DESCRIPTION AND PURPOSE OF THE CLINICAL SERVICE GUIDE

The Clinical Service Guide (CSG) contains clinical protocols for local health department (LHD) nurses that have been identified as Core Public Health Services by the Kentucky Department for Public Health (DPH). The purpose of this document is to clearly identify minimum program/grant requirements and provide information that will support LHD operation.

This reference contains guidelines and protocols for LHD to use in providing services. Each section is divided into two categories: clinical protocol for a LHD nurse and information required for LHD patient case management. Guidelines are recommendations for patient management that identify and/or support the use of a range of patient care interventions and approaches. Protocols are authoritative statements requiring a physician’s signature. In addition to these guidelines, nurses providing WIC services will follow all the federally approved WIC guidelines, policies and procedures in the WIC and Nutrition Services Manual and the Administrative Reference for WIC services.

These guidelines and protocols represent levels of care considered appropriate for staff at LHDs and are intended to be used without modification, unless a higher level of care is desired and supported at the local level. It is the responsibility of local staff, as appropriate, to develop additional guidelines and protocols that are desired at the local level. The Clinical Service Guide is not all-inclusive and does not supersede professional judgment, or the Kentucky Nurse Practice Act.

See:

1. KRS.314.011(8); 314.042(8); and 201 KAR 20:057 for Kentucky Nursing Practice
2. KY Board of Nursing – Scope of Practice Determination Guidelines
3. KBN Advisory Opinion Statement #14 – Roles of Nurses in the Implementation of Patient Care Orders
4. KBN Advisory Opinion Statement #15 – Role of Nurses in the Supervision and Delegation of Nursing Acts to Unlicensed Personnel

Connie Gayle White, MD
Senior Deputy Commissioner, KY Department for Public Health

______________________________

July 1, 2019

Date

______________________________

Medical Director

Date

______________________________

Local Health Department Name

FAMILY PLANNING STANDING ORDERS:

Physical Exam Deferral:

Provide three month supply of current method, DMPA, Ortho Evra® Patch, NuvaRing® or the following oral contraceptives:

______________________________

Initial Date

Approved ECP method and dosing:

______________________________

Initial Date
The intent of the clinical guidelines and protocols is to serve as a reference in the areas of adult and pediatric public health clinical practice. These guidelines and protocols are based on acceptable standards of care endorsed by, but not limited to the following:

<table>
<thead>
<tr>
<th>Name</th>
<th>Website</th>
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<tbody>
<tr>
<td>American Academy of Pediatric Dentistry</td>
<td><a href="http://www.aapd.org">www.aapd.org</a></td>
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<tr>
<td>American Academy of Pediatrics</td>
<td><a href="http://www.aap.org">www.aap.org</a></td>
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<tr>
<td>American Cancer Society</td>
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<td>American College of Nurse-Midwives</td>
<td><a href="http://www.acnm.org">www.acnm.org</a></td>
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<td>American College of Obstetrics and Gynecology</td>
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<td>American Diabetes Association</td>
<td><a href="http://www.diabetes.org">www.diabetes.org</a></td>
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<tr>
<td>American Dietetic Association</td>
<td><a href="http://www.eatright.org">www.eatright.org</a></td>
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<tr>
<td>American Heart Association</td>
<td><a href="http://www.americanheart.org">www.americanheart.org</a></td>
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<tr>
<td>American Lung Association</td>
<td><a href="http://www.lungusa.org">www.lungusa.org</a></td>
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<tr>
<td>American Medical Association</td>
<td><a href="http://www.ama-assn.org">www.ama-assn.org</a></td>
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<tr>
<td>American Nurses Association</td>
<td><a href="http://www.nursingworld.org">www.nursingworld.org</a></td>
</tr>
<tr>
<td>Centers for Disease Control and Prevention</td>
<td><a href="http://www.cdc.gov">www.cdc.gov</a></td>
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<tr>
<td>March of Dimes Birth Defects Foundation</td>
<td><a href="http://www.marchofdimes.com">www.marchofdimes.com</a></td>
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Other helpful web sites and resources are:

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<tr>
<th>Name</th>
<th>Website</th>
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<tbody>
<tr>
<td>Advisory Committee on Immunization Practices (ACIP)</td>
<td><a href="http://www.cdc.gov/vaccines/recs/ACIP">www.cdc.gov/vaccines/recs/ACIP</a></td>
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<tr>
<td>American Dental Association</td>
<td><a href="http://www.ada.org">www.ada.org</a></td>
</tr>
<tr>
<td>American Public Health Organization</td>
<td><a href="http://www.apha.org">www.apha.org</a></td>
</tr>
<tr>
<td>Arthritis Foundation</td>
<td><a href="http://www.arthritis.org">www.arthritis.org</a></td>
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<tr>
<td>Association of State &amp; Territorial Health Organizations</td>
<td><a href="http://www.astho.org">www.astho.org</a></td>
</tr>
<tr>
<td>Dept. for Health and Human Services</td>
<td><a href="http://www.os.dhhs.gov/">www.os.dhhs.gov/</a></td>
</tr>
<tr>
<td>Department for Public Health Website</td>
<td><a href="http://chfs.ky.gov/dph/">http://chfs.ky.gov/dph/</a></td>
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<tr>
<td>Disease Links</td>
<td><a href="http://www.nursing-links.com/diseases/">www.nursing-links.com/diseases/</a></td>
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<tr>
<td>Environmental Protection Agency</td>
<td><a href="http://www.epa.gov/enviro">www.epa.gov/enviro</a></td>
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<tr>
<td>First Candle/National SIDS Alliance</td>
<td><a href="http://www.firstcandle.org">www.firstcandle.org</a></td>
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<tr>
<td>Food &amp; Drug Administration (FDA)</td>
<td><a href="http://www.fda.gov">www.fda.gov</a></td>
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<tr>
<td>Healthfinder</td>
<td><a href="http://www.healthfinder.gov">www.healthfinder.gov</a></td>
</tr>
<tr>
<td>Immunization Action Coalition</td>
<td><a href="http://www.imunize.org/">http://www.imunize.org/</a></td>
</tr>
<tr>
<td>Internet Drug List</td>
<td><a href="http://www.rxlist.com">www.rxlist.com</a></td>
</tr>
<tr>
<td>Johns Hopkins Medical Library</td>
<td><a href="http://www.welch.jhu.edu/">www.welch.jhu.edu/</a></td>
</tr>
<tr>
<td>Kids Health</td>
<td><a href="http://kidshealth.org">http://kidshealth.org</a></td>
</tr>
<tr>
<td>KY Board of Nursing</td>
<td><a href="http://www.kbn.ky.gov">www.kbn.ky.gov</a></td>
</tr>
<tr>
<td>March of Dimes</td>
<td><a href="http://www.marchofdimes.com/">www.marchofdimes.com/</a></td>
</tr>
<tr>
<td>Mayo Clinic</td>
<td><a href="http://www.mayohealth.org">www.mayohealth.org</a></td>
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<tr>
<td>Medicine Net</td>
<td><a href="http://www.medicinenet.com">www.medicinenet.com</a></td>
</tr>
<tr>
<td>Morbidity and Mortality Weekly Report (MMWR)</td>
<td><a href="http://www.cdc.gov/mmwr/">www.cdc.gov/mmwr/</a></td>
</tr>
<tr>
<td>National Breast Cancer Foundation</td>
<td><a href="http://www.nationalbreastcancer.org">www.nationalbreastcancer.org</a></td>
</tr>
<tr>
<td>National Cancer Institute (NCI)</td>
<td><a href="http://www.nci.nih.gov">www.nci.nih.gov</a></td>
</tr>
<tr>
<td>National Center for Infectious Diseases</td>
<td><a href="http://www.cdc.gov/ncidod/">www.cdc.gov/ncidod/</a></td>
</tr>
<tr>
<td>National Institutes of Health (NIH)</td>
<td><a href="http://www.nih.gov">www.nih.gov</a></td>
</tr>
<tr>
<td>National Newborn Screening &amp; Genetics Resource</td>
<td><a href="http://genes-r-us.uthscsa.edu/">http://genes-r-us.uthscsa.edu/</a></td>
</tr>
<tr>
<td>Name</td>
<td>Website</td>
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<td>----------------------------------------------------------------------</td>
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<tr>
<td>National Organization for Rare Disorders</td>
<td><a href="http://www.rarediseases.org/">www.rarediseases.org/</a></td>
</tr>
<tr>
<td>Occupational Safety &amp; Health Administration (OSHA)</td>
<td><a href="http://www.osha.gov">www.osha.gov</a></td>
</tr>
<tr>
<td>Physicians’ Desk Reference (PDR)</td>
<td><a href="http://www.pdr.net">www.pdr.net</a></td>
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<tr>
<td>Proper Disposal of Prescription Drugs</td>
<td><a href="http://www.whitehouse.gov/ondcp">http://www.whitehouse.gov/ondcp</a></td>
</tr>
<tr>
<td>Save Babies Through Screening Foundation</td>
<td><a href="http://www.savebabies.org/">www.savebabies.org/</a></td>
</tr>
<tr>
<td>Tabers Online</td>
<td><a href="http://www.tabers.com">www.tabers.com</a></td>
</tr>
<tr>
<td>UK Medical Center Library</td>
<td><a href="http://www.mc.uky.edu/MedLibrary">www.mc.uky.edu/MedLibrary</a></td>
</tr>
<tr>
<td>Vaccines for Foreign Travel</td>
<td><a href="http://www.cdc.gov/travel/default.aspx">www.cdc.gov/travel/default.aspx</a></td>
</tr>
<tr>
<td>World Health Organization (WHO)</td>
<td><a href="http://www.who.int">www.who.int</a></td>
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Clinical Service Guide Forms:

All Forms, Teaching Sheets, & QA tools for CSG are located on the DPH Nursing Office Webpage.
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- Naloxone Auto Injector Protocol in the School Setting
- Naloxone Intranasal Protocol in the School Setting

Public Health Nursing Oral Health Protocols

- Fluoride Supplementation
- Fluoride Varnish
## SECTION CONTACTS

1. Cancer Screening/Follow-up .......................................................... [Colleen Toftness] 502-564-3236 ext. 4159
   [Ellen Barnard] 502-564-3236 ext. 4157
3. Family Planning ............................................................................ [Benita Decker] 502-564-3236 ext. 4169
5. HIV ................................................................................................. [Karen Sams] 502-564-6539 ext. 4281
6. Immunization ................................................................................ [Kristy Royalty] 502-564-4478 ext. 4254
7. Lab ................................................................................................ [Robin Cotten] 502-782-7711
8. Lead ............................................................................................... [Bethlyn Shepherd] 502-564-2154 ext. 4416
10. Oral Health ................................................................................... [Dr. Julie McKee] 502-564-3246 ext. 4421
13. Rabies ........................................................................................... [Dr. Kelly Giesbrect] 502-564-3418 ext. 4313
15. STD ............................................................................................... [Sheri White] 502-564-4804 ext. 4301
16. TB ................................................................................................. [Emily Anderson] 502-564-4276 ext. 4298
   [Maria Dalbey] 502-564-4276 ext. 4292
## MINIMAL REQUIREMENTS FOR A CANCER SCREENING VISIT

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th>INITIAL VISIT</th>
<th>ADDITIONAL VISITS</th>
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<tbody>
<tr>
<td><strong>Comprehensive Health History to include:</strong></td>
<td>Required (Health History and Physical Examination Form)</td>
<td>Required (Interval Health History and Physical Examination Form)</td>
</tr>
<tr>
<td>• Family history of breast/genital/colon-rectal cancers</td>
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<td>• LMP or date of menopause</td>
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<tr>
<td>• Contraceptive method if childbearing age</td>
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<tr>
<td>• Documentation of HRT or ERT if menopausal</td>
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<tr>
<td>• Date of last Pap/mammogram and results</td>
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<tr>
<td>• Previous abnormal Pap/HPV, diagnostics, treatments</td>
<td></td>
<td></td>
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<tr>
<td>• Previous breast problems, diagnostics, treatments</td>
<td></td>
<td></td>
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<tr>
<td>• Assessment: breast/cervical cancer risk factors, tobacco use</td>
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<tr>
<td><strong>Physical Examination to include:</strong></td>
<td>Required</td>
<td>Required (Exception: Pelvic exams are not required unless the patient is also getting a Pap/HPV test, but may be performed at clinician’s discretion)</td>
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<tr>
<td>• Documentation of general appearance and mental status</td>
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<tr>
<td>• Height/Weight/BMI</td>
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<td>• Blood pressure</td>
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<td>• Clinical breast examination for women aged 40 or older (as indicated for others)</td>
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<td>• Pelvic examination that includes visualization of the vulva, vagina, cervix/vaginal cuff and thorough bimanual including adnexae</td>
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<td>• Other as needed</td>
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<tr>
<td><strong>Laboratory:</strong> Pap test and/or HPV test (as indicated by age guidelines)</td>
<td>Required</td>
<td>Cervical Cancer Screening with a Pap and/or HPV test is not required annually; routine cervical cancer screening tests are repeated q. 3-5 years, as indicated</td>
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<tr>
<td>• Fecal occult blood testing (i.e., FIT, Guaiac) (age 50 and older or 45 and older for African American or family history)</td>
<td>Required</td>
<td>Required</td>
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<tr>
<td>o Follow manufacturer’s instructions</td>
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<td>o If positive, refer to M.D.</td>
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<tr>
<td>• Hemoglobin</td>
<td>If indicated</td>
<td>If indicated</td>
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<tr>
<td>• STD testing</td>
<td>If indicated by history/exam</td>
<td>If indicated by history/exam</td>
</tr>
<tr>
<td><strong>Referral for biennial mammogram (age ≥50) (annual mammograms as indicated; biennial mammograms for women under age 50 as indicated)</strong></td>
<td>Required</td>
<td>Required</td>
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<tr>
<td><strong>Counseling:</strong> (Documentation in medical record required)</td>
<td>Required</td>
<td>Required</td>
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<tr>
<td>- ACH-40 (“Improving Health for Women”) – CSEM given/counseled and patient verbalized understanding</td>
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<tr>
<td>• Breast Self-Awareness (optional teaching sheet)/CBE as indicated</td>
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<tr>
<td>• Benefits and risks of mammography (optional teaching sheet)</td>
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<tr>
<td>• Pap/Mammogram rescreening recommendations</td>
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<tr>
<td>• Regular exercise</td>
<td></td>
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<tr>
<td>• Adequate diet (low fat, high fiber, 5 fruits/vegetables daily)</td>
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<tr>
<td>• Osteoporosis/prevention and bone density testing</td>
<td></td>
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<tr>
<td>• Risks/Benefits of HRT if menopausal</td>
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<tr>
<td>• Contraception if needed</td>
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</tbody>
</table>
• Smoking risks/cessation and referral
• Immunization needs/update
• STD risk counseling if indicated
• Ovarian Cancer Screening at age 50 (age 25 if family history)
  (Locations: UKMC; Hardin, Mason, Floyd, McCracken, Greenup and Pulaski County Health Centers) call 1-800-766-8279 for appt.

<table>
<thead>
<tr>
<th>Documentation of Return Clinic Appointments</th>
<th>Required</th>
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<tr>
<td>Follow-up of Abnormal Test Results</td>
<td>Required</td>
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HELPFUL LINKS

Kentucky Women’s Cancer Screening Program
(KWCSP Approved CPT Codes can be found at this site)

Administrative Reference
BREAST CANCER SCREENING

Early diagnosis of breast cancer offers women more treatment options and greatly reduces mortality. Early diagnosis is aided by the triad of breast self-awareness and when indicated or age appropriate, a clinical breast exam (CBE) and regular mammography screening.

A. BREAST CANCER RISK FACTORS:
   1. Female age 40 or older; risk increases with age
   2. First degree relative (mother, sister, daughter) with history of breast cancer before the age of 50 (pre-menopausal) or a close relative with a male breast cancer or with a known BRCA (Breast Cancer Susceptibility gene) mutation, or if the patient herself has a known BRCA mutation. (See E. GENETIC COUNSELING/TESTING for definition of close relative.)
   3. Personal or family history of genetic syndromes such as Li-Fraumeni syndrome
   4. Personal history of a benign breast condition
   5. History of radiation treatments to the chest wall
   6. Early menarche (prior to age 12)
   7. Late menopause (after age 55)
   8. No pregnancies or first pregnancy after age 30
   9. Hormone use: some oral contraceptives and combination (estrogen and progestin used together) hormone replacement therapy
   10. Use of the drug diethylstilbestrol (DES) or intrauterine exposure to it.
   11. Overweight/Obese (especially after menopause)
   12. Lack of physical activity
   13. Alcohol consumption – risk increases with amount of alcohol consumed

B. BREAST SCREENING HISTORY:
   1. Include dates and results of previous mammograms
   2. Elicit personal history of breast symptoms including pain, tenderness, nipple discharge, palpable mass or skin changes
   3. Document any personal history of breast cancer and previous biopsies or treatments
   4. Screen for risk factors (listed above)

C. CLINICAL BREAST EXAMINATION AND MAMMOGRAPHY
   1. All females should be counseled on breast self-awareness beginning at age 21. Counseling shall be documented in the medical record (e.g. “Breast Self-Awareness counseling provided”) at the initial and annual visits.

