Schedule IUC follow-up appointment in 4-12 weeks or as recommended by the inserter.
- Encourage the client to call or come in for any questions or problems.

IUC insertion charting and tracking

- Document in chart that the patient package insert was reviewed with and given to the client.
- Record name of IUC, lot number, date of insertion, date for removal, and expiration date in the chart.
- If region uses a problem list, record “IUC surveillance” on problem list with insertion date as the date of onset.

IUC Warning Signs

All IUC clients must be counseled to report the signs of pelvic infection. These include:

- Malodor
- Fever (101°F or more without obvious cause)
- Sudden severe abdominal or suprapubic pain
- Dyspareunia

Other **WARNING SIGNS** that IUC clients must 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
- Exposure to gonorrhea/chlamydia/any STD
- Cannot feel string or can feel plastic
- Missed period or abnormal spotting or bleeding (infection or ectopic pregnancy)
- Flu-like illness (infection)

The following is a useful acronym to remember the IUC warning signs:

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

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 to 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:

- American College of Obstetricians and Gynecologists, "Intrauterine Devices", Number 59, Jan 2005
Contraceptive Technology, Twentieth Revised Edition, 2011, Robert A. Hatcher, MD et. al.
 Family Planning Clinical Guidelines, Tennessee Department of Health, 2011.
 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.
www.paragard.com
www.mirena-us.com
 Center for Disease Control and Prevention, U.S Medical Eligibility Criteria for Contraceptive Use, 2010, MMWR, Volume 59, June 18, 2010.

PROGESTIN-ONLY INJECTABLE CONTRACEPTION

GENERAL INFORMATION

A physical exam is not necessary to begin progestin-only injectable contraception. 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.

Progestin-only injectable contraceptives come in different dosages and require different routes of administration. PHNs will follow the package insert instructions for the particular progestin-only injectable product.

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, 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
- Sick cell screening

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.

- Syphilis serology
- Mantoux tuberculin test
- 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 progestin-only injectable contraceptive 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 progestin-only injectable side effects that have not responded to standard treatments, or complications, or warning signs. Record consultant instructions in chart.
- Blood pressure measurement, hemoglobin or hematocrit as indicated.
- Height for initial visit or annually for adolescents.
- Name, dosage, route, and frequency of the method.
- Informed consent form for an initial client or if giving the return client a new method.
- Document necessary health teaching to use method correctly and consistently.
- Document 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.

How to administer progestin-only injectable contraception:

Depo medroxyprogesterone (DMPA) is an aqueous suspension of microcrystals. All DMPA products 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 never rub the injection site after administration as this will disrupt the crystals and can lead to method failure (i.e., pregnancy). Progestin-only injectable contraceptives come in different dosages and require different routes of administration (subcutaneous or intramuscular). Follow the package insert instructions for the particular progestin-only injectable product.

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

Initial injection

- During first five days of normal menstrual period
- Within 7 days of childbirth, if the client is not breastfeeding
- When milk supply is well established, if client is exclusively breastfeeding but not before one month postpartum
- “DMPA Now” - The DMPA Now strategy provides the initial injection the day of the office visit using the same algorithm used for late re-injection found in Managing Contraception for Your Pocket. Always include the client in this decision-making process.

Subsequent injection

- 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.
- The package insert for Depo Provera 104 Subq® advises repeating injections every 12-14 weeks.
- The package insert for Depo Provera 150 IM® advises repeating injections every 11-13 weeks.
- If greater than the 13-week (or 14-week for sub q) interval, assess the client regarding unprotected intercourse. If the client has had unprotected intercourse, perform a pregnancy test. A two week wait and a second pregnancy test is NOT

the preferred approach UNLESS the client so chooses. Instead use the algorithm for late injections found in Managing Contraception for Your Pocket.

PLAN OF CARE FOR AN EXAM 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.

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. Always review past client counseling at each visit. Base current visit 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 record. 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, Robert A. Hatcher, MD, et. al., Twentieth Revised Edition 2011.
 Depo-Provera package Insert, Pfizer Pharmaceutical Company
 Depo-subQ Provera 104 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, 2010-12.
 “Family Planning Clinical Guidelines, Tennessee Department of Health, January 2011
 Center for Disease Control and Prevention, US Medical Eligibility Criteria for Contraceptive Use, MMWR Vol. 59, June 18, 2010.

PROGESTIN-ONLY PILLS (MINIPILL)

GENERAL INFORMATION

A physical exam is not necessary to begin progestin-only oral contraceptive pills (POPs). 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.

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, no restrictions

2 = May provide method, as the advantages generally outweigh the risks. 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
- Sick cell screening
- Syphilis serology
- Mantoux tuberculin test
- Pregnancy test
- Rubella titer
- Wet prep (examiner)

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.