   2. A clinical breast exam (CBE) should be offered *during the cancer screening visit* to females beginning at age 21 through age 39. A CBE should be done annually on women age 40 and older, high-risk women or any woman who presents with symptoms. During their cancer screening visits, women shall be informed to report any changes in their breasts noticed between visits to the Nurse Case Manager (NCM) at the Local Health Department (LHD) as soon as possible. Also, see Accepting Referrals from Outside Providers in the section TRACKING AND FOLLOW-UP REQUIREMENTS. If an
outside provider performed the previous CBE, thorough documentation of the exam done by that provider must be obtained, reviewed by the examining nurse at the LHD and placed in the patient’s chart.

*Offered in the context of informed decision-making, recognizing the uncertainty of additional benefits/harms of CBE beyond screening mammography. (Adapted from ACOG Practice Bulletin 179, July 2017)

3. The required method for performing the CBE is using the principles of positioning, three levels of palpation, and the vertical strip search pattern.

4. For Average-risk women, the LHD will follow the breast cancer screening guidelines recommended by the United States Preventive Services Task Force (USPSTF) for mammography screening:

* Ages 40-49: The decision to start screening mammography in women prior to age 50 should be an individual one. Women who place a higher value on the potential benefit than the potential harm may choose to begin biennial screening mammography between the ages of 40-49.

* Ages 50-74: Women age 50-74 years of age should have biennial screening mammography.

These guidelines are intended to guide screening of the general population. High-risk women will follow different, more frequent screening guidelines. If a woman over the age of 74 is still in good health and requests to continue biennial screening, she should be allowed to do so.

In menstruating women, the mammogram should be scheduled about 2 weeks after the LMP.

5. Transgender women (male-to-female) have different routine screening recommendations. For this population, it is recommended that screening mammography for average risk women be performed every 2 years once the woman has reached the age of 50 and has been on feminizing hormones at least 5 years. If there are no other risk factors (e.g. positive family history, BMI >35), provider and patient may agree to delay screening until the patient has been on feminizing hormones for up to 10 years.

6. Transgender men (female-to-male) who have not undergone a bilateral mastectomy should follow the same screening guidelines as non-transgender women. Prior to bilateral mastectomy, transgender men who meet all other KWCSP eligibility requirements can have their breast cancer screening and diagnostic services reimbursed through the program. Once a transgender man has undergone a bilateral mastectomy he will no longer qualify for KWCSP breast services reimbursement; a qualified clinician should determine his breast cancer screening needs.
Note: Transgender breast screening guidelines adopted from consensus recommendations from The Center of Excellence for Transgender Health and the World Professional Association for Transgender Health: http://transhealth.ucsf.edu/trans?page=protocol-screening#S2X.

7. A woman with breast implants will follow a routine (non-high risk) screening schedule, unless she is symptomatic. The mammography provider should be made aware of the implants, as extra views (e.g. implant displacement views) may need to be taken.

8. Women under the age of 40 who are either symptomatic, or asymptomatic but have been determined to be high-risk, can be evaluated with CBE, mammogram and/or a surgical consult. These services can be reimbursed with KWCSP funds for eligible women.

9. Women who are at high risk of developing breast cancer should be screened with both an annual mammogram and annual breast MRI, beginning at age 40, earlier if otherwise noted (below). A woman is considered high risk if any of the following are true:

   • She has a lifetime risk of 20% or more for development of breast cancer, based on risk assessment models, such as BRCAPRO, Claus, or Tyrer-Cuzick (IBIS), that are largely dependent on family history. (Risk assessment tools will not routinely be used, but as an option, a simple one can be found at: http://ibis.ikonopedia.com)
   • She has a first degree relative (mother, sister, daughter) with a history of premenopausal (before age 50) breast cancer or who is known to have a BRCA mutation, or if the woman herself has a known BRCA mutation, or if there is a personal or family history of genetic syndromes such as Li-Fraumeni syndrome. (Begin annual screening 10 years earlier than the age of family member at time of her breast cancer diagnosis, but not younger than age 25; if family member’s age at diagnosis is unknown, begin annual screening at age 35.)
   • She has a history of radiation treatments to the chest wall. (Begin annual screening 10 years after radiation was completed, but not younger than age 25.)
   • She has a history of pre-cancer/cancer of the breast. (Post-mastectomy women will have a diagnostic mammogram of the opposite breast.)

10. Any woman with an abnormal CBE should be referred for either a diagnostic mammogram (usually for women age 30 and older) or ultrasound (often preferred for woman under the age of 30 due to their typically dense breasts, but the radiologist may choose to do a diagnostic mammogram for the younger age woman as well.).

D. MAGNETIC RESONANCE IMAGING (MRI)

Women in the high risk category will be screened with an annual MRI as well as an annual mammogram. Otherwise, determination of the need for a MRI for patients will be made by the contracted breast surgeon or radiologist.

• KWCSP will reimburse Breast MRI when performed in conjunction with a mammogram when a client is considered “high risk” as determined in the previous section (Section C).
However, KWCSP will not reimburse Breast MRI when performed alone as a screening tool.

- KWCSP will reimburse Breast MRI when used to better assess areas of concern on a mammogram or for evaluation of a client with a past history of breast cancer after completing treatment.
- KWCSP will not reimburse Breast MRI when performed to assess the extent of disease in women who are already diagnosed with breast cancer.

**E. GENETIC COUNSELING/TESTING**

*The information below is adapted from the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin 182, September 2017. (Replaces Practice Bulletin 103, April 2009.*)

A woman affected by at least one of the following is at increased risk for having an inherited predisposition to breast and ovarian, tubal or peritoneal cancer. She should be advised of the need for genetic counseling and consideration of genetic testing:

- Epithelial ovarian, tubal or peritoneal cancer
- Breast cancer at age 45 years or less
- Breast cancer and has a *close relative* with breast cancer at age 50 years or less or close relative with epithelial ovarian, tubal or peritoneal cancer at any age
- Breast cancer at age 50 years or less with a limited or unknown family history
- Breast cancer and has two or more *close relatives* with breast cancer at any age
- Breast cancer and has two or more *close relatives* with pancreatic cancer or aggressive prostate cancer (Gleason score equal to or greater than 7)
- Two breast cancer primaries with the first diagnosed before age 50 years
- Triple-negative breast cancer at age 60 or less
- Breast cancer and Ashkenazi Jewish ancestry at any age
- Pancreatic cancer and have two or more *close relatives* with breast cancer; ovarian, tubal or peritoneal cancer; pancreatic cancer; or aggressive prostate cancer (Gleason score equal to or greater than 7)

A woman unaffected with cancer, but with one or more of the following has increased likelihood of having an inherited predisposition to breast and ovarian, tubal, or peritoneal cancer and should receive genetic counseling and be offered genetic testing:

- A first-degree or several *close relatives* that meet one or more of the conditions listed above
- A *close relative* carrying a known BRCA1 or BRCA2 mutation
- A *close relative* with male breast cancer

*Close relative means: parent, sibling or offspring (1<sup>st</sup> degree); grandparent, grandchild, uncle, aunt, nephew, niece, half-sibling (2<sup>nd</sup> degree); first cousin, great-grandparent or great-grandchild (3<sup>rd</sup> degree).
LHDs are not required to refer, only to recommend genetic counseling/testing to those patients for whom it is indicated. KWCSP funds cannot be used for genetic counseling/testing.

F. PATIENT EDUCATION ON BREAST HEALTH

1. Counseling with documentation at the initial and annual visits shall include teaching breast self-awareness, individual breast cancer risk factors/risk reduction, benefits/risks of mammography and the importance of regular screenings.
2. Patients with an abnormal CBE, mammogram, ultrasound or MRI will have documented counseling done as appropriate.
BREAST CANCER FOLLOW-UP

POST BREAST DIAGNOSTICS OR TREATMENT

Once a patient’s diagnostic procedures are complete and she has a diagnosis and treatment (if applicable), the contracted qualified clinician (breast surgeon, radiologist, etc.) will provide an order for the patient’s next screening. If this is not received, the NCM must contact the contracted qualified clinician to obtain an order. Even if the patient has a diagnosis with a benign finding, the clinician must give an order for the patient’s next screening schedule after follow-up of an abnormal screening test result.

A. SURGICAL REFERRALS

1. Women with an abnormal CBE must be referred for surgical consultation once a diagnostic mammogram and/or diagnostic ultrasound have been completed, regardless of imaging results, unless CBE is done by radiologist and found to be negative/benign. Thorough documentation by the radiologist shall be required.

2. Any patient with a bloody nipple discharge (unilateral or bilateral) requires a referral to a surgeon for evaluation.

3. Any patient with a spontaneous (without nipple stimulation) and/or unilateral nipple discharge requires a referral to a surgeon for evaluation.

4. Bilateral non-bloody discharge that occurs only with nipple stimulation does not need referral to a surgeon. This type of nipple discharge may be due to fibrocystic changes (usually greenish), hormonal imbalance, pregnancy, lactation and some medications (oral contraceptives, phenothiazides, anti-hypertensives, tranquilizers). If the clinician (MD or ARNP) determines the need for further evaluation of this type of nipple discharge, it typically is to either a gynecologist or endocrinologist.

5. If a patient presents with a “breast lump” that she has discovered herself but both the CBE and mammogram (or ultrasound) are normal, she may be referred to a surgeon for a second opinion. The patient may also be referred to another contracted provider for a second opinion for other concerns she may have regarding her care during screening. For KWCSP-eligible patients, the second opinion will be reimbursed by the program for services found on the list of KWCSP-approved CPT codes.

6. A patient who has a personal history of breast cancer shall be scheduled for a surgical consult with her annual mammogram/MRI regardless of CBE, mammogram or MRI results. A surgical consult is also required for women who have completed breast cancer treatment and are in need of orders for surveillance. Referral visits for these situations will be reimbursed by the KWCSP for program eligible women. If the provider determines that breast cancer surveillance should include tests/procedures not found on the KWCSP list of “Approved CPT Codes”, the NCM should contact the KWCSP staff for reimbursement approval. KWCSP staff can be reached at the Division of Women’s Health: 502-564-3236.

7. After an initial abnormal finding, when there is an order from a contracted qualified clinician (breast surgeon, radiologist, etc.) for frequent follow-up mammograms, ultrasounds, CBEs or surgical consults, these services will be paid for by the KWCSP until the provider has released the patient into normal routine screening. These follow-
up services may show normal or abnormal findings. However, the program will reimburse the continued frequent screening services until the patient is released to routine screening. National standards recommend frequent follow-up to continue for up to 2-3 years for specific original findings on radiology testing and clinical findings. The contracted qualified clinician (radiologist or breast surgeon) will make this determination.

**B. FOLLOW-UP**

1. Patients with an abnormal mammogram, MRI or ultrasound result shall be notified by the health department within 10 working days of receiving the result or within 30 days of the procedure, whichever comes first.
2. Referrals for a surgical consult or requests for additional imaging must be made within 3 weeks (21 days) of abnormal CBE or receipt of abnormal mammogram.
3. Copies of results from consults & diagnostic procedures (including pathology reports) will be received and placed in the medical record within 30 days of the consult or diagnostic procedure.
4. The month and year the next mammogram is due will be documented on the CH3A. A patient with normal screening results will follow the appropriate routine screening guidelines unless there is a reported change in her breasts. For patients who have been scheduled for abnormal test follow-up with a contracted provider, the order for the next mammogram or other future screening and diagnostic procedures shall be provided by the contracted qualified clinician (breast surgeon, radiologist, etc.) and noted in the patient’s chart. The NCM shall inform the patient of her next screening or diagnostic procedure that is ordered.
5. The interval between abnormal breast screening (date of screening) and final diagnosis should be 60 days or less. The interval between diagnosis (date of diagnosis) and initiation of treatment should also be 60 days or less.

**C. TREATMENT FOR PRE-CANCER/CANCER OF THE BREAST:**

Patients that have been screened/diagnosed through KWCSP or a KWCSP-designated entity may be eligible for the Breast and Cervical Cancer Treatment Program (BCCTP) if diagnosed with pre-cancer/cancer of breast. For more information and forms related to the BCCTP, please refer to their website at [https://chfs.ky.gov/agencies/dms/dpo/epb/Pages/bcctp.aspx](https://chfs.ky.gov/agencies/dms/dpo/epb/Pages/bcctp.aspx).

Below are some conditions that are considered precancerous conditions when found on a biopsy. If a patient receives one of these diagnoses or a diagnosis of cancer, she will require treatment. KWCSP-eligible women should apply for treatment through the Breast and Cervical Cancer Treatment Program (BCCTP). The NCM is responsible for initiating the BCCTP application.

**Breast Pre-cancerous Conditions:**
- Lobular carcinoma-in-situ
- Atypical hyperplasia
- Benign Phyllloides tumors
- Some types of papillomatosis
- Radial scar, sometimes referred to as sclerosing lesions

For more in-depth information on enrolling patients in treatment through the BCCTP see the section BREAST/CERVICAL CANCER TREATMENT THROUGH MEDICAID’S BREAST AND CERVICAL CANCER TREATMENT PROGRAM (BCCTP).

D. BI-RADS CLASSIFICATION OF MAMMOGRAM RESULTS AND MANAGEMENT

Category 0: **Assessment Incomplete**
This category indicates the need for additional imaging, which will be recommended by the radiologist or old films required for comparison.

Category 1: **Negative**
Recommendation should be made for routine follow-up according to the screening guidelines. Notify the patient when it is time for re-screening. (Refer to surgeon if CBE is abnormal)

Category 2: **Benign Finding**
Recommendation should be made for routine follow-up according to the screening guidelines. Notify the patient when it is time for re-screening. (Refer to surgeon if CBE is abnormal)

Category 3: **Probably Benign**
Follow-up should be provided according to the radiologist’s recommendation. Usually the radiologist will recommend a repeat mammogram in six months. Counsel the patient on the results of the mammogram and provide a re-screening appointment. (Refer to surgeon if CBE is abnormal)

Category 4: **Suspicious Abnormality**
A biopsy should be considered. Refer to a surgeon for further evaluation. Counsel the patient on the results of the mammogram and assure that arrangements are made for the surgical consultation.

Category 5: **Highly Suggestive of Malignancy**
There is probability of cancer. Refer to a surgeon for further evaluation. Counsel the patient on the results of the mammogram and assure that the arrangements are made for the surgical consultation.

Category 6: **Known Biopsy-Proven Malignancy-Appropriate Action Should Be Taken**
This category is reserved for lesions identified on the imaging study with biopsy proof of malignancy prior to definitive therapy.

Unsatisfactory: Not a BI-RADS classification. This result indicates that the mammogram is technically unsatisfactory and cannot be read by the radiologist; it must be repeated.
ALGORITHM FOR BREAST CANCER SCREENING FOLLOW-UP

ANNUAL CLINICAL BREAST EXAMINATION

NORMAL & BENIGN FINDINGS ON CBE
(Includes fibrocystic changes & normal nodularity)

1. REPEAT CBE IN ONE YEAR IF 40 OR OLDER, HIGH RISK OR PER PATIENT REQUEST

2. BIENNIAL SCREENING MAMMOGRAM IF
   AGE 50-74 (or ages 40-49 who choose to have mammography screening)

3. IF SCREENING MAMMOGRAM IS ABNORMAL, PATIENT TO BE NOTIFIED WITHIN 10 DAYS OF RECEIVING THE RESULT OR WITHIN 30 DAYS OF THE PROCEDURE (whichever comes first)

4. A FINAL DIAGNOSIS OBTAINED WITHIN 60 DAYS OF DETECTION OF THE ABNORMALITY (from date screened)

ABNORMAL CBE
(Discrete mass or abnormal thickening)

1. BREAST ULTRASOUND (ages 29 and under)

2. DIAGNOSTIC MAMMOGRAM (ages 30 & older) and ultrasound if needed

3. SURGICAL REFERRAL APPOINTMENT WITHIN 3 WEEKS OF DISCOVERY OF ABNORMAL CBE
   (Regardless of ultrasound and/or mammogram results-unless CBE repeated by radiologist and normal/benign result must have thorough documentation from radiologist)

4. FINAL DIAGNOSIS OBTAINED WITHIN 60 DAYS OF DETECTION OF ABNORMALITY (from date screened)
CERVICAL CANCER SCREENING

Routine periodic screening encourages early identification of precancerous conditions of the cervix and early stage diagnosis of cervical cancer. Most cervical cancer can be PREVENTED with detection and early treatment of precancerous lesions.

A. CERVICAL CANCER RISK FACTORS
This is an overall list of factors and/or behaviors which may increase the risk for cervical cancer. Some factors on this list are not considered when making the determination for a patient’s Pap screening interval. See “Cervical Cancer Screening Guidelines” for factors that are used to determine when a patient is considered “high-risk” and not eligible for increasing the time interval between screenings.

1. History of HPV and/or Dysplasia
2. Multiple (3 or more) sexual partners in lifetime
3. A sex partner with multiple sex partners
4. A sex partner who has had a partner with HPV/dysplasia/cervical cancer
5. Cigarette smoking (any amount)
6. Beginning sexual intercourse at a young age (age 18 or less)
7. History of 2 or more sexually transmitted infections
8. Intrauterine exposure to diethylstilbestrol (DES)
9. Infrequent screening (≥5 years since last Pap)
10. Immunosuppressed (HIV/AIDS, diabetes, transplant recipient, chronic steroid use, auto-immune disorders)

B. CERVICAL SCREENING HISTORY
1. Elicit date and result of last Pap test
2. Determine if a previous history of an abnormal Pap and/or HPV
3. Determine if history of a previous colposcopy & biopsy and/or treatment
4. Screen for risk factors (listed above)
5. Screen for history of abnormal bleeding patterns

C. PELVIC EXAMINATION
The purpose of this section is to outline components of a pelvic exam, when to start screening, and how often to continue screening.

The pelvic examination serves multiple purposes, including the assessment of the vulva, vagina, cervix, uterus and adnexa. The pelvic examination includes:

- inspection of the external genitalia, urethra and introitus;
- examination of the vagina and cervix; and
- bimanual examination of the uterus, cervix, adnexa and ovaries.

If indicated, rectovaginal examination is performed as a part of the examination. Some health care providers incorporate the rectovaginal examination as part of the routine examination.
A pelvic examination may be performed as preventive care for all women 21 years of age and older, but it is not required annually. It is required as part of the cervical cancer screening visit when a Pap and/or HPV test is done.* A bimanual pelvic examination is generally not necessary at the initial reproductive health visit. A general physical examination, including an external genital examination, may be done because it allows assessment of secondary sexual development, reassurance and education. A “teaching” external-only genital examination can provide an opportunity to familiarize adolescents with normal anatomy, assess adequacy of hygiene and allow the health care provider an opportunity to visualize the perineum for any anomalies. Pelvic examination need only be performed in adolescents when it is likely to yield important information regarding conditions such as amenorrhea, abnormal bleeding, vaginitis, presence of a possible foreign body, pelvic pain, pelvic mass or a sexually transmitted disease (STD). If the patient has had sexual intercourse, screening for STDs is important. Refer to STD Guidelines.

RNs must refer any abnormal finding on the pelvic examination to a midlevel or higher clinician or a contracted gynecologist for further evaluation.

Adapted from ACOG Committee Opinion, Number 431, May 2009.

*For guidance on when to perform a pelvic exam, apart from the cancer screening Pap test, see the algorithm entitled “Algorithm for Deciding if a Pelvic Exam is Necessary During a Family Planning Visit”, found in the FP section of the CSG.

D. CERVICAL CANCER SCREENING GUIDELINES
For average-risk women, the LHD will follow the cervical cancer screening guidelines recommended by the United States Preventive Services Task Force (USPSTF):

**Ages 21-29:** Pap test every 3 years

**Ages 30-65:** Women in this age group have 3 choices:

1.) Pap test every 3 years
   or
2.) Primary hrHPV test every 5 years
   or
3.) Co-test (Pap and HPV) every 5 years

These guidelines are intended to guide screening of the general population. High-risk women will follow different, more frequent screening guidelines.

Routine cervical cancer screening begins at age 21 with the Pap test, to be repeated every 3 years. At age 30, a woman can choose to continue with the Pap test every 3 years, or have a primary hrHPV test every 5 years, or have a co-test (Pap test and HPV test) every 5 years. Abnormal test results can alter the screening schedule.

Patients with a cervical history of CIN2, CIN3 or cervical cancer, in utero exposure to DES or who are immunocompromised, as stated above, are considered high-risk patients when
determining their cancer screening interval options. **These women require more frequent screening and should be screened according to orders from the contracted gynecologist.**

*Note: The physician who treats a patient’s CIN2, CIN3 or cervical cancer will determine the interval between future screenings and the length of screening surveillance, including possible extension of screening past the age of 65.*

**FOR ALL PATIENTS WHO ARE SENT TO A CONTRACTED GYNECOLOGIST OR COLPOSCOPIST:**

Once her diagnostic procedures are complete and she has a diagnosis and treatment if applicable, the contracted clinician (gynecologist or colposcopist) who diagnoses and/or treats will provide an order for the patient’s future screening schedule. If this is not received, the NCM must contact this provider to obtain an order. If a patient has a history of colposcopy at another provider’s office, the records and order for future screening schedule should be obtained from that office.

- **SPECIAL POPULATIONS:**

Women with the following high-risk conditions should be screened according to orders from the contracted gynecologist regardless of their age: immunosuppression (i.e., renal transplant, etc.), HIV infection, history of CIN2, CIN3, cervical cancer or DES exposure in utero. If uncertain of whether a patient’s condition/disease would cause immunosuppression, consult your medical director or contracted clinician. KWCS funds can be used for annual cervical cancer screening among women who are considered high-risk.

The NCM shall contact the contracted provider to determine screening guidelines for patients with a history of pre-cancer or cancer of the cervix or to determine cervical cancer surveillance needs. The type of follow-up will often be determined by the provider according to the extent of the cancer. KWCS funds can be used to reimburse for routine cervical cancer surveillance for 20 years post-treatment for women with a history of cervical neoplasia or in situ disease, or can reimburse indefinitely for surveillance of women with a history of invasive cervical cancer, as long as the woman is in good health. If the provider determines that cervical cancer surveillance should include tests/procedures not found on the KWCS list of “Approved CPT Codes”, the NCM should contact the KWCS staff for reimbursement approval. KWCS staff can be reached at the Division of Women’s Health: 502-564-3236.

**WOMEN FOLLOWING HYSTERECTOMY**

- Women at any age following a hysterectomy with removal of the cervix who **do not** have a positive history of CIN2, CIN3 or cervical cancer should not be screened for cervical cancer using any modality according to the ACS-ASCCP-ASCP screening guidelines released in Nov. 2012.

- Women at any age following a hysterectomy with removal of the cervix who **do have** a positive history of CIN2, CIN3 or cervical cancer should be screened as stated in the
preceding section, titled “Special Populations”. Vaginal/vulvar/labial Pap tests or biopsies shall be performed by the LHD contracted clinician (gynecologist or colposcopist) for patients with a history of CIN2, CIN3, cervical cancer or for an abnormal physical finding during an exam performed at the LHD. KWCSP funds can be used to reimburse for the vaginal Pap tests and/or diagnostic follow-up for eligible women in this situation.

- Women for whom the reason for the hysterectomy or final diagnosis of no neoplasia or invasive cancer cannot be documented, should continue cervical cancer screening until there is a 10-year history of negative screening results, including documentation that Pap tests were technically satisfactory.

**VULVAR. LABIAL OR VAGINAL ABNORMALITIES**
- If a vulvar or labial lesion is found during an examination, the patient shall be informed that this abnormal finding will need follow-up to rule out cancer. The contracted clinician (gynecologist or colposcopist) will perform vulvar and labial screening/diagnostic follow-up. Vulvar or labial procedures will not be reimbursed by the KWCSP.
- Follow-up for any abnormal findings of the vagina, vulva or labia will be determined by the gynecologist who performs the screening and/or diagnostic procedures for the patient.

**WOMEN OLDER THAN 65**
Women older than 65 with documentation of adequate negative prior screening, who are not otherwise at high risk for cervical cancer and have no history of CIN2, CIN3 or cervical cancer within the last 20 years should not be screened. Adequate negative prior screening is three consecutive negative cytology results or two consecutive negative co-tests or primary HPV tests within the 10 years before cessation of screening, with the most recent test occurring within the past 5 years.

**WOMEN IN ABNORMAL FOLLOW-UP**
Guidance for follow-up of an abnormal Pap test result is found under the heading of MANAGEMENT OF ABNORMAL PAP TEST RESULTS in the CSG. Guidance for follow-up of an abnormal primary HPV test result is found under the heading THE PRIMARY HPV TEST AND MANAGEMENT OF ABNORMAL RESULTS in the CSG. This information should be referenced when planning case management. However, the contracted qualified clinician (gynecologist, colposcopist, etc.) who provides the colposcopy and/or treatment will direct patient care. Services that can be reimbursed are found on the KWCSP list of “approved CPT codes”. Medical providers and patients shall be made aware of services that can be reimbursed. Once a patient’s diagnostic procedures are complete and she has a diagnosis and treatment if applicable, the contracted clinician who diagnoses and/or treats will provide an order for the patient’s next screening. If this is not received, the NCM must contact this provider to obtain an order.

**WOMEN WHO HAVE RECEIVED HPV VACCINE**
Women who have received the HPV vaccine should continue to be screened according to the age-appropriate guidelines.

Age – Delineated Cervical Cancer Screening Schedule

Ages < 21
- No Screening

Ages 21-29
- Screen Every 3 yr
  (annually if History of CIN2/3, HIV positive, immunosuppressed, history of DES exposure)

Ages 30-65
- History of CIN2/3, HIV-positive, immunosuppressed, history of DES exposure
  - YES
    - Annual screening or per guidelines in cases of CIN 2/3
  - NO
    - Primary HPV or Co-test
    - Cytology (Pap only)
    - Repeat every 3 yr

Ages > 65
- Discontinue screening IF:
  1. Adequate negative prior screening*
  2. No CIN2 or greater within 20 years
  3. No exposure to DES in utero
  4. No history of cervical cancer
  5. Not immunosuppressed

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* Adequate negative prior screening is three consecutive negative cytology results or two consecutive negative co-tests or primary HPV tests within the 10 years before cessation of screening, with the most recent test occurring within the past 5 years.
CERVICAL CANCER FOLLOW-UP

A. THE BETHESDA 2014 SYSTEM
The Bethesda System for reporting cervical and/or vaginal cytology is the recognized system for reporting results. The LHD is required to contract with a laboratory that uses this system of reporting. The state computerized reporting options for Pap test findings and the protocols for management of abnormal findings are based on the Bethesda 2014 System.

SPECIMEN TYPE
Indicate conventional smear (Pap smear), liquid-based preparation (Pap test) vs. other

SPECIMEN ADEQUACY
- Satisfactory for evaluation (describe presence or absence of endocervical/transformation zone component and any other quality indicators, e.g. partially obscuring blood, inflammation, etc.)
- Unsatisfactory for evaluation (specify reason)
  - Specimen rejected/not processed (specify reason)
  - Specimen processed and examined, but unsatisfactory for evaluation of epithelial abnormality because of (specify reason)

GENERAL CATEGORIZATION (optional)
- Negative for intraepithelial lesion or malignancy
- Other: see Interpretation/Result (e.g. endometrial cells in a woman aged \( \geq 45 \) years)
- Epithelial cell abnormality: see Interpretation/Result (specify “squamous” or “glandular”, as appropriate)

INTERPRETATION/RESULT
- Negative for Intraepithelial Lesion or Malignancy
  (When there is no cellular evidence of neoplasia, state this in the General Categorization above and/or in the Interpretation/Result section of the report – whether or not there are organisms or other non-neoplastic findings)
- Non-Neoplastic Findings (optional to report)
  - Non-neoplastic cellular variations
    - Squamous metaplasia
    - Keratotic changes
    - Tubal metaplasia
    - Atrophy
    - Pregnancy-associated changes
  - Reactive cellular changes associated with:
    - Inflammation (includes typical repair)
      - Lymphocytic (follicular) cervicitis
    - Radiation
    - Intrauterine contraceptive device (IUD)
  - Glandular cells status posthysterectomy
- Organisms
  - Trichomonas vaginalis
  - Fungal organisms morphologically consistent with Candida spp.
  - Shift in flora suggestive of bacterial vaginosis
  - Bacteria morphologically consistent with Actinomyces spp.
  - Cellular changes consistent with herpes simplex virus
  - Cellular changes consistent with cytomegalovirus
- Other
  - Endometrial cells (in a woman aged \( \geq 45 \) years)
    (Also specify if “negative for squamous intraepithelial lesion”)
- Epithelial Cell Abnormalities
o Squamous Cell
  - Atypical squamous cell cells
    - Of undetermined significance (ASC-US)
    - Cannot exclude HSIL (ASC-H)
  - Low-grade squamous intraepithelial lesion (LSIL)
    (Encompassing: HPV/mild dysplasia/CIN-1)
  - High-grade squamous intraepithelial lesion (HSIL)
    (Encompassing: moderate and severe dysplasia, CIS; CIN-2 and CIN-3)
    - With features suspicious for invasion (if invasion is suspected)
  - Squamous cell carcinoma

o Glandular Cell
  - Atypical
    - Endocervical cells (NOS or specify in comments)
    - Endometrial cells (NOS or specify in comments)
    - Glandular cells (NOS or specify in comments)
  - Atypical
    - Endocervical cells, favor neoplastic
    - Glandular cells, favor neoplastic
  - Endocervical adenocarcinoma in situ
  - Adenocarcinoma
    - Endocervical
    - Endometrial
    - Extrapertine
    - Not otherwise specified (NOS)

- Other Malignant Neoplasms (specify)

ADJUNCTIVE TESTING

Provide a brief description of the test method(s) and report the result so that it is easily understood by the clinician

COMPUTER-ASSISTED INTERPRETATION OF CERVICAL CYTOLOGY

If case examined by an automated device, specify the device and result

EDUCATIONAL NOTES AND COMMENTS APPENDED TO CYTOLOGY REPORTS (optional)

Suggestions should be concise and consistent with clinical follow-up guidelines published by professional organizations (references to relevant publications may be included)

(From: The Pap Test and Bethesda 2014/Nayer and Wilbur)
B. PATIENT EDUCATION ON CERVICAL HEALTH
1. Counseling on cervical cancer risk factors, Human Papillomavirus (HPV) testing and risk reduction (including smoking cessation) during screening visits is required. Smokers must be offered referral to the Quit Now Kentucky tobacco quit line and/or Freedom from Smoking classes.
2. Counseling on the HPV vaccination shall be provided to the patient and the parent of minors when applicable.
3. Patients must have documented counseling as appropriate.

C. FOLLOW-UP
1. Refer patient if abnormal cervix or polyps visualized.
2. Patients with abnormal cervical cancer screening tests shall be notified within 10 working days from the date the abnormal test result is received at the clinic.
3. Referral appointments must be made within 3 weeks (21 days) of the clinic receiving the abnormal screening test result. Any delay in meeting this timeframe must be documented in the patient’s medical record, including any “1st available” appointment
4. A final diagnosis must be made within 60 days of the cervical cancer screening. The final diagnosis is based on colposcopy and biopsy results. Treatment should be initiated 60 days or less from the date of diagnosis of a pre-cancer or cancer of the cervix.
5. Results of referrals including colposcopy, biopsy path reports, cryotherapy, Loop electrosurgical excision procedure (LEEP) procedure and pathology reports, Cold Knife Conization (CKC) procedure and pathology reports and Laser treatment documentation must be received within 30 days of the procedure.
6. The month and year the next Pap test is due is to be documented on the progress note. The nurse’s note should include the doctor’s or colposcopist’s name, date and source of the order (verbal order, doctor’s office note in chart, etc.) for the next screening or diagnostic procedure.

D. THE PRIMARY HPV TEST AND MANAGEMENT OF ABNORMAL RESULTS
The Primary hrHPV test is the newest cervical cancer screening choice for average-risk women. It is included as a screening option in the USPSTF cervical cancer screening guidelines for women who are 30-65 years old (the same population who are eligible for the co-test). Only one specific test has FDA approval for primary HPV screening, the cobas HPV Test; only the approved test should be used for primary HPV screening.

The ASCCP and SGO have provided interim guidance for managing results of the Primary HPV test. An algorithm is provided below. Though interim guidelines do not specify which test to perform at 1-year follow-up in women with positive HPV primary screening test results and negative genotyping and cytology test results, co-testing is a reasonable choice (ACOG Practice Bulletin, Number 168, Reaffirmed 2018). NCMs in the LHD should receive the 1-year follow-up orders from the contracted gynecologist.
If the hrPrimary HPV test is negative, normal screening intervals will continue. If the test is positive for HPV 16/18, refer for colposcopy. If the test is negative for HPV types 16/18 but positive for other high-risk HPV types, reflex cytology is performed, and if the results are abnormal, refer for colposcopy. If cytology is normal, follow-up in 12 months according to orders from the contracted gynecologist.

**E. MANAGEMENT OF ABNORMAL PAP TEST RESULTS**
(Numbers correspond to PSRS submission)

Follow-up for any abnormal findings of the vagina, vulva or labia will be determined by the contracted clinician (gynecologist or colposcopist) who performs the screening and/or diagnostic procedures for the patient. Also, see SCREENING AND REIMBURSEMENT INFORMATION FOR VAGINAL, LABIAL OR VULVAR PROCEDURES

#1 SATISFACTORY / NEGATIVE FOR INTRAEPITHELIAL LESION

Refer patient if abnormal cervix or polyps visualized

Management of Women Age 30 and older with Co-Testing:

**CYTOLOGY NEGATIVE- HPV NEGATIVE (COTESTING)**
- SEE CERVICAL CANCER SCREENING GUIDELINES AT THE BEGINNING OF THE CERVICAL CANCER SCREENING SECTION for scheduling patient’s next screening unless she is currently in abnormal follow-up. If the current Pap result was part of follow-up for a previous abnormal, refer to physician’s order for next screening.

**CYTOLOGY NEGATIVE-HPV POSITIVE (CO-TESTING)**
Women co-testing HPV positive, cytology negative should be followed with either:

Option 1) Repeat Co-testing in 1 year **if this was her first co-test.**
*If this was her second follow-up co-test,* with result of ASCUS OR HPV positive, she should be referred for colposcopy. If the second follow-up co-test is Cytology Negative and HPV Negative, then Repeat Co-Testing @ 3 years.

OR

Option 2) perform immediate HPV DNA Typing / genotype-specific testing for HPV16 alone or for HPV 16/18. **AT THIS TIME CDC POLICY ONLY ALLOWS REIMBURSEMENT FOR HPV PANEL.**

If HPV 16 and HPV 18 is negative, rescreen in 1 year with co-testing. If HPV 16 or HPV 18 is positive, refer for colposcopy.