- HIV testing
- Urinalysis
- Gonorrhea and chlamydia screening

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

ASSESSMENT

Appropriate for Progestin Only Pills use with or without 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 POP at bedtime for nausea), complications, or warning signs. Record consultant instructions in chart.
- Blood pressure measurement, hemoglobin or hematocrit as indicated.
- Name, dosage, route, and frequency of the progestin-only oral 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. (The preferred method of starting POPs is “Quick Start.” See the 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

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 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 the 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, Robert A. Hatcher, MD, 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 2010-2012.

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.

The Family Planning Clinical Guidelines includes a section with detail information on policy, federal sterilization requirements, selection criteria, sterilization consent forms, and general instructions.

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 lovemaking
- 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 in choice of method

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 lovemaking
- Short recovery time
- Vasectomy is equally effective, simpler, safer, and much less expensive than BTL
- Privacy in choice of method

Disadvantages of female sterilization include:

- Inherent risks associated with any surgery, namely, 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 very 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 about having the procedure
- Menstrual irregularities, increased dysmenorrhea, and premenstrual syndrome are reported by some women following BTL (research thus far has been unable to support any pattern of identifiable changes)
- Possibility of ectopic pregnancy if method fails

Disadvantages of male sterilization include:

- Inherent risks associated with any surgery, namely, infection, injury to other organs, hemorrhage, and complications of anesthesia
- Initial cost may be high
- Some clients may have regrets about having the procedure
- Procedure to reverse sterilization is difficult, has limited success rates, is very 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

- Current Family Planning client with current history and physical examination
- Discuss all available options of contraception
- Offer condoms, foam, or film for protection against STDs, if appropriate
- Provide written and oral instructions regarding various components of sterilization
- Obtain informed consent for sterilization
- Update immunizations, as indicated
- 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 STDs and HIV
- Provide verbal and written information regarding possible danger signs following sterilization and the necessary steps in follow-up
- Refer to “All Methods, Initial and/or Annual Family Planning Visit” section 2.010 of PHN Protocol for additional teaching
- 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 maladjustment

REFERENCES

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

QUICK REFERENCE TO STERILIZATIONS

1. Office of Population Affairs, Program Guidelines for Project Grants for Family Planning Services, January 2001

2. 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
- Clients with medical contraindication to use of temporary methods
- Older client
- Clients who have had multiple pregnancies
- Clients with other high risks
- 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 or emotional conditions that could interfere with informed consent
- Client or couple feels they are not yet ready to assume the responsibility of parenthood
- Client counts on reversing the operation in case of change of circumstances such as remarriage or death of children

3. 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.

QUADRIVALENT HUMAN PAPILLOMAVIRUS (HPV) VACCINE (GARDASIL® by Merck)

GENERAL INFORMATION

Human Papillomavirus (HPV) is the most common sexually-transmitted virus in the United States, with about 40 known strains. More than half of sexually-active men and women are infected with HPV at some point in their lives. Most HPV infections are asymptomatic and resolve on their own; however, certain HPV types can cause cervical cancer, oropharyngeal cancers, other rare genital cancers, and genital and respiratory tract warts. Approximately 22,000 HPV 16- or 18-related cancers occur in the United States each year; about 7,000 of them in males.

HPV vaccine is an inactivated vaccine, administered intramuscularly. Gardasil® is licensed by the Food and Drug Administration (FDA) for administration to males and females aged 9 years through 26 years. The vaccine is given in a three-dose series. It protects against HPV 16 and 18, which cause 70% of cervical cancer in the United States and HPV 6 and 11, which cause 90% of genital warts. The vaccine has no effect on pre-existing HPV infections; however, of the sexually active young women in the clinical trials, >90% were susceptible to at least 3 of the 4 vaccine strains.

GlaxoSmithKline produces the HPV vaccine Cervarix®, which targets the cancer-causing HPV strains 16 and 18, but does not prevent genital warts. It is FDA-licensed for females only, aged 9 through 25 years as a 3-dose series for use on a 0, 1 month, 6 month schedule. Because of its more limited indication, Cervarix® is not generally stocked by health departments; if a woman has already started the HPV vaccine series with an unknown brand or Cervarix® and she needs to be vaccinated at the health department, the HPV vaccine that is available may be used to complete the series.

The 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).

ACIP Recommendations for Use:

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 and all males 13 through 21 years is recommended. 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.

	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

Contraindications to giving the vaccine include the following: Severe allergic (anaphylactic) reaction to a previous dose of the vaccine 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 for use if recipient is known to be pregnant

Special Situations (per ACIP):

Breastfeeding is not a contraindication to immunization

A history of abnormal Pap smears, genital warts or other HPV infection is not a contraindication to vaccination. Persons with this history 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

Syncope (especially common in adolescents)

PLAN

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

Referral Indicators

Please consult Department of Health policy (policy provided with protocol cover letter) concerning eligibility for federally-funded and state or locally-funded vaccine. Only children under 19 years eligible for the Vaccines for Children (VFC) Program may receive federally-funded vaccine.

REFERENCES

Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP) Recommendations for the Use of Quadrivalent HPV Vaccine, MMWR March 12, 2007 / 56(Early Release);1-24

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm> Last accessed January 27, 2010.