**CYTOLOGY NEGATIVE BUT EC/TZ ABSENT/INSUFFICIENT**

- AGES 21-29: routine screening (HPV testing is unacceptable)
- AGES 30 and OLDER:
  1. HPV Negative: routine screening
  2. HPV Positive: Cytology plus HPV testing in 1 year OR Genotyping
  3. HPV Unknown: HPV testing (Preferred) OR Repeat Cytology in 3 years (Acceptable).
     If HPV testing is negative then can return to Routine screening but if HPV is positive then will need to repeat Cytology and HPV test in 1 year OR Genotyping

**SATISFACTORY/NEGATIVE FOR INTRAEPITHELIAL LESION WITH PRESENCE OF ORGANISMS OR REACTIVE CELLULAR CHANGES:**

- Clinician consult to decide if treatment is indicated
- Repeat Pap test at next scheduled screening

**ENDOMETRIAL OR GLANDULAR CELLS PRESENT ON A NEGATIVE PAP:**

When there is a result of endometrial cells in a woman ≥ 45 years of age on a negative Pap test result, the NCM shall contact the contracted provider. The NCM will provide all pertinent medical history to the physician including past cervical history and test results, age, and current Pap results. The physician will determine follow-up for the patient. If the patient is KWCSP eligible, services on the approved CPT code list will be reimbursed by the program.

**#2 ATYPICAL SQUAMOUS CELLS OF UNDETERMINED SIGNIFICANCE (ASC-US)**


**Women ages 21-24:**

1. Repeat Cytology @ 12 months (Preferred)
**#3 ATYPICAL SQUAMOUS CELLS CANNOT RULE OUT HIGH GRADE (ASC-H)**

**Women ages 21-24:**
- Refer for colposcopy (immediate LEEP is unacceptable)

**Women ages 25 and older:**
- Refer for colposcopy evaluation regardless of HPV status

**#4 LOW GRADE INTRAEPITHELIAL NEOPLASIA (CIN I, Mild dysplasia, HPV) (LSIL)**

**Women ages 21-24:**
1. Repeat Cytology @ 12 months (Preferred)
   - **NEG, ASCUS, LSIL results: need to Repeat Cytology @ 12 months and if Negative x 2 then return to routine screening** If this repeat is ASCUS or greater refer to colposcopy.  
   - **On the first repeat cytology if result is ASCUS-H, AGC, HSIL need to Refer for Colposcopy**

2. Reflex HPV Testing (Acceptable)
   - If HPV Negative then return to Routine screening (if she is not considered high risk according to the criteria found under Cervical Cancer Screening Guidelines in the CSG)
   - If HPV Positive then Repeat Cytology at 12 months (See two bullets under #1 for follow-up).
Women ages 25 and older:
With Negative HPV Test: Repeat Co-Testing @ 1 year (Preferred) OR refer for Colposcopy (Acceptable). If Repeat Co-Testing is done and Cytology is Negative and HPV is Negative then may repeat Co-Testing @ 3 years. If Repeat Co-Testing is done and Cytology is ASCUS or worse OR HPV Test is Positive then would refer for Colposcopy.
  1. With No HPV Test: Refer for Colposcopy
  2. With Positive HPV Test: Refer for Colposcopy

#5 HIGH GRADE INTRAEPITHELIAL NEOPLASIA (CIN II, CIN III, Moderate-Severe dysplasia, or carcinoma-in-situ) (HSIL)

Women ages 21-24:
• Refer for Colposcopy evaluation (Immediate LEEP is unacceptable)

Women ages 25 and older:
• Refer for colposcopy evaluation or LEEP.
• The contracted provider shall perform a review of the cytology, colposcopy, and histology results when no lesion or only biopsy-confirmed CIN 1 is identified after colposcopy in women with HSIL Pap test reports. If the review yields a revised interpretation, management should follow guidelines for the revised interpretation; if a cytological interpretation of HSIL is upheld or if review is not possible, a diagnostic excisional procedure (e.g., LEEP) is preferred in nonpregnant patients.

#6 SQUAMOUS CELL CARCINOMA
• Refer to a qualified provider

#7 ADENOCARCINOMA OR ADENOCARCINOMA-IN-SITU
• Refer to a qualified provider

#8 UNSATISFACTORY
1. HPV unknown (any age): Repeat Cytology after 2-4 months
2. HPV Negative (age 30 and older): Repeat Cytology after 2-4 months
3. HPV Positive (age 30 and older): Repeat Cytology after 2-4 months OR Refer for Colposcopy (either is Acceptable)
   *If Repeat Cytology is:
   Abnormal: Manage per ASCCP guidelines (See Management of Abnormal Pap Test Results per CSG)
   Negative: Routine Screening (HPV negative or unknown) OR Cotesting @ 1 year (HPV positive)
   Unsatisfactory: Refer for Colposcopy

#9 ATYPICAL GLANDULAR CELLS OF UNDETERMINED SIGNIFICANCE (AGC)
• Contact contracted provider for order of follow-up. The NCM will provide all pertinent medical history to the physician including past cervical history and test results, age, and current Pap results. The physician will determine follow-up for the patient. If the patient is KWCSLP eligible, services on the approved CPT code list in the CSG will be reimbursed by the program.
The Consensus Guidelines updated 2012-2013 for cervical follow-up are on the American Society for Colposcopy and Cervical Pathology website at http://www.asccp.org/. Due to copyright restrictions, we are unable to include the ASCCP algorithms in the CSG. However, LHD nurses are encouraged to print the cytology follow-up algorithms from the ASCCP website for their own use.

F. POST COLPOSCOPY EVALUATION OR TREATMENT
Once a patient’s diagnostic procedures are complete and she has a diagnosis and treatment (if applicable), the contracted qualified clinician (gynecologist, colposcopist, etc.) providing the colposcopy and/or treatment will provide an order for the patient’s next screening. If this is not received, the NCM must contact this provider to obtain an order. Even if the patient has a diagnosis with a benign finding, the contracted clinician who provided this diagnosis must give an order for the patient’s next screening schedule after follow-up of an abnormal screening test result.

LOOP ELECTRICAL EXCISION PROCEDURE (LEEP), Diagnostic vs Treatment
A local surgical procedure known as a LEEP or a cone biopsy can be considered either a diagnostic or treatment procedure.

A patient’s colposcopy biopsy may be benign, show mild dysplasia or a biopsy may not be performed. However, a physician may determine that it is necessary to perform a LEEP to obtain a more comprehensive or accurate specimen.

- When a patient’s colposcopy biopsy is benign, mild or a biopsy was not performed, a LEEP would be considered a diagnostic procedure and would be covered under the KWCSP.
- When a LEEP procedure is performed on a patient who had a colposcopy diagnosis of HSIL, the LEEP would be considered treatment and should be covered under the BCCTP.

The NCM shall ensure that the patient begins the application process for the BCCTP after receiving the colposcopy diagnosis of cancer or pre-cancer.

G. TREATMENT FOR PRE-CANCER/ CANCER OF THE CERVIX
Patients that have been screened or diagnosed through KWCSP or a KWCSP-designated entity may be eligible for the Breast and Cervical Cancer Treatment Program (BCCTP) if diagnosed with pre-cancer/cancer of cervix (includes endocervical). For more information and forms related to BCCTP, please refer to their website at https://chfs.ky.gov/agencies/dms/dpo/epb/Pages/bcctp.aspx.

Below are some conditions that are considered pre-cancerous conditions when found on a biopsy. If the patient receives one of these diagnoses or a diagnosis of cancer, she is eligible for the BCCTP.

Cervical Pre-cancerous Conditions:
- High grade squamous epithelial lesions (HSIL)
- Adenocarcinoma-in-Situ

For more in-depth information on enrolling patients in treatment through the BCCTP, see the section BREAST/CERVICAL CANCER TREATMENT THROUGH MEDICAID’S BREAST AND CERVICAL CANCER TREATMENT PROGRAM.
BREAST/CERVICAL CANCER TREATMENT THROUGH MEDICAID’S BREAST AND CERVICAL CANCER TREATMENT PROGRAM (BCCTP):

Once a woman is screened or diagnosed through the KWCSP or a KWCSP-designated entity and is found to have a pre-cancer or cancer of the breast or cervix, the NCM shall begin the application process for the BCCTP.

To be eligible for Medicaid, an applicant or recipient shall be a citizen of the United States as verified through documented evidence presented during initial application as required in 907 KAR 1:011. The LHD shall verify patient’s identity and citizenship by viewing the patient’s driver license and birth certificate. For patients who were born in Kentucky and do not have a copy of their birth certificate or for more information about the citizenship documentation requirement, contact the Department for Medicaid Services at 1-800-635-2570. Other patients will need to contact Vital Statistics in their state of birth in order to obtain an original birth certificate. A passport may also be used for documentation of both identity and citizenship.

Complete the Pre-screening Eligibility Form using the Medicaid web application. Then, complete application and call Medicaid for confirmation number. The original signed application, Pre-screening Eligibility Form and proof of identity and citizenship should be maintained in the patient’s chart in the administrative section.

As stated on the Department for Medicaid Services BCCTP website, some patients may require longer than the standard period of treatment and may be granted a Medicaid eligibility extension. An eligibility extension form (MAP - 813D Breast and Cervical Cancer Treatment Program Extension) can be obtained from the department's website or by calling toll-free 1-800-807-1232.

During the initial BCCTP application process, the NCM shall inform the patient to contact the NCM two weeks prior to the end of her Medicaid eligibility period if her treatment plan will extend past that eligibility period. Extension requests must be initiated by the treating physician. The NCM will assist the physician in obtaining an extension form to complete on the patient’s behalf.

When extension request review is completed, recipients will receive a notice of their new eligibility status.

TREATMENT PROGRAM ELIGIBILITY INFORMATION

- A Pap test, mammogram, ultrasound or MRI does not provide a definitive diagnosis of pre-cancer or cancer. These are considered screening tests.
- A patient must have a biopsy that confirms either a diagnosis of cancer or pre-cancer of the cervix or breast for her to be eligible for the BCCTP.
- Cancer or pre-cancer of the vagina, vulva, labia or uterine/endometrial lining do not make a patient eligible for the BCCTP. The BCCTP is for cancer or pre-cancer treatment of the breast or cervix for women screened or diagnosed through the KWCSP or KWCSP-designated entity.
- A result of HSIL on a biopsy of the cervix (CIN II or greater) is required for a patient to be considered eligible clinically for the BCCTP.
- Once the biopsy diagnosis is confirmed, the NCM will begin the process of ensuring that an application is completed for the patient to be enrolled with Medicaid (BCCTP).
• The NCM is responsible for initiating the BCCTP application when a final diagnosis has been received and patient eligibility determined. Support staff at the LHD may assist or perform the application process.

• The NCM should inform the patient that she should return to the LHD in the event that treatment has ended and her oncologist or other provider will no longer follow her for surveillance. KWCSP can reimburse for breast/cervical cancer surveillance. The appropriate contracted provider (e.g. surgeon, gynecologist) shall be contacted when surveillance orders are needed. If the provider determines that cervical cancer surveillance should include tests/procedures not found on the KWCSP list of approved CPT codes, the NCM should contact the KWCSP staff for reimbursement approval. KWCSP staff can be reached at the Division of Women’s Health: 502-564-3236.
TRACKING AND FOLLOW-UP REQUIREMENTS

The Local Health Department (LHD) is accountable for tracking KWCS patients with abnormal screening test results to ensure these women receive the necessary re-screening or diagnostic follow-up services to reach a timely final diagnosis and begin treatment. This includes those patients where the screening occurred in another program such as family planning, pediatrics, or prenatal. Insured women with abnormal results should be referred to their primary care physician/medical home for necessary follow up. Each clinic site is responsible for assigning this tracking responsibility to a Registered Nurse, Advanced Registered Nurse Practitioner or Licensed Practical Nurse. The nurse that assumes this responsibility is referred to as the Nurse Case Manager (NCM).

Prior to assuming the role and responsibilities of NCM with the KWCS, the nurse must complete the following educational modules on TRAIN:

- How to Best Utilize the State’s Breast and Cervical Cancer Screening and Treatment Programs (Course # 1009091)
- Cancer Screening and Follow-Up Using the Core Clinical Service Guide (Course # 1044117)
- Kentucky Public Health Nurse Case Management: Helping Women with Abnormal Breast and Cervical Cancer Screening Results (Course # 1013696)
- Documentation: Kentucky Public Health Nurse Case Management for Abnormal Breast and Cervical Cancer Screening Follow-up (Course # 1020005)

The following modules are highly recommended:

- Who are the Never and Rarely Screened? Kentucky Women Share Insights about the Impact of their Care and How You Can Make the Difference (Part 1 Course # 1010683, Part 2 Course # 1010684)

TRAINING IN ADDITION TO MODULES FOR NEW NURSE CASE MANAGERS

When there is a staff change for the NCM position, the Nursing or Clinical Supervisor must notify the Clinical Coordinator of the KWCS at 502-564-3236, as soon as possible. One-on-one training will be provided to each new NCM by the QA Nurse Consultant. This training may be provided by ITV, telephonically or in person.

BACKUP NURSE CASE MANAGERS

There must also be another RN, LPN or APRN, a back-up NCM, who is knowledgeable about cancer screening follow-up and is available to assume the Nurse Case Manager’s (NCM) role and responsibilities in the event the NCM is absent for more than seven calendar days. A timely diagnosis is crucial to creating positive outcomes in cancer screening. Completion of the modules listed above are also required of the backup NCM prior to assuming NCM duties; the one-on-one training is optional.

NURSE CASE MANAGER DUTIES

Tracking and follow-up can be time consuming and therefore it is recommended that professional and support staff work as a team toward this effort. The NCM is required to provide patient contact, counseling, tracking,
and follow-up while the support staff may assist the case manager by scheduling appointments, obtaining records, and electronic entry of data. The NCM shall review all patient appointment arrangements and medical records to provide detailed documentation in the Progress Notes of the patient’s medical chart. Administrative time is imperative for NCMs to meet program requirements. The NCM should assure that all aspects of the case management process are appropriately documented in the patient’s service record.

The NCM must have an organized manual or electronic tracking system in place to assure that patients receive appropriate and timely intervention. It is also strongly recommended that the WH-58 Case Management Form side (in this section) be used to assist staff with this required tracking and follow-up.

It is the responsibility of the KWCSP Nurse Case Manager (NCM) to contact the patient, surgeon or oncologist to ensure the patient has begun treatment for a cancer or pre-cancerous condition. The patient must have had a service that either removed part or all of her cancer or received chemotherapy or radiation to reduce her cancer for her treatment to be considered started. The NCM does not continue to provide case management for treatment once a patient is on the treatment program (BCCTP). The patient’s care will be managed by her Kentucky Medicaid health care providers. The NCM does not need to request treatment records. However, the NCM must document on the CH-3 nursing notes, the type of treatment that began the patient’s care and the date that it was performed. The NCM shall document the source of this information (doctor’s name and specialty, patient, etc.).

For further testing and management after the initial abnormal result, patients who qualify for KWCSP should be case managed by the local health department according to program guidelines. However, when a patient has a medical home, the patient may be referred back to the primary care physician for follow-up management, after the patient is informed of the abnormal test and need for follow-up. Health departments should have good communication with local medical home providers so that each provider’s role and expectations are clear.

A flowchart outlining the case management guidelines can be found at the end of the Cancer Screening/Follow-up Section.

A. **Informing the Patient of Abnormal Results**

Patients with an abnormal Pap test or mammogram result must be notified within 10 working days from receipt of the abnormal test result or within 30 days from the test date (whichever comes first) following this plan of action:

1. Whenever possible, the NCM shall contact the patient by telephone and have her come to the clinic for face-to-face counseling for abnormal test results. It is expected that the clinic has emergency numbers for all “no home contact” patients. Guidance for “no home contact” patients and minors is found in KRS 214.185.
2. When the patient comes in to the Health Department for counseling, test results and recommendations for follow-up are reviewed with the patient, options discussed and a letter explaining the result in writing is given to the patient. Arrangements for follow-up are then made (see Section B). The visit shall be documented in the patient chart.
3. If the NCM is unable to make verbal contact with the patient by phone then an attempt to contact the patient by letter on the same day as the unsuccessful phone call is necessary. The letter shall inform the patient about the abnormal test result with instructions to contact the NCM at the health department.
4. If the patient does not respond within 10 working days after the letter is mailed, the nurse shall then send a certified letter to the patient informing her of her abnormal test results with instructions to contact the health department.

Once the above has been completed with no response then it is appropriate to document the patient as lost to follow-up.

B. Follow-up for Abnormal Test Results

All patients with abnormal lab tests need follow-up. Patients who meet eligibility criteria for KWCSP must be referred according to program guidelines to contracted specialists for further testing/evaluation. Other patients may have a medical home (regular source of medical care) outside of the local health department (LHD). The patient’s medical home/PCP can be determined at registration.

Medical homes may include private physicians, Passport providers, Primary Care Centers, FQHC’s, and Community Health Centers. These providers will be responsible for arranging and providing follow-up care for their patients. Each local health department should maintain open communication with primary care providers in their area to be sure there is agreement on roles and expectations for follow-up of patients with abnormal results.

B1. Follow-up Arrangements for KWSCP-eligible Patients

1. The NCM will schedule an appointment for the patient with a KWSCP contracted provider for the appropriate follow-up testing or evaluation. A referral letter and reports of the abnormal test results are sent to the contracted provider who will be seeing the patient.
2. The NCM tracks to see that the patient showed for the appointment and documents the visit in the patient’s chart.
3. The NCM collects reports from the contracted provider and makes arrangements for further diagnostic testing as ordered.
4. If the patient does not keep an appointment for a scheduled consult appointment, diagnostic procedure, treatment, or follow-up/repeat Pap, a certified letter will be sent to the patient within 10 working days of the missed appointment. No further follow up tracking is needed for these patients. If the patient reschedules a missed appointment after receiving a certified letter and then does not keep that appointment, a second certified letter is not necessary.
5. All attempts of patient contact shall be documented in the progress notes (CH3A).
6. If the patient is a minor with a potentially life-threatening test result (includes a “HSIL” or “ASC-H” result on a Pap test or a “Suspicious Abnormality” or “Highly Suggestive of Malignancy” mammogram or ultrasound result) and cannot be contacted, the parent or guardian must be contacted. Minors shall be made aware of this policy at the screening visit.

B2. Follow-up Arrangements for Patients with a Medical Home

1. The NCM will schedule an appointment for the patient with their PCP for the appropriate follow-up testing or evaluation. A referral letter and reports of the abnormal test results along with past pertinent abnormal cervical cancer screening/diagnostic tests and results are sent to the Primary Care provider who will be seeing the patient. Document in the progress notes (CH3A) all transfer of care actions provided for the patient.
   NOTE: It is imperative that the PCP is informed of any of their patient’s abnormal test results. This will allow the PCP to assure that the patient receives the appropriate follow-up care.
2. If the patient is a minor with a potentially life-threatening test result (includes a “HSIL” or “ASC-H” result on a Pap test or a “Suspicious Abnormality” or “Highly Suggestive of Malignancy”
mammogram or ultrasound result) and cannot be contacted, the parent or guardian must be contacted. Minors shall be made aware of this policy at the screening visit.

3. All attempts of contact with the patient and PCP shall be documented in the patient’s progress notes (CH3A).

C. **Other Situations:**

Patients who are not KWCSP eligible and do not have a medical home: Local Health Departments may screen some patients who are not eligible for KWCSP and do not have a medical home. Efforts should be made to find the patient a medical home. If that is not possible, then the LHD may manage these patients following KWCSP protocols and providers. Efforts should be made to find other resources for financial assistance in these circumstances as they would not be covered by the KWCSP.

**Work-up Refused:** occurs when a patient has been notified and counseled (by phone or in person) regarding an abnormal result and either fails to keep a referral appointment for diagnostics/treatment or verbalizes her desire not to seek follow-up. The date of final contact should be noted in the service record (CH3A) and on WH-58 Data Collection Form side.

**Lost to Follow-up:** occurs when unable to inform and counsel the patient, either by phone or in person, regarding an abnormal test result. The date of the final contact attempt should be noted in the service record (CH3A) and on WH-58 Data Collection Form side.

**ACCEPTING REFERRALS/FOLLOW-UP REFERRAL REQUIREMENTS:**

Healthcare providers should be encouraged to refer uninsured women to the local health department as soon as possible to determine eligibility for the Kentucky Women’s Cancer Screening Program (KWCSP).

In the event a KWCSP eligible woman presents to the LHD for cancer-screening services, but has had a physical examination within the past 12 months that included CBE, Pelvic and Pap test from another healthcare provider, the following are requirements of the Kentucky Women’s Cancer Screening Program.

1. The woman must meet the eligibility requirements of the program and provide consent for services.
2. The patient is responsible for bringing her records at time of visit or having them sent to LHD prior to the visit. This will enable the LHD provider to assess if all the minimum requirements were met. These records must include copies of the actual physical examination (including CBE and pelvic examination) and a copy of the Pap test result as well as any other pertinent laboratory work such as stool for occult blood, hemoglobin, blood sugar, and cholesterol results. (A note from a physician such as “normal CBE needs mammogram” is not acceptable for medical record documentation).
3. The comprehensive health history form must be completed and reviewed with the patient. The height, weight, BMI and blood pressure should be obtained and recorded.
4. If the physical examination portion of the visit was completed elsewhere (within past 12 months) the nurse or clinician shall document on the physical exam form “See incoming records for the physical examination.”
5. If the provider has failed to provide documentation of ANY of the minimal requirements on the patient, the LHD is responsible for completing these components prior to referral for screening or diagnostic services.
6. It is the responsibility of the LHD to educate providers as to the minimal referral requirements of the program in order to accept patients for screening and possibly follow-up diagnostic services.
Able to contact pt by phone within 10 working days of receipt of abnormal test result or 30 days from procedure.

Schedule counseling appointment.

Pt. shows for counseling appt. NO

Counsel, give letter w/ result & schedule follow-up. Refer to LHD/Dx contracted provider or PCP.

Send copy of results, hx to LHD contracted provider. Send copy of results, hx to PCP.

YES

Assure that results are obtained & documented. Evaluate results for further need of diagnostic services.

NO

Did patient keep appointment?

YES

Does pt. require further diagnostics per report?

YES-Notify pt. & coordinate further dx procedures.

NO-Contact pt. & counsel regarding further screening recommendation.

Did pt. keep secondary dx follow-up appointments for services?

YES-Assure that results are obtained & documented. Contact pt. by phone within 10 working days of receipt or 30 days from procedure date to discuss further screening/dx results.

Could patient be reached by phone?

YES-Assure that pt. understands further screening recommendations.

NO

Send certified letter within 10 working days of missed appt. & document pt. refused.

Send letter to pt. w/ regarding abnormal results & need to contact LHD.

Did pt. contact LHD within 10 working days of letter being mailed?

YES-Schedule counseling appointment. See left side of diagram

NO-Send certified letter to pt.

Response from pt. within 10 working days of certified letter.

NO-Document lost to follow-up

YES-Schedule appointment. See left side of diagram.

NO
Emergencies
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CLINICAL PROTOCOLS

Medical Emergencies ........................................................................................................

Emergency Equipment, Supplies & Medications ..............................................................

Medical Emergencies Protocol .......................................................................................  
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  Dosages for Epinephrine Administered IM .................................................................
  Dosages for Diphenhydramine HCL (Benadryl®) Administered Orally ....................
  Dosages for Diphenhydramine HCL (Benadryl®) Administered IM ..........................

Naloxone Narcan Auto Injector ....................................................................................

Naloxone Intranasal .......................................................................................................
MEDICAL EMERGENCIES

LHDs should be prepared for medical emergencies, particularly, life-threatening drug reactions. Established procedures, adequate and properly maintained equipment, and appropriately trained staff are essential.

- Protocols for emergency care for anaphylactic reactions, and management of vasovagal reactions and syncope should be signed by a local physician and a copy kept with the emergency supplies.
- If the LHD stocks an Automated External Defibrillator (AED) device, it must develop and maintain local policies on its use and maintenance.
- LHD prepared for more extensive emergency measures should have a locally developed protocol in place to guide staff.
- Emergency equipment, supplies, and medications should be maintained on a crash cart or emergency tray.
- An inventory list is to be kept with the crash cart or emergency tray and monitored monthly according to an established schedule to ensure that they are not depleted or expired. Emergency supplies should be sealed when not in use.
- All physicians, clinicians, and nurses should be certified in CPR.
- All staff should be offered the opportunity to participate in CPR training.
- At a minimum, all staff must know their role in an emergency situation.
- All staff should have access to the Poison Control phone number, 1-800-222-1222, and it should be posted in a prominent place.
EMERGENCY EQUIPMENT, SUPPLIES, AND MEDICATIONS

Inventory List*

(When Equipment and Supplies are replaced, LHDs should order Latex-free.)

- AMBU bag – at least 1 Adult and 1 Pediatric unit (Latex-free), checked for physical integrity at least monthly and replaced per manufacturer’s recommendations.
- One-way masks – at least 1 adult and 1 pediatric mask, latex-free, and at least one replacement piece for each mask.
- Sphygmomanometer, age appropriate, ex. pediatric, adult, extra-large – serviced according to manufacturer’s recommendations.
- Stethoscope.
- Flashlight and extra batteries.
- Oxygen tank with mask (serviced yearly and checked monthly).
- Syringes and needles of various sizes, including filtered needles for use with ampoules (for the removals of minute particles of glass, filtered needles are not to be used for administration).
- Alcohol swabs or sponges.
- Gloves, latex-free.
- Aqueous epinephrine (1:1000); in either prefilled syringes, EpiPen® Auto-Injectors (0.3 mg) and EpiPen® Jr (0.15 mg) Auto-Injectors, or ampoules; at least 4 but more for medically isolated clinics. DO NOT BUY 30 mL vials of aqueous epinephrine.
- Diphenhydramine hydrochloride (HCL) (Benadryl® elixir) Liquid (Each 5 mL contains 12.5 mg of Diphenhydramine HCL); Diphenhydramine hydrochloride (Benadryl® Injection) 50 mg/mL in ampoules, disposable syringes, or vials, (a minimum of 4).
- Poison Control phone number 1-800-222-1222.
Find Your Local Poison Center:
http://www.aapcc.org/dnn/AAPCC/FindLocalPoisonCenters.aspx
- Kentucky Regional Poison Center
Medical Towers South, Suite 847
234 East Gray Street
Louisville, KY 40202
Emergency Phone: (800) 222-1222
http://www.krpc.com/
- Emergency equipment, supplies and medications inventory list with log of monthly reviews/inventory.
- Emergency protocols signed by a local physician.

*A copy of the Emergency Equipment, Supplies, and Medications list is to be placed on the crash cart, emergency tray, or off-site emergency kits with a copy of the current signed protocols.

LHDs may develop modified equipment lists and modified emergency and anaphylactic shock protocols for off-site service or alternate service delivery sites. These should, at a minimum, include epinephrine and diphenhydramine hydrochloride, as well as access to a phone to summon emergency personnel (911).
**MEDICAL EMERGENCIES PROTOCOL**

For various reasons in a LHD setting, a patient may complain of feeling “light headed”, “faint”, or actually “passing out”. This may be as simple as a reaction to certain sensory stimuli, real or perceived pain, or sudden changes in position or as severe as an acute medical condition, such as cardiac or other life threatening conditions.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syncope/Vasovagal Reaction “light headed – fainting”</td>
<td></td>
</tr>
<tr>
<td>Response to patient is usually immediate when measures are taken.</td>
<td>• ABC’s (Airway, Breathing, Circulation)</td>
</tr>
<tr>
<td></td>
<td>• Place patient in supine position and loosen clothing.</td>
</tr>
<tr>
<td></td>
<td>• Elevate lower extremities 20–30 degrees.</td>
</tr>
<tr>
<td></td>
<td>• Monitor and record BP, pulse and respirations.</td>
</tr>
<tr>
<td></td>
<td>• Document all findings and actions in patient’s medical record.</td>
</tr>
<tr>
<td></td>
<td>• Question patient after episode about feelings prior to syncope and whether this is an isolated event or “usual response” to certain stimuli.</td>
</tr>
<tr>
<td></td>
<td>• Advise patient to report this to their physician or primary care provider for further investigation.</td>
</tr>
<tr>
<td>Suspected Severe, Acute Medical Condition</td>
<td>• ABC’s</td>
</tr>
<tr>
<td>including cardiac arrest, shock, hemorrhage, and/or aspiratory difficulties</td>
<td>• Call for staff assistance</td>
</tr>
<tr>
<td></td>
<td>• Maintain <strong>AIRWAY</strong>, provide <strong>CPR</strong> if necessary</td>
</tr>
<tr>
<td></td>
<td>o Place patient in supine position and loosen clothing.</td>
</tr>
<tr>
<td></td>
<td>o Monitor and record vital signs.</td>
</tr>
<tr>
<td></td>
<td>• Call 911 or local Emergency Medical Services immediately (preferably have someone not involved in direct patient care make the call).</td>
</tr>
</tbody>
</table>

*Place a copy of this protocol on the crash cart, emergency tray with the Emergency Equipment, Supplies and Medications Inventory List and the Treatment of Anaphylactic Shock Protocol. Modified emergency and anaphylactic shock protocols may be developed locally for off-site service.*
<table>
<thead>
<tr>
<th>Condition</th>
<th>Observation/Assessment</th>
<th>Intervention (Mild and Moderate Reactions)</th>
</tr>
</thead>
</table>
| MILD REACTION (May rapidly progress to a more severe reaction) | • Generalized flush  
• Red, itchy, eyes  
• Itching at the injection site or at other body sites  
• Localized to generalized urticaria (hives)  
• Vomiting, abdominal pain | • ABC’s.  
• Call 911 or local EMS STAT (Preferably have someone not involved in direct patient care make the call).  
• Place patient in supine position.  
• Monitor vital signs.  
• GIVE OXYGEN BY MASK, if any respiratory symptoms are present  
  ○ Special instructions** for O2 administration, if given (O2 flow rate, lpm)  
• FIRST-LINE TREATMENT: GIVE AGE AND WEIGHT APPROPRIATE DOSES OF EPINEPHRINE, intramuscularly, preferably in the anterolateral thigh (See Table 1). Repeat every 5–15 minutes, up to 3 doses, depending on patient’s response  
• SECONDARY TREATMENT: As an adjunct to epinephrine, give weight or age appropriate doses of diphenhydramine HCL orally or intramuscularly (See Table 2 or Table 3). DO NOT GIVE diphenhydramine HCL to infants aged less than 7 months  
• Continue to observe for change in symptoms (lessening or worsening)  
• Maintain accurate emergency flow sheet showing:  
  ○ Date  
  ○ Time of occurrence  
  ○ Vital Signs  
  ○ Medication(s) (time, dosage, response,, name of healthcare personnel who administered the medication)  
  ○ Immediate therapy  
  ○ Disposition of patient (transfer for further emergency care ASAP)  
• Send summary of emergency treatment with patient with written assessment of patient’s condition at time of transfer.  
• Document all measures taken in patient’s medical record and place allergy label on front of patient’s medical record. Advise patient (parent) about the drug or trigger that caused reaction.  
• Advise patient (parent) to report reaction to their physician or primary care provider. |
| MODERATE REACTION | • Mild to moderate wheezing  
• Coughing  
• Complains of generalized itching, itching throat  
• Generalized urticaria (hives)  
• Swelling of lips, face, tongue, eyelids, hands, feet, or genitalia.  
• Vomiting, diarrhea, and/or abdominal pain | |

* Place a copy of this protocol on the crash cart, emergency tray with the Emergency Equipment, Supplies and Medications Inventory List and Medical Emergencies Protocol. Modified emergency and anaphylactic shock protocols may be developed locally for off-site service.

** Oxygen flow rates, particularly for infants and children, depend upon the equipment available. LHDs should consult the equipment manufacturer for relevant information and annotate protocols with the appropriate oxygen flow rates.  
<table>
<thead>
<tr>
<th>Condition</th>
<th>Observation/Assessment</th>
<th>Intervention (Severe Reaction)</th>
</tr>
</thead>
</table>
| SEVERE REACTION | • Anxiety  
• Shortness of Breath  
• Severe Wheezing  
• Progressive swelling of lips, face, tongue, eyelids, hands, feet, or genitalia.  
• Progressive generalized urticaria (hives)  
• Restlessness  
• Headache  
• Vomiting  
• Incontinence  
• Cyanosis  
• Confusion  
• Weak rapid pulse  
• Hypotension  
• Shock  
• Unconsciousness | • ABC’s  
→ Call 911 or local EMS STAT (Preferably have someone not involved in direct patient care make the call).  
• Place patient in supine position.  
• Elevate legs and loosen clothing.  
• Elevate head, if breathing is difficult.  
• Monitor pulse and respiration, mental status q 1–2 minutes.  
• Monitor BP – age 3 years and up  
→ GIVE OXYGEN BY MASK (Maintain airway – hypoxia can result from hypotension and upper airway edema).  
  o Special Instructions** for O2 administration, if given  
  (O2 flow rate, lpm) _______  
• FIRST-LINE TREATMENT: GIVE AGE AND WEIGHT APPROPRIATE DOSES OF EPINEPHRINE, intramuscularly, preferably in the anterolateral thigh (See Table 1). Repeat every 5–15 minutes, up to 3 doses, depending on patient’s response  
• SECONDARY TREATMENT: As an adjunct to epinephrine, give weight or age appropriate doses of diphenhydramine HCL intramuscularly (See Table 3). DO NOT GIVE diphenhydramine HCL to infants aged less than 7 months  
• Perform cardiopulmonary resuscitation, if necessary  
• Maintain accurate emergency flow sheet showing:  
  o Date  
  o Time of occurrence  
  o Vital Signs  
  o Medication(s) (time, dosage, response,, name of healthcare personnel who administered the medication)  
  o Immediate therapy  
  o Disposition of patient (transfer for further emergency care ASAP)  
• Send summary of emergency treatment with patient with written assessment of patient’s condition at time of transfer.  
• Document all measures taken in patient’s medical record and place allergy label on front of patient’s medical record. |

* Place a copy of this protocol on the crash cart, emergency tray with the Emergency Equipment, Supplies and Medications Inventory List and Medical Emergencies Protocol. Modified emergency and anaphylactic shock protocols may be developed locally for off-site service.

** Oxygen flow rates, particularly for infants and children, depend upon the equipment available. LHDs should consult the equipment manufacturer for relevant information and annotate protocols with the appropriate oxygen flow rates.