GARDASIL® [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine] Vaccine package insert, Merck, copyright 2006, Revised April 2011.

Cervarix [Bivalent Human Papillomavirus (Types 16, 18) Vaccine, Recombinant] Prescribing Information, GlaxoSmithKline, copyright 2009. Revised February 2012.

http://us.gsk.com/products/assets/us_cervarix.pdf

Centers for Disease Control and Prevention. Vaccine Information Statement – HPV (Human Papillomavirus) Vaccine 2/22/2012.

<http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hpv-gardasil.pdf>. Last accessed March 20, 2012.

CDC. Recommendations on the Use of Quadrivalent Human Papillomavirus Vaccine in Males — Advisory Committee on Immunization Practices (ACIP), 2011. MMWR December 23, 2011. <http://www.cdc.gov/mmwr/pdf/wk/mm6050.pdf>. Last accessed February 15, 2012.

MEASLES, MUMPS, RUBELLA VACCINE (MMR)

GENERAL INFORMATION – MMR is a live virus vaccine that is administered subcutaneously. MMR vaccine may be stored in the refrigerator or freezer and should be used within 8 hours of reconstitution.

Contraindications and Precautions, include the following:

Severe allergic (e.g., anaphylaxis) reaction to vaccine component, such as gelatin or neomycin, or to a previous dose of MMR vaccine (Refer)

Moderate to severe acute illness (wait until resolving)

Pregnancy (if known, testing is not required before vaccinating)

Known severe immunodeficiency (e.g., from hematologic or solid tumors; receiving chemotherapy; congenital immunodeficiency; or, patients with HIV and severe immunocompromise) (Refer)

Patients currently on long term immune suppression therapy: has had ≥ 14 days of ≥ 2 mg/kg/day (or, ≥ 20 mg/day) of prednisone, or equivalent. (Defer vaccination until high dose therapy has been stopped for 1 month).

Recent (within 11 months) antibody-containing blood product (specific interval depends upon the blood product – see CDC’s General Recommendations on Immunization for details)

MMR vaccine may be given on the same day as other live virus vaccines (e.g. varicella) however, if not given on the same day, they must be separated by 4 weeks (28 days).

If not given on the same day, wait 4 weeks from date of MMR vaccine to administer TST.

History of thrombocytopenic purpura or thrombocytopenia (low platelet count) (Refer)

Note: The following are NOT contraindications or precautions to MMR vaccination: egg allergy; breast feeding or pregnant household contact; oral low dose, short course or inhaled steroid use.

Adverse events

Common: Susceptible recipients may develop the following mild symptoms caused by measles vaccine virus replication 5 to 12 days after immunization:

1-2 days of fever of 103°F or higher (5-15%)

rash (5%)

Joint symptoms (pain or inflammation) with onset 1-3 weeks after vaccination and lasting up to 3 weeks (up to 25% of adult females, uncommon in children and males)

Rare:

severe allergic reaction (e.g., anaphylaxis)

pain in arms and legs 1-3 weeks after vaccination

thrombocytopenia

parotitis

deafness

encephalopathy

ACIP Recommended Populations

NOTE: See current policy from the Tennessee Immunization Program for guidance concerning which recommended persons are eligible for federally funded vaccine

All children (2 doses)

Adults born after 1957 (at least 1 dose if no acceptable history of disease), with emphasis on certain groups at higher risk of infection or complication:

Women of childbearing age (who have never had MMR or who lack serologic evidence of immunity)

Unvaccinated HIV patients without evidence of severe immunocompromise

College students (2 doses required by state law for full time students in TN)

International travelers (total of 2 doses, §federal vaccine only for ages 6 months through 18 years)

Healthcare workers (2 doses or evidence of immunity)

Vaccinate susceptible persons age 6 months and up within ≤72 hours of exposure to measles

Administration of Vaccine:

Give first dose at 12-15 months of age

Give second dose at 4-6 years* (recommended if born after 1957)

MMR vaccine may be given simultaneously with all other vaccines; if MMR and varicella (or another live virus vaccine) are not administered at the same visit, they should be separated by at least 28 days

For children traveling outside the United States:

6-11 months: 1 MMR before travel (because it gives less than ideal protection, this extra dose does not count toward the 2 dose routine MMR series).

12 months or up: should get 2 doses of MMR before travel (28 days apart, minimum interval). Two doses after 12 months of age completes the MMR series.*

Vaccine is not needed if patient has laboratory evidence of immunity to all three (measles, mumps and rubella). However, if any is negative, documentation of 2 MMR doses is needed.

*The 2nd dose of MMR is recommended routinely at 4-6 yrs of age but may be administered during any visit, provided at least 1 month has elapsed since receipt of the 1st dose and that both doses are administered beginning at or after 12 months of age.

PLAN

Have patient or accompanying adult read Vaccine Information Statement
Counsel regarding benefits, side effects, and management
Counsel females of childbearing age to avoid pregnancy for 28 days post vaccination (document LMP)
Administer unit dose of MMR subcutaneously
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

NOTE: Any dose of MMR vaccine given earlier than 4 days before the 1st birthday will not count as one of the routine two-dose series; persons who have not received 2 doses of measles mumps and rubella-containing vaccines, such as those who received only a monovalent measles vaccine or combined Measles/Rubella (MR) vaccine should complete a 2 dose series of MMR.

Referral indicators (in addition to contraindications or precautions listed above):

Uncontrolled neurological conditions, such as uncontrolled seizures
Active untreated tuberculosis

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

REFERENCES

Manufacturer Packet Inserts.
National Childhood Vaccine Injury Act, 1986.
Epidemiology and Prevention of Vaccine-Preventable Diseases. Department of Health and Human Services, Centers for Disease Control and Prevention, 12th Ed., May 2011.

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 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.

**TETANUS, DIPHTHERIA, AND PERTUSSIS VACCINE
TETANUS, DIPHTHERIA, AND ACELLULAR PERTUSSIS
(Tdap) VACCINE FOR CHILDREN AND ADOLESCENTS
(7 through 18 years)
(ADACEL™ OR BOOSTRIX™)**

GENERAL INFORMATION

Tdap vaccine is inactivated and contains no live organisms. The vaccine protects against tetanus (“lockjaw”), diphtheria, and pertussis (“whooping cough”). Like tetanus and diphtheria, immunity to pertussis wanes following childhood immunization or disease. Two Tdap vaccines were licensed in 2005 by the U.S. Food and Drug Administration (FDA) as a **ONE-TIME DOSE**:

ADACEL™ (Sanofi Pasteur) is licensed **for ages 11 through 64 years**.

BOOSTRIX™ (GlaxoSmithKline) is licensed **for ages 10 years and older..**

Tdap is currently recommended by the Advisory Committee on Immunization Practices (ACIP) for routine use in adolescents aged 11 through 18 years. Subsequent routine Td BOOSTERS are recommended every 10 years (see Td protocol).

Tdap vaccine may be given at the same time as other immunizations, including meningococcal vaccine. It may be given before or after meningococcal vaccine if both vaccines cannot be given simultaneously.

Tdap SHOULD NOT BE GIVEN TO PERSONS WHO HAVE ALREADY RECEIVED Tdap. It should be given if the patient is unable to verify they have had Tdap.

Note: The CDC published ACIP recommendations in January 2011 that differ from the current manufacturers’ package inserts on age and dose intervals. ACIP guidelines for the use of vaccines take priority and should be followed as written below.

ACIP Recommendations for Use (updated January 2011):

Tdap may be used **ONE TIME** either as a routine **BOOSTER** dose, **OR** as one of a **PRIMARY** vaccine series, **OR** for tetanus **PROPHYLAXIS** in accordance with standard guidelines for wound management.

Timing of Tdap: May be administered regardless of interval since the last tetanus- or diphtheria-containing vaccine.

Note: A “complete” primary series of pertussis vaccine in childhood is typically defined as 5 doses of DTaP. Four doses of DTaP is considered complete when the 4th dose is given after the 4th birthday.

Children (7 through 10 years) who have not had a complete primary series of pertussis vaccine as defined above: give one dose of Tdap. Use Td for any additional doses necessary to complete the primary series of tetanus immunization.

Adolescents (11 through 18 years) who had a complete primary series of tetanus-containing vaccine in childhood - A single dose of Tdap is routinely recommended and should be given to **all children** between ages 11-12 years; administer at ages 13-18 years to any child that has not already received a Tdap.

Adolescents (11 through 18 years) who have not had a primary series of tetanus-containing vaccine - A single dose of Tdap should be **substituted for one Td** in the 3-dose primary series; it is preferred as the first dose.

Any pregnant adolescent who had a complete primary series of tetanus containing vaccine in childhood but has not received the recommended single dose of Tdap between ages 11-12, should be given Tdap after 20 weeks gestation unless contraindicated. Adolescents who fail to receive Tdap before or during pregnancy should receive a dose immediately post-partum.

REFERRAL INDICATORS (PER ACIP)

Contraindications to giving the vaccine include the following:

- History of an immediate severe allergic reaction (anaphylaxis) to any of the three components of Tdap (i.e., tetanus, diphtheria, or pertussis vaccines) or to any combination vaccine containing Tdap components
- History of encephalopathy (e.g., coma, prolonged seizures) within 7 days of administration of a pertussis-containing vaccine that is not attributable to another identifiable cause; tetanus/diphtheria vaccine (Td) should be used instead of Tdap in such patients

Precautions which may require referral include the following:

- History of Arthus-type hypersensitivity reactions (extensive painful limb swelling within hours of injection) following prior tetanus vaccination; such patients should not be given any tetanus-containing vaccine more frequently than every 10 years
- A current progressive neurologic disorder, uncontrolled epilepsy, or progressive encephalopathy; defer vaccination with pertussis-containing vaccine until treatment regimen is established and condition is stabilized, Td may be used
- History of a severe allergic reaction (anaphylaxis) to latex¹
- Guillain-Barre syndrome (GBS) within 6 weeks after a previous dose of a tetanus toxoid-containing vaccine
- Patient has an acute moderate-to-severe illness, with or without fever; vaccination should be deferred until illness has resolved

PLAN

- Provide current Vaccine Information Sheet (VIS) about Tdap and the benefits of vaccination
- Counsel regarding benefits, side effects, and management
- Shake the vial well, administer 0.5 ml of vaccine INTRAMUSCULARLY
- Remind that tetanus/diphtheria vaccine boosters are recommended every 10 years
- Advise to wait in clinic 20 minutes after injection
- Record manufacturer and lot number of the vaccine administered, date, name, address and title of the person administering vaccine

¹ Boostrix™ pre-filled syringes contain latex. Adacel™ products and Boostrix™ single dose vials do not contain latex; there is no precaution against the use of these products in patients with latex allergy.

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

Referral Indicators:

History of an immediate severe allergic reaction (anaphylaxis) to prior tetanus, diphtheria, or pertussis vaccines
 History of encephalopathy (e.g., coma, prolonged seizures) within 7 days of administration of a pertussis-containing vaccine
 Refer for precautions as indicated

Follow-up:

Return for Td booster in 10 years, or for the next scheduled dose if administering a catch-up primary series.
 Return for wound management as required

REFERENCES

- Advisory Committee on Immunization Practice (ACIP) Votes to Recommend Routine Use of Combined Tetanus, Diphtheria and Pertussis (Tdap) Vaccines for Adolescents, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Atlanta, GA 30333, June 30, 2005
- Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (ADACEL™) Vaccine package insert, Sanofi Pasteur (Aventis Pasteur), June 2005
- Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (BOOSTRIX™) Prescribing information, GlaxoSmithKline, May 2005, revised January 2009. http://us.gsk.com/products/assets/us_boostrix.pdf
- Centers for Disease Control and Prevention, Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis (Tdap) Vaccine from the Advisory Committee on Immunization Practices, 2010. MMWR. <http://www.cdc.gov/mmwr/pdf/wk/mm6001.pdf> Last accessed January 14, 2011.

**TETANUS, DIPHTHERIA, AND PERTUSSIS VACCINE
TETANUS, DIPHTHERIA, AND ACELLULAR PERTUSSIS
(Tdap) VACCINE FOR ADULTS (19 and up)
(ADACEL™ OR BOOSTRIX™)**

GENERAL INFORMATION

Tdap vaccine is inactivated and contains no live organisms. The vaccine protects from tetanus (“lockjaw”), diphtheria, and pertussis (“whooping cough”). Immunity wanes following childhood immunization. With pertussis, adults may suffer prolonged coughing illness and may infect others, including infants at risk for severe complications.

ADACEL™ (Sanofi Pasteur) was licensed in 2005 by the U.S. Food and Drug Administration (FDA) for ages **11 through 64 years** as a **ONE-TIME DOSE**.

BOOSTRIX™ (GSK) is licensed for ages **10 years or older** as a **ONE-TIME DOSE**.

The Advisory Committee on Immunization Practices (ACIP) recommends providers should not miss an opportunity to vaccinate persons aged 65 years and older with Tdap, and may administer the vaccine that they have available. When feasible, for adults aged 65 years and older, Boostrix should be used; however, either vaccine product administered to a person aged 65 years and older provides protection and is considered valid.

Tdap is routinely recommended by the ACIP for any person age 11 years or older who has not yet had Tdap, regardless of interval since last tetanus booster. (See the Tdap protocol for adolescents for recommendations ages 7 through 18 years). **Subsequent routine Td BOOSTERS are recommended every 10 years** (see Td protocol).

Tdap is especially important for pregnant women, healthcare personnel and persons who care for or live with infants under age one, in order to help prevent exposing the infant to pertussis disease (“cocooning”)

Tdap vaccine may be given at the same time as other immunizations, including meningococcal vaccine. It may be given before or after meningococcal vaccine if both vaccines cannot be given simultaneously.

Tdap is approved only as a ONE TIME dose; however, Tdap SHOULD be given if there is no documentation of a previous dose of Tdap.

Note: The ACIP now recommends the use of Tdap for pregnant women and all adults who have not previously had a dose of Tdap, regardless of the interval since the recipient’s last Td. These ACIP recommendations differ from the manufacturer package insert and take priority over information contained in the package insert.

ACIP Recommendations for Use:

Tdap may be used **ONE TIME** either as a routine **BOOSTER** dose, **OR** as one of a **PRIMARY** vaccine series, **OR** for tetanus **PROPHYLAXIS** in accordance with standard guidelines for wound management:

Adults (19 and older): A single dose of Tdap is routinely recommended to any adult who has not had a dose of Tdap. Adults who have completed a primary series of tetanus containing vaccine in the past are routinely recommended to have a booster dose of tetanus containing vaccine every 10 years. The next tetanus booster would be due 10 years after the dose of Tdap.