Table 1: Dosages for Epinephrine Administered Intramuscularly

The recommended dose of epinephrine is 0.01 mg/kg body weight. Repeat every 5–15 min. up to 3 doses, depending on patient’s response.

<table>
<thead>
<tr>
<th>Age Group:</th>
<th>Range of Weight (Pounds)*</th>
<th>Range of Weight (Kilograms)†</th>
<th>Epinephrine Dose: 1 mg/mL injectable (1:1000 dilution) intramuscular (IM) Minimum dose: 0.05 mL</th>
<th>Epinephrine Auto-Injector (EpiPen)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants and Children</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - 6 months</td>
<td>9 - 19 lbs</td>
<td>4 - 8.5 kg</td>
<td>0.05 mL (or mg)</td>
<td>Off label</td>
</tr>
<tr>
<td>7 - 36 months</td>
<td>20 - 32 lbs</td>
<td>9 - 14.5 kg</td>
<td>0.1 mL (or mg)</td>
<td>Off label</td>
</tr>
<tr>
<td>37 - 59 months</td>
<td>33 - 39 lbs</td>
<td>15 - 17.5 kg</td>
<td>0.15 mL (or mg)</td>
<td>0.15 mg</td>
</tr>
<tr>
<td>5 - 7 years</td>
<td>40 - 56 lbs</td>
<td>18 - 25.5 kg</td>
<td>0.2 - 0.25 mL (or mg)</td>
<td>0.15 mg</td>
</tr>
<tr>
<td>8 - 10 years</td>
<td>57 - 76 lbs</td>
<td>26 - 34.5 kg</td>
<td>0.25 - 0.3 mL† (or mg)</td>
<td>0.15 mg or 0.3 mg</td>
</tr>
<tr>
<td>Teens</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 - 12 years</td>
<td>77 - 99 lbs</td>
<td>35 - 45 kg</td>
<td>0.35 - 0.4 mL (or mg)</td>
<td>0.3 mg</td>
</tr>
<tr>
<td>13 - 18 years</td>
<td>100+ lbs</td>
<td>46+ kg</td>
<td>0.5 mL (or mg)‡</td>
<td>0.3 mg</td>
</tr>
<tr>
<td>Adults</td>
<td>19 years &amp; older</td>
<td>100+ lbs</td>
<td>46+ kg</td>
<td>0.5 mL (or mg)‡</td>
</tr>
</tbody>
</table>

Note: If body weight is known, then dosing by weight is preferred. If weight is not known or readily available, dosing by age is appropriate.

* Rounded weight for infants, children, and teens at the 50th percentile for each age range
† Maximum dose for children
‡ Maximum dose for teens and adults
Table 2: Dosages for Diphenhydramine HCL (Benadryl®) Administered Orally

The recommended dose of diphenhydramine HCL is 1 – 2 mg/kg body weight.

<table>
<thead>
<tr>
<th>Age Group:</th>
<th>Range of Weight (Pounds)</th>
<th>Range of Weight (Kilograms)</th>
<th>Benadryl Dose, given orally:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants and Children</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - 6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 - 36 months</td>
<td>20 - 32 lbs</td>
<td>9 - 14.5 kg</td>
<td>12.5 mg/5 mL liquid,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>12.5 mg/5 mL liquid</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose, orally, mL</td>
</tr>
<tr>
<td></td>
<td>DO NOT GIVE TO THIS AGE GROUP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>37 - 59 months</td>
<td>33 - 39 lbs</td>
<td>15 - 17.5 kg</td>
<td>12.5 mg/5 mL liquid,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>12.5 mg/5 mL liquid</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose, orally, mL</td>
</tr>
<tr>
<td>5 - 7 years</td>
<td>40 - 56 lbs</td>
<td>18 - 25.5 kg</td>
<td>12.5 mg/5 mL liquid,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>12.5 mg/5 mL liquid</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose, orally, mL</td>
</tr>
<tr>
<td>8 - 12 years</td>
<td>57 - 99 lbs</td>
<td>26 - 45 kg</td>
<td>12.5 mg/5 mL liquid,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>12.5 mg/5 mL liquid</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose, orally, mL</td>
</tr>
<tr>
<td>Teens</td>
<td>100+ lbs</td>
<td>46+ kg</td>
<td>12.5 mg/5 mL liquid,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>12.5 mg/5 mL liquid</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose, orally, mL</td>
</tr>
<tr>
<td>Adults</td>
<td>100+ lbs</td>
<td>46+ kg</td>
<td>12.5 mg/5 mL liquid,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>12.5 mg/5 mL liquid</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose, orally, mL</td>
</tr>
</tbody>
</table>

**Note:** If body weight is known, then dosing by weight is preferred. If weight is not known or readily available, dosing by age is appropriate.

*Rounded weight for infants, children, and teens at the 50th percentile for each age range
† Maximum dose for children
‡ Maximum dose for teens and adults
<table>
<thead>
<tr>
<th>Age Group:</th>
<th>Range of Weight (Pounds)*</th>
<th>Range of Weight (Kilograms)*</th>
<th>Benadryl Dose, given by injection:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>50 mg/mL injectable IM</td>
</tr>
<tr>
<td>Infants and Children</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - 6 months</td>
<td>20 - 32 lbs</td>
<td>9 - 14.5 kg</td>
<td>10 mg – 20 mg</td>
</tr>
<tr>
<td>7 - 36 months</td>
<td>DO NOT ADMINISTER TO THIS AGE GROUP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>37 - 59 months</td>
<td>33 - 39 lbs</td>
<td>15 - 17.5 kg</td>
<td>15 mg – 30 mg</td>
</tr>
<tr>
<td>5 - 7 years</td>
<td>40 - 56 lbs</td>
<td>18 - 25.5 kg</td>
<td>20 mg – 30 mg</td>
</tr>
<tr>
<td>8 - 12 years</td>
<td>57 - 99 lbs</td>
<td>26 - 45 kg</td>
<td>30 mg†</td>
</tr>
<tr>
<td>Teens</td>
<td>13 - 18 years</td>
<td>100+ lbs</td>
<td>46+ kg</td>
</tr>
<tr>
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</tr>
</tbody>
</table>

**Note:** If body weight is known, then dosing by weight is preferred. If weight is not known or readily available, dosing by age is appropriate.

*Rounded weight for infants, children, and teens at the 50th percentile for each age range
† Maximum dose for children
‡ Maximum dose for teens and adults
Naloxone (NARCAN)

Auto-Injector

Indications

Naloxone is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

- Naloxone is intended for immediate administration as emergency therapy in settings where opioids may be present.
- Naloxone is not a substitute for emergency medical care. When in doubt, if an individual is unresponsive and an opioid overdose is suspected, administer naloxone as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death.
- Call 911 to activate EMS immediately after administering the first dose of naloxone.

Signs and Symptoms of Opioid Overdose

All local health department nurses should be trained on how to recognize the signs and symptoms of an opioid overdose requiring the use of a naloxone. Symptoms of an opioid overdose requiring the use of naloxone may include but are not limited to the following:

- extreme sleepiness (inability to awaken verbally or upon sternal rub)
- breathing problems which can range from slow to shallow breathing in a patient that cannot be awakened
- fingernails or lips turning blue/purple
- extremely small “pinpoint” pupils
- slow heartbeat and/or low blood pressure

Signs of overmedication which may progress to overdose include:

- unusual sleepiness
- drowsiness or difficulty staying awake despite loud verbal stimulus or vigorous sternal rub
- mental confusion
- slurred speech
- intoxicated behavior
- slow or shallow breathing
- extremely small “pinpoint” pupils, although normal size pupils do not exclude opioid overdose
- slow heartbeat
- low blood pressure
- difficulty waking the person from sleep
It is important to note that not all signs and symptoms may be present during an opioid overdose. If the individual is not responsive to shaking, yelling or vigorously rubbing their sternum, ACT PROMPTLY!!

- CALL FOR HELP
- CHECK FOR BREATHING
- CALL 911 IMMEDIATELY
- GET THE NALOXONE

Dosage, Route and Anatomical Site

There are multiple routes of administration for FDA approved naloxone: intramuscular, subcutaneous and intravenous. For the purposes of this protocol, the use of the FDA approved naloxone via prefilled syringe as well as the auto-injector will be reviewed.

Most patients respond by returning to spontaneous breathing, with minimal withdrawal symptoms. The response generally occurs within 3 to 5 minutes of naloxone administration. Rescue breathing should continue while waiting for the naloxone to take effect.

Preparing naloxone in a pre-filled syringe:

- Quickly open the box and pull out the pre-filled 1 milliliter syringe
- Attach the 1-1 ½ inch needle to the syringe
- Remove the safety cap on the needle
- Quickly push the needle straight down into the outer mid-thigh muscle, through the clothes if necessary and push down on the plunger
- Put the needle/syringe in a sharps container

Use of the naloxone auto injector:

- Pull auto injector from the outer case
- Quickly visually inspect the naloxone auto injector through the viewing window for particulate matter and discoloration prior to administration. Do not administer unless the solution is clear and the glass container is undamaged
- Remove the safety cap, pull firmly
- Immediately place the auto injector against the outer mid-thigh, through the clothes if necessary, and press firmly and hold for 5 seconds. You may hear a normal clicking sound.
- To reduce the chance of an accidental injection to yourself, do not touch the base of the auto-injector which is where the needle comes out. If an accidental injection happens, get medical help right away.
- If the individual is breathing on their own, place them in the recovery position.

Naloxone will continue to work for as long as 30 to 90 minutes, but after that time, overdose symptoms may return.
ASSURE 911 HAS BEEN CALLED and that EMS has been activated. If no one has yet called 911, IMMEDIATELY CALL 911.

After giving naloxone, stay with the individual. If they are breathing on their own, to decrease the individual’s chance of choking on their vomit, place them in the recovery position, on their side and support the body with one bent knee with the face turned to the side.

STAY WITH THE PERSON AND MONITOR FOR RESPIRATORY DISTRESS. Provide rescue breathing as necessary. It is necessary to seek immediate emergency medical assistance (911) after delivering the first dose of naloxone, keep the patient under continued surveillance and repeat doses of naloxone as necessary.

REPEATNALOXONE ADMINISTRATION IF SYMPTOMS CONTINUE. The duration of action of most opioids is likely to exceed the 30-90 minutes that naloxone will be effective, resulting in a return of respiratory and/or central nervous system depression, even after an initial improvement in symptoms. If the desired response is not obtained after 2 or 3 minutes, another dose of naloxone may be administered if available.

If after 1-2 doses of naloxone there is no breathing or breathing continues to be shallow, lay the person on their back and continue to perform rescue breathing while waiting for the naloxone to take effect, the person breathes for themselves or EMS arrives.

Contraindications
NARCAN is contraindicated in patients known to be hypersensitive to naloxone hydrochloride or to any of the other ingredients.

Warnings and Precautions

- Due to the duration of action, keep the patient under continued surveillance and repeated doses of naloxone should be administered, as necessary, while awaiting emergency medical assistance.
- Other supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.
- Reversal of respiratory depression by partial agonists or mixed agonists/antagonists such as buprenorphine and pentazocine, may be incomplete.
- Use in patients who are opioid dependent may precipitate acute abstinence syndrome.
- Patients with pre-existing cardiac disease or patients who have received medications with potential adverse cardiovascular effects should be monitored in an appropriate healthcare setting.
- In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated.
Adverse Reactions

- The following adverse reactions have been identified during use of naloxone hydrochloride in the post-operative setting: Hypotension, hypertension, ventricular tachycardia and fibrillation, dyspnea, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as sequelae of these events.
- Excessive doses of naloxone hydrochloride in post-operative patients have resulted in significant reversal of analgesia and have caused agitation.
- Abrupt reversal of opioid effects in persons who were physically dependent on opioids has precipitated signs and symptoms of opioid withdrawal including: body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, tachycardia.
- In the neonate, opioid withdrawal signs and symptoms also included: convulsions, excessive crying, hyperactive reflexes.

To report SUSPECTED ADVERSE REACTIONS, contact kaleo, Inc. at 1-855-773-8946 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Storage and Handling

- Store naloxone at controlled room temperature 15°C to 25°C (59°F to 77°F) and in a dark area.
- The naloxone should be checked monthly to ensure proper storage, expiration date, and medication stability. Expired naloxone or those with discolored solution or solid particles should not be used. Discard them in a sharps container.
- Local health department clinical staff should be familiar with the type of naloxone maintained by their agency and its use.
- Local health department clinical staff should refer to the package insert and store naloxone hydrochloride according to the individual manufacturer’s direction.

Other Important Notes

Naloxone is supplied in a carton containing two pre-filled naloxone hydrochloride injections, USP 0.4 mg auto-injectors and a single black and white trainer that can be used for practice.
NAOXONE
INTRANASAL

Indications and Usage

- Nasal Spray is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
- NARCAN Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.
- NARCAN Nasal Spray is not a substitute for emergency medical care.

Dosage and Administration

- NARCAN Nasal Spray is for intranasal use only.
- Seek emergency medical care immediately after use.
- Administer a single spray of NARCAN Nasal Spray to adults or pediatric patients intranasally into one nostril.
- Administer additional doses of NARCAN Nasal Spray, using a new nasal spray with each dose, if the patient does not respond or responds and then relapses into respiratory depression, additional doses of NARCAN Nasal Spray may be given every 2 to 3 minutes until emergency medical assistance arrives.
- Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.
- To access the Narcan Nasal Spray Quick Start Guide, please see the Narcan Nasal Spray instructions at: https://www.narcan.com/pdf/NARCAN-Quick-Start-Guide.pdf

Dosage Forms and Strength

Nasal spray: 4 mg of naloxone hydrochloride in 0.1 mL

Signs and Symptoms of Opioid Overdose

All local health department nurses should be trained on how to recognize the signs and symptoms of an opioid overdose requiring the use of a naloxone. Symptoms of an opioid overdose requiring the use of naloxone may include but are not limited to the following:

- extreme sleepiness (inability to awaken verbally or upon sternal rub)
- breathing problems which can range from slow to shallow breathing in a patient that cannot be awakened
- fingernails or lips turning blue/purple
- extremely small “pinpoint” pupils
- slow heartbeat and/or low blood pressure
Signs of overmedication which may progress to overdose include:

- unusual sleepiness
- drowsiness or difficulty staying awake despite loud verbal stimulus or vigorous sternal rub
- mental confusion
- slurred speech
- intoxicated behavior
- slow or shallow breathing
- extremely small “pinpoint” pupils, although normal size pupils do not exclude opioid overdose
- slow heartbeat
- low blood pressure
- difficulty waking the person from sleep

Naloxone will continue to work for as long as 30 to 90 minutes, but after that time, overdose symptoms may return.

ASSURE 911 HAS BEEN CALLED and that EMS has been activated. If no one has yet called 911, IMMEDIATELY CALL 911.

After giving naloxone, stay with the individual. If they are breathing on their own, to decrease the individual’s chance of choking on their vomit, place them in the recovery position, on their side and support the body with one bent knee with the face turned to the side.

STAY WITH THE PERSON AND MONITOR FOR RESPIRATORY DISTRESS. Provide rescue breathing as necessary. It is necessary to seek immediate emergency medical assistance (911) after delivering the first dose of naloxone. Keep the patient under continued surveillance and repeat doses of naloxone as necessary.

REPEATNALOXONE ADMINISTRATION IF SYMPTOMS CONTINUE. The duration of action of most opioids is likely to exceed the 30-90 minutes that naloxone will be effective, resulting in a return of respiratory and/or central nervous system depression, even after an initial improvement in symptoms. If the desired response is not obtained after 2 or 3 minutes, another dose of naloxone may be administered if available.

If after 1-2 doses of naloxone there is no breathing or breathing continues to be shallow, lay the person on their back and continue to perform rescue breathing while waiting for the naloxone to take effect, the person breathes for themselves or EMS arrives.
Contraindications

Hypersensitivity to naloxone hydrochloride

Warnings and Precautions

- Risk of Recurrent Respiratory and CNS Depression: Due to the duration of action of naloxone relative to the opioid, keep patient under continued surveillance and administer repeat doses of naloxone using a new nasal spray with each dose, as necessary, while awaiting emergency medical assistance.
- Risk of Limited Efficacy with Partial Agonists or Mixed Agonists/Antagonists: Reversal of respiratory depression caused by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses may be required.
- Precipitation of Severe Opioid Withdrawal: Use in patients who are opioid dependent may precipitate opioid withdrawal. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated. Monitor for the development of opioid withdrawal.
- Risk of Cardiovascular (CV) Effects: Abrupt postoperative reversal of opioid depression may result in adverse CV effects. These events have primarily occurred in patients who had preexisting CV disorders or received other drugs that may have similar adverse CV effects. Monitor these patients closely in an appropriate healthcare setting after use of naloxone hydrochloride.

Adverse Reactions

The following adverse reactions were observed in a NARCAN Nasal Spray clinical study: increased blood pressure, musculoskeletal pain, headache, nasal dryness, nasal edema, nasal congestion, and nasal inflammation.

To report SUSPECTED ADVERSE REACTIONS, contact Adapt Pharma, Inc. at 1-844-4NARCAN (1-844-462-7226) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
How To Administer Intranasal Narcan

How to use NARCAN nasal spray:

Step 1. Lay the person on their back to receive a dose of NARCAN Nasal Spray.

Step 2. Remove NARCAN Nasal Spray from the box. Peel back the tab with the circle to open the NARCAN Nasal Spray.