Adults (19 and older) WITHOUT A COMPLETE PRIMARY SERIES of Td-containing vaccine - A single dose of Tdap should be substituted for one Td in the primary series; it is preferred as the first dose.

Adults (19 and older), REQUIRING TETANUS PROPHYLAXIS FOR WOUND MANAGEMENT - A single dose of Tdap should be given, if available, if the patient has not had Tdap before (See Protocol for Wound Management); otherwise, Td should be used.

PREGNANCY: Unless contraindicated, **Tdap should be given to each pregnant woman after 20 weeks gestation if she has not previously had a dose of Tdap.** Women who fail to receive Tdap before or during pregnancy should receive a dose immediately post-partum.

DOSING INTERVALS since last tetanus vaccine dose: Tdap should be given regardless of the interval since the last tetanus-containing vaccine.

REFERRAL INDICATORS (PER ACIP)

Contraindications to giving the vaccine include the following:

History of an immediate severe allergic reaction (anaphylaxis) to any of the three components of Tdap (i.e., tetanus, diphtheria, or pertussis vaccines) or to any combination vaccine containing Tdap components

History of encephalopathy (e.g., coma, prolonged seizures) within 7 days of administration of a pertussis-containing vaccine that is not attributable to another identifiable cause; tetanus/diphtheria vaccine (Td) should be used instead of Tdap in such patients

Precautions which may require referral include the following:

History of Arthus-type hypersensitivity reactions (extensive painful limb swelling within hours of injection) following tetanus vaccination administered <10 years previously; such patients should not be given any tetanus-containing vaccine more frequently than every 10 years

A current unstable neurologic disorder, uncontrolled epilepsy, or progressive encephalopathy; defer vaccination with pertussis-containing vaccine until treatment regimen is established and condition is stabilized; Td may be used

Guillain-Barre syndrome (GBS) within 6 weeks after a previous dose of a tetanus toxoid-containing vaccine

Defer immunization if the patient has an acute moderate-to-severe illness, with or without fever, until illness has resolved

PLAN

Provide current Vaccine Information Sheet (VIS) about Tdap and the benefits of vaccination
 Counsel regarding benefits, side effects, and management
 Shake the vial well, administer 0.5 ml of vaccine INTRAMUSCULARLY
 Remind that tetanus/diphtheria vaccine boosters are recommended every 10 years
 Advise to wait in clinic 20 minutes after injection
 Record manufacturer and lot number of the vaccine administered, date, name, address and title of the person administering vaccine
 Instruct patient to contact Health Department if adverse reaction occurs (complete appropriate form)

Referral Indicators:

History of an immediate severe allergic reaction (anaphylaxis) to prior tetanus, diphtheria, or pertussis vaccines
 History of encephalopathy (e.g., coma, prolonged seizures) within 7 days of administration of a pertussis-containing vaccine
 Refer or defer immunization for precautions as indicated

Follow-up:

Return for Td booster in 10 years (or for next dose, if completing a primary series)
 Return for wound management as required

REFERENCES

- Centers for Disease Control and Prevention. Preventing Tetanus, Diphtheria, and Pertussis Among Adults: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP) and Recommendation of ACIP, supported by the Healthcare Infection Control Practices Advisory Committee (HICPAC), for Use of Tdap Among Health-Care Personnel. MMWR 2006;55(No. RR-17).
- Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (ADACEL™) Vaccine package insert, Sanofi Pasteur (Aventis Pasteur), June 2005. Revised 2/22/2012.
- Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (BOOSTRIX™) Prescribing information, GlaxoSmithKline, July 2011, revised March 2012. http://us.gsk.com/products/assets/us_boostrix.pdf
- Centers for Disease Control and Prevention. FDA Approval of Expanded Age Indication for a Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine. MMWR 2011;60(No. 37): pp. 1279-1280.
- Centers for Disease Control and Prevention. Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap) in Pregnant Women and Persons Who Have or Anticipate Having Close Contact with an Infant Aged <12

Months — Advisory Committee on Immunization Practices (ACIP), 2011. MMWR 2011;60(No. 41): pp1424-1426.

ACIP provisional recommendations for adults aged 65 years and older on use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) and guidance on use of Tdap products for adults aged 65 years and older. <http://www.cdc.gov/vaccines/recs/provisional/Tdap-feb2012.htm>. Last accessed March 22, 2012.

TETANUS AND DIPHTHERIA TOXOID, ADULT TYPE

Td (Adult Type)

GENERAL INFORMATION

Tdap is recommended for most persons aged 11 years and older who have not yet received it (see Tdap protocol for adolescents 11 through 18 years or the protocol for adults ≥ 19 years). Subsequent routine Td boosters are recommended every 10 years.