Step 3. Hold the NARCAN Nasal Spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.

Step 4. Tilt the person’s head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril until your fingers on either side of the nozzle are against the bottom of the person’s nose.

Step 5. Press the plunger firmly to give the dose of NARCAN Nasal Spray.

Step 6. Remove the NARCAN Nasal Spray from the

Step 7. Get emergency medical help right away.

- Move the person on their side (recovery position) after giving NARCAN Nasal Spray.
- Watch the person closely.
- If the person does not respond by waking up, to voice or touch, or breathing normally another dose may be given. NARCAN Nasal Spray may be dosed every 2 to 3 minutes, if available.
- Repeat Steps 2 through 6 using a new NARCAN Nasal Spray to give another dose in the other nostril. If additional NARCAN Nasal Sprays are available, Steps 2 through 6 may be repeated every 2 to 3 minutes until the person responds or emergency medical help is received.

Step 8. Put the used NARCAN Nasal Spray back into its box.

Step 9. Throw away (dispose of) the used NARCAN Nasal Spray in a place that is away from children.
**HOW NALOXONE IS SUPPLIED**

Intranasal naloxone is supplied in a carton containing two blister packages each with a single NARCAN Nasal Spray (single 4 mg dose of naloxone hydrochloride intranasal spray).

For questions regarding dosage or timing of the brand being used, please see product package insert instructions developed by the manufacturer.

**STORAGE AND HANDLING OF INTRANASAL NALOXONE**

Store NARCAN Nasal Spray in the blister and cartons provided in a controlled room temperature 15°C to 25°C (59°F to 77°F) and in a dry, dark area.

The naloxone should be checked monthly to ensure proper storage, expiration date, and medication stability.

Local Health Department clinical staff should be familiar with the type of naloxone maintained by the clinic and its use.

Local Health Departments should refer to the package insert and store naloxone hydrochloride according to the individual manufacturer’s direction.

**REFERENCES AND SOURCES**

6. Percocet® (oxycodone hydrochloride and acetaminophen tablets) [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc; 2013.
7. Opana® (oxymorphone hydrochloride tablet) [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc; 2013.

**Additional Resources**

14. [http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm391465.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm391465.htm)
# Family Planning

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<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>• Mental Health</td>
<td>• Mental Health</td>
<td>• Identify any changes to medical history</td>
<td>• Mental Health</td>
<td>• Date of last menstrual period</td>
<td>• Medical History (STD-1)</td>
</tr>
<tr>
<td>• Alcohol and Drug Use</td>
<td>• Alcohol and Drug Use</td>
<td>• Identify any changes to reproductive history since initial visit</td>
<td>• Alcohol and Drug Use</td>
<td>• Partner/sexual history</td>
<td>- Symptom description and onset</td>
</tr>
<tr>
<td>• Tobacco use</td>
<td>• Tobacco use</td>
<td>• Compliance with routine contraceptive method</td>
<td>• Date of unprotected sex</td>
<td>• Reproductive Life Plan</td>
<td>- Current Medications</td>
</tr>
<tr>
<td>• Immunizations</td>
<td>• Immunizations</td>
<td>• Side effects to present method</td>
<td>• Complete menstrual history</td>
<td>• Present contraceptive use</td>
<td>- Current allergies</td>
</tr>
<tr>
<td>• Chronic health conditions</td>
<td>• Chronic health conditions</td>
<td>• Risk of abuse, neglect, violence, exploitation</td>
<td>• Reproductive Life Plan</td>
<td>• Contraceptive accident or failure</td>
<td>- History of hospitalizations, major injuries, or surgeries</td>
</tr>
<tr>
<td>• Current Medications</td>
<td>• Current Medications</td>
<td>• Multivitamin use</td>
<td>• Sexual health assessment</td>
<td>• Signs/symptoms ectopic pregnancy</td>
<td>- Current medical conditions</td>
</tr>
<tr>
<td>• Risk of abuse, neglect, violence, exploitation</td>
<td>• Risk of abuse, neglect, violence, exploitation</td>
<td>• FEMALES:</td>
<td>• Sexual practices (e.g. vaginal, anal, oral)</td>
<td>• Pregnancy planned or unplanned</td>
<td>- Sexual health history</td>
</tr>
<tr>
<td>• Multi vitamin use</td>
<td>• Multivitamin use</td>
<td>- Complete menstrual history</td>
<td>• Number and gender of partners</td>
<td>• Risk of abuse, neglect, violence, exploitation</td>
<td>- Partner history</td>
</tr>
<tr>
<td>• Females:</td>
<td>• Females:</td>
<td>- Gynecological history</td>
<td>• Pregnancy Prevention including current and previous use of methods, difficulties with contraception, desired contraceptive method</td>
<td>• STD/HIV risk or exposure</td>
<td>- Reproductive Life Plan</td>
</tr>
<tr>
<td>- Complete menstrual history</td>
<td>- Complete menstrual history</td>
<td>- Obstetrical history</td>
<td>• STD history</td>
<td>• Compliance with routine contraceptive method</td>
<td></td>
</tr>
<tr>
<td>- Gynecological history</td>
<td>- Gynecological history</td>
<td>• Reproductive Life Plan</td>
<td>• Practices to prevent STDs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Obstetrical history</td>
<td>- Obstetrical history</td>
<td>• Sexual health assessment</td>
<td>• Partner history of STDs, IV drug use, sex with multiple partners</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Reproductive Life Plan</td>
<td>• Reproductive Life Plan</td>
<td>- Sexual practices</td>
<td>- Partner history of STDs, IV drug use, sex with multiple partners</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Sexual health assessment</td>
<td>- Sexual practices</td>
<td>- Number and gender of partners</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Number and gender of partners</td>
<td>- Number and gender of partners</td>
<td>- Pregnancy Prevention including current and previous use of methods, difficulties with contraception, desired contraceptive method</td>
<td></td>
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<tr>
<td>- STD history</td>
<td>- STD history</td>
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<td>• STDs</td>
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<tr>
<td>- Practices to prevent STDs</td>
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</tr>
</tbody>
</table>

| • Height, weight, BMI | • Baseline weight, BMI | • Blood Pressure, as indicated | • Blood Pressure, as indicated | • Observe for abuse or domestic violence | • Physical exam, as indicated. Use STD-1 (males) or FPS-1 (females) |
| • Blood Pressure      | • Blood Pressure | | | • Blood pressure | | |
| • Physical exam       | • Pregnancy status | | | • Height/weight/BMI (If ≥25, recommend nutritional counseling) | | |
| • Pelvic exam as indicated by sexual health history and Cancer Screening Guidelines (see KWCSM matrix), Clinical Breast Exam per Cancer Screening Guidelines | • Other physical assessment, as indicated | | | • Mental status | | |
| | | | | • Pelvic exam if indicated | | | |

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### Contraceptive Service Visits

<table>
<thead>
<tr>
<th>Initial and Annual Visit</th>
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<th>STD Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>As clinically indicated:</td>
<td>Pregnancy test, if indicated</td>
<td>STD, HIV, Hepatitis C testing, if indicated</td>
<td>STD, HIV, Hepatitis C testing, if indicated</td>
<td>• Urine Pregnancy Test Negative Result</td>
<td>• STD, HIV, and HCV testing as indicated</td>
</tr>
<tr>
<td>• Pap test as recommended by Cancer Screening Guidelines.</td>
<td>STD, HIV, Hepatitis C based on sexual health history</td>
<td>• CHlamydia/Gonorrhea-annual routine screening for age ≤ 24 years</td>
<td>• CHlamydia/Gonorrhea-annual routine screening for age ≤ 24 years</td>
<td>• STD, HIV, Hepatitis C testing based on risk factors</td>
<td>• Other tests, as indicated (e.g. HBV)</td>
</tr>
<tr>
<td>• CHlamydia/Gonorrhea-annual routine screening for age ≤ 24 years</td>
<td>Other per patient assessment</td>
<td>Other per patient assessment</td>
<td>Other per patient assessment</td>
<td>• CHlamydia/Gonorrhea-annual routine screening for age ≤ 24 years</td>
<td>• See STD guidelines</td>
</tr>
<tr>
<td>• STD, HIV, Hepatitis C based on sexual health history</td>
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<tr>
<td>• Other per patient assessment</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>FPEM 19 – Family Planning Booklet</th>
<th>FPEM 19 – Family Planning Booklet</th>
<th>As assessed for individual patient needs</th>
<th>Follow appropriate contraceptive services protocol if patient desires contraceptive method.</th>
<th>Follow appropriate contraceptive services protocol if patient desires contraceptive method.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive Life Plan</td>
<td>Reproductive Life Plan</td>
<td></td>
<td>May provide the following, if indicated:</td>
<td>May provide the following, if indicated:</td>
</tr>
<tr>
<td>Method specific FPEM</td>
<td>Method specific FPEM</td>
<td></td>
<td>- FPEM-1 Benefits of planned pregnancy; compliance with routine method</td>
<td>- FPEM-1 Benefits of planned pregnancy; compliance with routine method</td>
</tr>
<tr>
<td>- Follow up visit as needed</td>
<td>- Follow up visit as needed</td>
<td></td>
<td>- ACHI-9 Healthier Lifestyles for Family Planning</td>
<td>- ACHI-9 Healthier Lifestyles for Family Planning</td>
</tr>
<tr>
<td>Adolescent Client Counseling:</td>
<td>Adolescent Client Counseling:</td>
<td></td>
<td></td>
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<tr>
<td>- Abstinence</td>
<td>- Abstinence</td>
<td></td>
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<tr>
<td>- Parental Involvement</td>
<td>- Parental Involvement</td>
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<tr>
<td>- Sexual Coercion</td>
<td>- Sexual Coercion</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>NEGATIVE PREGNANCY TEST</strong></th>
<th><strong>POSITIVE PREGNANCY TEST</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Options Counseling to identify woman’s choice to maintain the pregnancy, adoption, or termination of pregnancy</td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

July 2019
<table>
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<tbody>
<tr>
<td>Topics to consider:</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>- Benefits of family</td>
<td>Counsel client, as indicated, based on history and assessment. See “Topics to consider” in the initial and annual visit column -</td>
<td></td>
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<tr>
<td>- resources for mental</td>
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<tr>
<td>- health and/or substance abuse;</td>
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</tr>
<tr>
<td>- domestic violence hotline and rape crisis hotline;</td>
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<tr>
<td>- how to use a condom;</td>
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<tr>
<td>- STD/HIV education;</td>
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<tr>
<td>- screening pap test;</td>
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<tr>
<td>- other topics as indicate</td>
<td></td>
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</tr>
<tr>
<td>RN may provide OCPs, DMPA, rings or patches if unable to provide the initial/annual exam. The initial/annual exam may be deferred up to 3 months if the physician/APRN responsible for the medical direction of family planning services signs the deferred exam protocol (ACH 264B).</td>
<td></td>
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</tr>
<tr>
<td>- Contraceptive method of choice</td>
<td>Contraceptive method of choice- up to 3 month supply</td>
<td>Contraceptive method of choice</td>
<td>Provide with FDA Approved emergency contraception</td>
<td>POSITIVE TEST - Provide services based on choice of options for pregnancy and resources for prenatal, care, adoption, foster care, or termination as appropriate.</td>
<td>Follow-up appointment for test results and/or treatment</td>
</tr>
<tr>
<td>- Multivitamins (Folic Acid supplementation)</td>
<td>Multivitamins (Folic Acid supplementation)</td>
<td></td>
<td>May provide with contraceptive method of choice as defined in the deferred exam protocol</td>
<td>Presumptive eligibility and follow-up to Community Based Services for full Medicaid benefits (if indicated)</td>
<td>Linkage for partner services</td>
</tr>
<tr>
<td>- Follow-up visit as indicated</td>
<td>Follow-up visit for annual exam and as indicated</td>
<td></td>
<td>Schedule a family planning visit, as needed</td>
<td>A genetic services referral should be recommended for previous birth defects, including NTD</td>
<td>Condoms</td>
</tr>
<tr>
<td>- Backup barrier method</td>
<td>Backup barrier method</td>
<td></td>
<td>Provide backup or barrier method, as needed</td>
<td>Refer for prenatal appointment to LHD or private MD</td>
<td>Contraceptive method, as indicated</td>
</tr>
<tr>
<td>- As assessed for individual patient needs</td>
<td>Provide 24 hour Emergency Number</td>
<td></td>
<td>Multivitamins (Folic Acid supplementation)</td>
<td>Prenatal Vitamins</td>
<td>Follow the contraceptive services protocol</td>
</tr>
<tr>
<td>- Provide 24 hour Emergency Number</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

The Matrix identifies the minimal requirements for providing family planning services. Clinicians and nurses must follow the Title X Clinical Requirements outline in the Training Guidelines and Program Descriptions Section of the AR
PROTOCOL FOR DEFERRING A PHYSICAL EXAMINATION BEFORE DISPENSING OR ADMINISTERING A CONTRACEPTIVE

An initial or annual physical may need to be deferred before dispensing or administering a prescriptive contraceptive for a variety of reasons including, but not limited to, the patient’s request, renewal of existing method, recent birth, lack of available clinic appointment time and/or the APRN/MD is not available, or patient is at risk for pregnancy and requests to start on a hormonal method.

The following guidelines represent the absolute minimal requirements that must be met prior to deferring the physical examination.

1. Complete family planning minimum requirements matrix except for physical exam.
2. Use the CDC U.S. Medical Eligibility Criteria for Contraceptive Use to screen for contraindications to a specific method based on patient and family medical history and risk factors.
3. Counsel the patient on the benefits/risks/side effects and the correct use of the desired birth control method.
4. Obtain the patient’s written consent for the method of choice on consent form ACH-264-B and provide appropriate handout(s).
5. Patient should be given foam and/or condoms for backup and STD protection.
6. Patient should be told not to smoke and the risks associated with doing so should be discussed.
7. An appointment for a physical examination should be given. If the patient misses the appointment, attempts to follow-up should be made and documented in the patient’s medical record.

The patient may have her physical examination deferred up to three months if the above evaluation has been done and contraindications have been eliminated. Choose one of the options below and schedule the patient within three months for her examination with the APRN/MD. The order for the prescriptive method must be signed by the APRN/MD within 10 days of providing the method.

1. Provide three month supply of current method, Ortho Evra® Patch, NuvaRing® or the following oral contraceptive/s as per standing orders for RNs outlined on the introduction/signature page.
2. Provide one injection of Depo-Provera 150 mg deep IM in the gluteus maximus or deltoid muscle as instructed by package insert.
3. Provide one injection of Depo-Provera SQ 104 mg into anterior thigh or abdomen as instructed by package insert.

References:
1. Providing Quality Family Planning Services (QFP)
ESTROGEN/PROGESTERONE CONTRAINDICATIONS

1. Severe hypertension
2. Thrombophlebitis, thromboembolic disease or history of deep venous thrombosis or pulmonary embolism, including family history of unexplained VTE at an early age (e.g. Factor V Leiden mutation)
3. Stroke or heart disease
4. Diabetes with vascular involvement
5. Severe migraine with aura or other neurologic symptoms
6. Lupus
7. Current or past history breast cancer
8. Liver disease or dysfunction, jaundice
9. Smoking after 35 years for estrogen only
10. Smoking cessation for all ages should be encouraged for all methods
11. Hypersensitivity to any components in any method - Anaphylaxis and Anaphylactoid Reaction
12. Undiagnosed vaginal bleeding

This is not a complete list of contraindications. Nurses should use the “Managing Contraception On The Go” and the CDC U.S. Medical Eligibility Criteria for Contraceptive Use to screen for contraindications to specific methods based on patient and family medical history and risk factors.

ALL patients on hormonal methods must be counselled on potentially serious side effects, referred to as "ACHES":

Abdominal pain (stomach pain);
Chest pain;
Headaches (severe);
Eye problems (blurred vision); and/or
Swelling and/or aching in the legs and thighs.

These symptoms may indicate a serious disorder, such as liver disease, gallbladder disease, stroke, blood clots, high blood pressure, or heart disease. They should contact their doctor immediately or go to an emergency room or urgent care center for evaluation.

References:


DEPO-PROVERA (DMPA)

A. Indications and Usage
   1. Depo-Provera is a contraceptive injection that contains medroxyprogesterone acetate, a derivative of progesterone.
2. **WARNING: LOSS OF BONE MINERAL DENSITY**

- Women who use Depo-Provera Contraceptive Injection (Depo-Provera CI) may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible.
- It is unknown if use of Depo-Provera Contraceptive Injection during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk for osteoporotic fracture in later life.
- Depo-Provera Contraceptive Injection should not be used as a long-term birth control method (i.e., longer than 2 years) unless other birth control methods are considered inadequate.

Revised by FDA 10/2010 and 1/2017

3. Patients on Depo-Provera for 2 years or more should be counseled on the possibility of bone loss with long term use. If the patient chooses to continue Depo-Provera greater than 2 years, a waiver (FP-2) should be signed annually.

4. All women using DMPA, including teens, should be instructed to eat foods high in calcium or be encouraged to take calcium supplements; ages 19-50 take 1000 mg, <18 years take 1200 mg of calcium daily.

5. Situations where another method may be considered inadequate include noncompliance to other methods, contraindications to estrogen use, severe dysmenorrhea and need for amenorrhea.

6. Depo-Provera must be shaken vigorously immediately prior to use; the solid particles will not maintain adequate dispersion to prevent difficulty in withdrawing/injecting the full dose.