Appropriate candidates for Td include the following:

At least seven years of age and older and requiring tetanus immunization for whom Tdap is not recommended (e.g., medical contraindication, previous dose of Tdap, or child 7-9 years of age who had a complete DTaP vaccination series)

No previous dose of Td, or at least 4-8 weeks after Td #1 or 6 months after Td #2

Ten years since last tetanus-containing vaccine (DTP, DTaP, Tdap or Td)

Contraindications include the following:

History of severe allergic reaction (i.e., anaphylaxis) to a previous dose of any tetanus- or diphtheria-containing vaccine or component of the vaccine

Precautions include the following:

Defer vaccination until resolution of moderate to severe acute illness

History of Arthus-type hypersensitivity reactions (extensive painful limb swelling within hours of injection) following tetanus vaccination administered <10 years previously; such patients should not be given any tetanus-containing vaccine more frequently than every 10 years

Guillain-Barre syndrome (GBS) within 6 weeks after a previous dose of a tetanus toxoid-containing vaccine

Severe (anaphylactic) latex allergy; vial stopper and pre-filled syringes may contain latex (see package insert of specific product)

PREGNANCY: Pregnancy is not a contraindication to Td or Tdap; if tetanus vaccination during pregnancy is indicated, Tdap is preferred and should be administered to those who have not had a dose of Tdap (see **protocol**). Td should be given to pregnant women if they have had an incomplete primary series of tetanus vaccine and require additional doses of tetanus-containing vaccine after the single dose of Tdap.

PLAN

Have patient or accompanying adult read Vaccine Information Statement/Vaccine Information Material

Counsel regarding benefits, side effects, and management

Administer 0.5 cc of Td INTRAMUSCULARLY

Advise to wait in clinic 20 minutes after injection

Record manufacturer and lot number of the vaccine administered, date of administration and provision of VIS, 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:

History of severe reaction to previous dose of tetanus- or diphtheria-containing vaccine (DTP / DTaP / DT / Td)

History of severe latex allergy (if Td vial stopper or pre-filled syringe contains latex, see package insert)

Needs tetanus immune globulin (TIG) for wound management

If severe reaction is identified following vaccine administered by health department personnel, VAERS Report Form must be completed

Follow-Up:

If no primary series, return for Td #2 in 4-8 weeks or for Td #3 in 6-12 months [use Tdap for one of the doses if not previously administered]

Return for Td booster in 10 years, according to current immunization schedule

Return for wound management as required (see Tetanus Prophylaxis in Wound Management Protocol)

REFERENCES

Packet Insert: <http://www.fda.gov/downloads/BiologicsBloodVaccines/UCM152826.pdf> last accessed March 21, 2012.

Current Vaccine Information Statement: <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-td-tdap.pdf> last accessed March 21, 2012.

Centers for Disease Control and Prevention, Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis (Tdap) Vaccine from the Advisory Committee on Immunization Practices, 2010. MMWR. <http://www.cdc.gov/mmwr/pdf/wk/mm6001.pdf> Last accessed January 14, 2011.

Centers for Disease Control and Prevention. FDA Approval of Expanded Age Indication for a Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine. MMWR 2011;60(No. 37): pp. 1279-1280.

Centers for Disease Control and Prevention. Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap) in Pregnant Women and Persons Who Have or Anticipate Having Close Contact with an Infant Aged <12 Months — Advisory Committee on Immunization Practices (ACIP), 2011

ACIP provisional recommendations for adults aged 65 years and older on use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) and guidance on use of Tdap products for adults aged 65 years and older. <http://www.cdc.gov/vaccines/recs/provisional/Tdap-feb2012.htm>. Last accessed March 22, 2012.

VARICELLA VACCINE (VARIVAX® by Merck)

GENERAL INFORMATION

Varicella virus causes chickenpox and lies dormant in nerve roots following the primary infection. The virus can cause recurrent infection, resulting in herpes zoster (“shingles”). The virus is highly contagious and enters the body through the respiratory tract or mucus membranes. Up to 90% of susceptible household contacts of persons with chickenpox will become infected. In the U.S. each year, before routine vaccination, there were about 4 million cases of chickenpox, resulting in 11,000 hospitalizations and 100 deaths, with the highest risk of death among susceptible adults.

Varicella vaccine is a live attenuated (weakened) virus vaccine derived from the Oka strain of varicella and administered subcutaneously; it is licensed by the Food and Drug Administration (FDA) for administration to persons 12 months of age and older. Two doses of the vaccine are recommended for all recipients, including a second dose for those who may have had a single dose earlier in childhood. A single dose confers approximately 70-90% protection from disease; the seroconversion rate of 2-dose recipients is approximately 99%. The vaccine is not recommended for persons with evidence of immunity to varicella (see below).

The vaccine may be simultaneously administered with other vaccines, including other live virus vaccines. It is stored frozen at an average temperature of $\leq -15^{\circ}\text{C}$ (5°F), but not below -50°C . It must be discarded if not administered to the recipient within 30 minutes of reconstitution.

Evidence of immunity to varicella:

Persons with evidence of immunity to varicella should not be vaccinated. Acceptable evidence includes the following (Advisory Committee on Immunization Practices, ACIP, 2006):

1. Documentation of age-appropriate vaccination:
 - a. Children 12 months up to school entry: one dose
 - b. School-aged children: 2 doses
2. Laboratory evidence of immunity or laboratory confirmation of disease
3. Born in the US before 1980 (this is insufficient evidence for healthcare workers or pregnant women)
4. Healthcare provider diagnosis of varicella or provider verification of a patient’s credible reported history of varicella disease (for “atypical” or “mild” disease, this verification should include an epidemiologic link to a person with typical disease or laboratory confirmation, because other diseases may mimic atypical varicella)
5. Healthcare provider diagnosis of herpes zoster

ACIP Recommendations for Use:

- Routine immunization schedule: first dose at age 12-15 months, second dose at age 4-6 years (before starting school) (See below)
- A second, catch-up dose is recommended for all children and adults who previously had received only one dose (unless they have appropriate evidence of immunity due to breakthrough disease)
- Adults (2-dose series) for whom it is medically indicated (in other words, they do not meet criteria for immunity listed above)

NOTE: See current policy from the Tennessee Immunization Program for guidance concerning which recommended persons are eligible for federally-funded vaccine.

Routine Immunization Schedule

Dose Number	Recommended age at administration	Minimum interval to next dose
Dose 1	12-15 months	3 months (age 1-12 years)** 4 weeks (28 days) (age >13 years) **At any age, a second dose administered at least 28 days after the first dose does not need to be repeated
Dose 2	4-6 years	

Contraindications to giving the vaccine include the following:

Evidence of immunity (per above criteria)

Pregnancy

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

Anaphylactic reaction to a previous dose of the vaccine or any component (including neomycin and gelatin)

Blood dyscrasias, leukemia, lymphoma of any type, other malignant neoplasm affecting the bone marrow or lymphatic system

Primary or acquired cellular immunodeficiencies (e.g., AIDS or clinical manifestations of HIV)

Untreated, active tuberculosis (not latent tuberculosis infection)

Family history of congenital or hereditary immunodeficiency in a first-degree relative (e.g., parent or sibling), unless the immunocompetence of the recipient has been clinically confirmed by a physician or verified by a laboratory

Ongoing immunosuppressive therapy (does not apply to corticosteroid replacement therapy)

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

Persons on steroid therapy not otherwise immunocompromised (refer)

Impaired humoral immunity or asymptomatic HIV infection (refer)

Receipt of a blood or plasma transfusion or immune globulin within the past 5 months (defer vaccination until at least 5 months after receipt of blood products)

Varicella vaccine may be given on the same day as other live virus vaccines (e.g., MMR); however, if not given on the same day, they must be separated by 4 weeks (28 days).

If not given on the same day, wait 4 weeks (28 days) from date of varicella vaccine to administer TST.

Special Situations (per ACIP):

Breastfeeding is not a contraindication to immunization

Vaccinees who are healthcare workers or household contacts of susceptible, high risk persons in whom a vaccine-related vesicular rash develops should avoid contact with such persons while they have the rash

Women should be advised to avoid becoming pregnant for at least 1 month (per ACIP) following vaccination, though having a pregnant household contact is not a contraindication to vaccination

Aspirin use during natural varicella disease is associated with Reye's Syndrome and recipients should be advised to avoid salicylates for 6 weeks following vaccination

Adverse Reactions:

Soreness, swelling or redness around the injection site within 48 hours of immunization

An injection site or full body rash up to 1 month following vaccination in $\leq 5\%$ of Recipients

PLAN

Ask parent/guardian or recipient about contraindications, precautions

Have parent/guardian or recipient read Vaccine Information Statement

Reconstitute vaccine and administer the vaccine subcutaneously according to the manufacturer instructions

Counsel regarding side effects of vaccine, e.g., rash

Advise women of child-bearing age to avoid becoming pregnant for at least 1 month

Advise that recipients should avoid use of salicylates (e.g., aspirin) for 6 weeks

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

Referral Indicators

Persons with impaired immune systems (acquired or primary)

Persons on steroid therapy (other than corticosteroid replacement)

REFERENCES

Advisory Committee on Immunization Practices (ACIP) Provisional Recommendations for Prevention of Varicella, posted August 2006.

http://www.cdc.gov/nip/vaccine/varicella/varicella_acip_recs_prov_june_2006.pdf Last accessed October 31, 2006.

VARIIVAX® [Varicella Virus Vaccine Live (Oka/Merck)] Vaccine package insert, Merck, copyright 2001. Centers for Disease Control and Prevention. Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1996; 45 (No. RR-11): pp1-36.

Centers for Disease Control and Prevention. Prevention of Varicella: updated recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1999; 48 (No. RR-6): pp1-5.

Centers for Disease Control and Prevention. Vaccine Information Statement – Varicella Vaccine 12/16/98. <http://www.cdc.gov/nip/publications/VIS/visvaricella.pdf> Last accessed October 31, 2006.