7. See DMPA Matrix - Research demonstrates **quick start** on the day of visit increases prevention of unintended pregnancy and compliance. A back up method must be used for the first 7 days unless the first injection is given during the first 5 days of a normal menstrual period.

B. Prescribing Precautions

1. Use the CDC U.S. Medical Eligibility Criteria for Contraceptive Use to screen for contraindications to this method based on patient and family medical history and risk factors.

2. See: [Estrogen/Progesterone Contraindications](#)

C. Patient Counseling

1. Review and provide FPEM-6 at initial injection.

2. Emphasize the importance of getting the next injections every 11–13 weeks for Depo-Provera 150 mg IM and every 12–14 weeks for Depo-Provera 104 mg SQ; counsel on using a barrier method if late for the next appointment.

3. This method does not protect against STD/HIV. A barrier method is recommended for high risk individuals.

4. Counsel on risk of potential bone loss and calcium supplementation.

5. Counsel on potential side effects. Menstrual irregularities (bleeding and spotting), usually resolves with continued use and may result in amenorrhea. May cycle on low dose estrogen if problem persists; abdominal pain/discomfort; weight gain > 10 lbs at 24 months; depression, and decreased libido.

References:

2. FDA: [https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020246s036lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020246s036lbl.pdf)
(m.Qu than 13 and ON weeks since last injection) of DMPA

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Last menstrual period started ≤ 5 days

YES

Inject DMPA or start new method. No backup needed.

NO

Unprotected intercourse since last menstrual period?

YES

Result of UCG pregnancy Test

Negative

Consider pregnancy test

Positive

Inject DMPA or start new method. Use backup for 7 days

NO

Unprotected intercourse ≤ 5 days ago?

YES

No Method. Counsel on pregnancy options

No

that negative pregnancy test not conclusive, but DMPA and other hormonal methods won't affect fetus

Patient desires DMPA NOW

NO concerned that she could be pregnant

Offer barrier method or new method for 14 days

YES

Inject DMPA now use backup for 7 days

Repeat pregnancy test in 2 weeks

Positive

No Method; counsel on options

Negative

Injection given 2 mago?

YES

Return for next shot in 11 to 13 weeks

Inject DMPA or start new method with backup x 7 days

---
EMERGENCY CONTRACEPTIVE PILLS (ECPs)

Start ECPs as soon as possible, after patient presents with history of unprotected or inadequately protected sexual intercourse. Some ECPs can be used up to 120 hours (5 days), but sooner is better. ECP is most effective if taken immediately or within 12 hours. For more information, go to:
http://www.planonestep.com/hcp/
http://www.mynextchoiceonedose.com/
http://www.ella-rx.com/

Obtain and document history including LMP, compliance with contraceptive use, history of sexual assault and/or possible STD exposure

Performing a Urine Pregnancy Test is Optional

- Positive
  - DO NOT GIVE ECP—Refer to Pregnancy Test Matrix
  - (No benefit, no dangers)

- Negative (or, deferred pregnancy)
  - Counsel patient on potential side effects and need for reliable, consistent contraception
  - For a list of FDA approved COCs for emergency contraception and dosage guidelines see: http://ec.princeton.edu/questions/dose.html.

Advise patient to drink a glass of milk and/or eat a snack with each dose. May also recommend over the counter (OTC) medication (e.g., Dramamine) if using COC’s for nausea. If patient vomits within one hour of the dose, repeat the dose.

- Menstrual period within 21 days?
  - Yes
  - If not already done, counsel patient to initiate the contraceptive of her choice—a method she will use consistently and correctly
  - Advise patient to see clinician and have pregnancy test
  - No

See the name of the specific ECP method and dosing approved as a standing order for RNs on the introduction/signature page.

References:

INTRAUTERINE DEVICE (IUD)
Mirena, Liletta, Skyla, ParaGard, etc.

A. Indications and Usage
1. Use the CDC U.S. Medical Eligibility Criteria for Contraceptive Use to screen for contraindications to this method based on patient and family medical history and risk factors.
2. Data support the safety of IUDs for most women, including adolescents.
3. Chlamydia and gonorrhea testing in high risk patients may be performed. Proceed with insertion and treat any positive findings promptly without the removing device.
4. A pregnancy test performed on the day of insertion shall be negative.
5. If the retrieval threads cannot be visualized, identifying the location of the IUD by ultrasound is advisable and pregnancy, uterine perforation or expulsion should be ruled out.
6. If a pregnancy occurs with an IUD, contact a medical provider for immediate treatment.
7. ParaGard is a non-hormonal IUD and provides 10 years of long acting contraceptive.
8. Mirena is a progestin IUD and provides 5 years of long acting contraceptive.
9. Liletta and Skyla are progestin IUDs and provide 3 years of long acting contraceptive.

B. Prescribing Precautions
1. Use the CDC U.S. Medical Eligibility Criteria for Contraceptive Use to screen for contraindications to screen for contraindications to this method based on patient and family medical history and risk factors.
2. Women with current (known) STD, pelvic inflammatory disease, or purulent cervicitis must wait 3 months after treatment.
3. Uterus < 6 cm or > 9 cm but may be able to use if > 9 cm; upper limit of 10–12 cm.
4. Uterine infection in past 3 months post-delivery.
5. History of intrauterine distortion diagnosed by ultrasound.
6. Known or suspected uterine or cervical cancer; unresolved abnormal Pap smear.
8. Mirena, Liletta and Skyla Contraindications: Estrogen/Progestosterone Contraindications

C. Patient Counseling
1. Prior to IUD insertion, the patient will be counseled on the long term benefits, risks, side effects, and contraindications to the method.
2. The patient must be provided with the package insert and FPEM-10 with adequate time allowed for her questions to be answered prior to signing the consent.
3. Patient shall be taught how to check her IUD strings once a month.
4. The patient with an IUD insertion shall have a return appointment with the clinician within 4–6 weeks post insertion for follow-up.
5. Patients should be aware that dizziness or cramping may occur at the time of IUD insertion or removal.
6. This method does not protect against STD/HIV. A barrier method is recommended for high risk individuals.

References:
6. www.archfoundation.com
COMBINED (ESTROGEN and PROGESTIN CONTAINING) METHODS 
(Pills, Patch, Ring)

A. Indications and Usage
   1. Non-contraceptive benefits include decreased risk of ovarian and endometrial cancer, decrease in PID, ectopic pregnancy, dysmenorrhea, and menstrual blood loss.
   2. QUICK START: Start the pill in the office regardless of time of cycle. Use 7 days of back-up contraception.

B. Prescribing Precautions
   1. Use the CDC U.S. Medical Eligibility Criteria for Contraceptive Use to screen for contraindications to this method based on patient and family medical history and risk factors.
   2. See: Estrogen/Progestrone Precautions
   3. Pills ONLY- Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of contraceptive drug products. Counsel patients to use a back-up method or alternative method of contraception. Some drugs or herbal products that may decrease the effectiveness of hormonal contraceptive include: barbiturates, bosantan, carbamazepine, felbamate, griseofulvin, oxcarbazepine, phentoin, rifampin, St. John’s wort, and topiramate.

C. Patient Counseling
   1. The patient shall be counseled on the benefits, risks, and potential side effects, including warning signs for blood clots, and provided the FPEM-4.
   2. This method does not protect against STD/HIV. A barrier method is recommended for high risk individuals.
   3. The healthcare provider shall instruct the patient about how to take the tablets and when to initiate them.
   4. Dangers of smoking shall be discussed with any patient who smokes and she shall be offered a cessation program.
   5. New OC users may be provided 3–4 cycles of pills and asked to return in 3 months for a supply visit for evaluation. At that time, she may be provided the remainder of the practitioner’s order.
   6. When consideration is given to switching to an alternative formulation to reduce or eliminate troublesome side effects, the change generally should be made only after giving the current OC at least a two to three-month trial.
   7. Counsel on missed pills and risk of pregnancy
   8. Resuming regular use of contraceptive after use of ECPs
      a. Start using regular method immediately. ECPs offer no lingering reliable protection
      b. If missed OCs, restart day after ECPs taken (no need to catch up missed pills)

References:
PROGESTIN ONLY ORAL CONTRACEPTIVES
(POP’s)

A. Indications and Usage

1. Mechanism of action is prevention of ovulation and endometrial thinning.
2. Recommended patient profile is women wanting contraception but are unable to use Estrogen (i.e. > 35 years old and smoking).

B. Prescribing Precautions: See Depo-Provera (progestin) Prescribing Precautions

1. See: Estrogen/Progestosterone Precautions
2. Use the CDC U.S. Medical Eligibility Criteria for Contraceptive Use to screen for contraindications to this method based on patient and family medical history and risk factors.
3. Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of contraceptive drug products. Some drugs or herbal products that may decrease the effectiveness of hormonal contraceptive include: barbiturates, bosentan, carbamazepine, felbamate, griseofulvin, oxcarbazepine, phenytoin, rifampin, St. John’s wort, and topiramate. Counsel patients to use a back-up method or alternative method of contraception.

C. Patient Counseling

1. **Stress the need for compliance taking the pill every day at a consistent time.**
2. The patient shall be counseled on the benefits, risks, and potential side effects, including warning signs for blood clots, and provided the FPEM-5.
3. Side Effects: menstrual irregularities (bleeding and spotting), usually resolves with continued use and may result in amenorrhea. May cycle on low dose estrogen if problem persists; abdominal pain/discomfort; weight gain > 10 lbs at 24 months; depression, and decreased libido.
4. This method does not protect against STD/HIV. A barrier method is recommended for high risk individuals.
5. The healthcare provider shall instruct the patient about how to take the tablets, when to initiate them and what to do if miss doses.
6. New OC users may be provided 3–4 cycles of pills and asked to return in 3 months for a supply visit for evaluation. At that time, she may be provided the remainder of the practitioner’s order.
7. Resuming regular use of contraceptive after use of ECPs
   a. Start using regular method immediately. ECPs offer no lingering reliable protection.
   b. If missed OCs, restart day after ECPs taken (no need to catch up missed pills). Stress the need for compliance taking the pill at a consistent time daily.

References:

2. [http://www.janssenpharmaceuticalsinc.com](http://www.janssenpharmaceuticalsinc.com)
**NuvaRing®**

*(etonogestrel/ethinyl estradiol vaginal ring)*

A. Indications and Usage
   1. NuvaRing® is a non-biodegradable, flexible, transparent, odorless to almost colorless, combination contraception vaginal ring containing two active components, a progestin (etonogestrel) and an estrogen (ethinyl estradiol).
   2. The flexible ring is made of ethylene vinylacetate polymer and is 5.4 cm. in diameter.
   3. The recommended patient profile is the woman who desires long-term reversible contraception, difficulty in using a daily method, and is comfortable with self-vaginal insertion/removal.

B. Prescribing Precautions
   1. Use the CDC U.S. Medical Eligibility Criteria for Contraceptive Use to Screen for contraindications to this method based on patient and family medical history and risk factors. See: [Estrogen/Progestosterone Contraindications](#).
   2. There is not convincing data that broad spectrum antibiotics increase the failure of this product.
   3. Women with genital prolapse, severe constipation and/or frequent vaginal infection (i.e. recurrent yeast infection) may not be a good candidate.

C. Patient Counseling/Evaluation
   1. Provide package insert on how to use the ring and the FPEM-9.
   2. This method does not protect against STD/HIV. A barrier method is recommended for high risk individuals.
   3. The first ring should be inserted any time during the first five days of a normal menstrual period; use additional backup method for the first seven days of ring use.
   4. The ring is not removed for intercourse. Douching is discouraged but topical therapies are allowed.
   5. The ring is removed at the end of three weeks of wear; then, after one ring-free week, the woman inserts a new ring. The woman’s menstrual period occurs during the ring-free week. No special accuracy is required for ring placement.
   6. The ring is small and flexible, so most women will not feel pressure or discomfort; and it is not likely to be uncomfortable for a partner during intercourse.
   7. The woman should always have two rings on hand, in case one is lost.
   8. If the ring is left in place longer than three weeks, the user is still protected from pregnancy for up to 35 days by the same ring. *The NuvaRing® remains effective for well beyond 21 days, thus allowing clinicians flexibility in how often they may tell women the ring must be replaced.*
   9. Extra rings should be stored in the refrigerator or cool place until ready to use.

References:

Ortho Evra® Contraceptive Patch  
(norelgestromin/ethinyl estradiol transdermal system)

A. Indications and Usage
   1. Ortho Evra® is a combination transdermal contraceptive patch (4.5 cm square) that contains 6 mg of norelgestromin and 0.75 mg of ethinyl estradiol.
   2. The recommended patient profile is the woman who desires long-term reversible contraception, who experiences difficulty in using a daily method, but who is committed to changing the patch on a weekly basis may prefer this method.

B. Prescribing Precautions
   1. Use the CDC U.S. Medical Eligibility Criteria for Contraceptive Use to screen for contraindications to this method based on patient and family medical history and risk factors.
   2. See: Estrogen/Progestrone Contraindications
   3. Women weighing more than 198 pounds should be told that the patch may be less effective and they should consider using a backup method. Some clinicians recommend using another method if woman is >198 pounds.
   4. Bolded Warning issued Nov 2005 (Revised 9/06) advises “that women who use Ortho Evra® are exposed to about 60 percent more total estrogen in their blood than if they were taking a typical birth control pill containing 35 micrograms of estrogen. However, the maximal blood level of estrogen (peak blood levels) is about 25% lower with Ortho Evra® than with typical birth control pills. While the estrogen level with the patch remains constant for one week until the patch is removed, the peak blood levels with a daily birth control pill rapidly declines to levels that are lower than on the Ortho Evra®.” The manufacturer advises healthcare providers to balance the higher exposure and the possible increased risk of VTE against the chance of pregnancy if the patch is not used; contraceptive options other than the patch should be considered for women with risk factors for thromboembolic disease.

C. Patient Counseling/Evaluation
   1. Review instructions for use and provide package insert and FPEM-8.
   2. This method does not protect against STD/HIV. A barrier method is recommended for high risk individuals.
   3. Only one patch at a time is worn. A replacement patch should be on hand at all times.
   4. A patch is worn one week for each of three consecutive weeks, and then removed for a week to permit breakthrough bleeding. Following the completion of Week Four, a new cycle is undertaken, which would be the same as the day after Day 28.
   5. If the patch-free interval is more than 9 days (late restart), apply a new patch and use back up contraception x 7 days
   6. A woman can switch from the pill to the Ortho Evra® Patch any time in the cycle. Do not wait to complete pack of pills.
   7. Do not skip patches even if there is infrequent intercourse.
   8. Store at room temperate away from moisture and heat. Do not store in a refrigerator or freezer.

References:
   2. www.orthoevra.com
Nexplanon

Nexplanon replaced Implanon in 2012.

A. Indications and Usage
Nexplanon is a single 4 cm long and 2mm in diameter implant that releases the progestin etonogestrel at a rate of 60 micrograms daily. Nexplanon is placed under the skin of upper arm with a 16 gauge disposable, preloaded inserter.
1. Nexplanon is effective for at least 3 years.
2. Progestin-only contraceptives are particularly important for women who cannot use a contraceptive that contains estrogen.

B. Prescribing Precautions
1. See: Estrogen/Progesterone Contraindications
2. Use the CDC U.S. Medical Eligibility Criteria for Contraceptive Use to screen for contraindications to this method based on patient and family medical history and risk factors.
3. Insertion and removal shall be performed by a medical provider with special training and manufacture recommendations.
4. This method does not protect against STD/HIV. A barrier method is recommended for high risk individuals.
5. Menstrual cycle disturbances, including menstrual irregularities. If bothersome may provide several cycles of low dose pills, patch or ring, or NSAIDs.
6. Initiating method: If insertion within 7 days of LMP, no back up needed. If later than 7 days from LMP, use back up for 7 days. If has been on DMPA, insert at time next injection due. No back up needed.
7. Arm pain after insertion: rule out nerve damage or infection, check dressing to assure not too tight, apply ice pack for 24 hours, and direct to take acetaminophen or NSAID. If infection, do not remove if no abscess or cellulitis, clean insertion site with antiseptic, oral antibiotics for 7 days. Recheck in 24-48 hours for effectiveness of treatment and at end of antibiotic therapy. If abscess or cellulitis present, remove implant and treat with antibiotic therapy and wound care.

C. Patient Counseling/Evaluation
1. Prior to Nexplanon insertion, the patient will have been counseled on the benefits, risks, side effects, and contraindications to the method.
2. The patient must be provided with the package insert and FPEM-7 with adequate time allowed for her questions to be answered prior to signing the consent.
3. Patient should be provided wound care instructions and signs and symptoms of a skin infection.
4. This method does not protect against STD/HIV. A barrier method is recommended for high risk individuals.

References:

POSTPARTUM, BREASTFEEDING, AND CONTRACEPTIVES

Planning for postpartum (PP) contraception should begin during pregnancy and use of birth control should be initiated as early as possible. Encourage women to have a contraceptive plan.

- Initiate contraception 2-4 weeks after delivery because most couples resume intercourse within a few weeks after delivery.
- Spacing of pregnancies is important to maternal and child health. Pregnancies spaced at least 18-23 months apart are less likely to have preterm delivery, low birth weight, and small for gestational age infants.
- Ovulation may precede first menses. Pelvic rest (no douching, no sex, and no tampons) is generally recommended for 4-6 weeks and/or lochia stops. Lochia is normal uterine discharge of blood, tissue and mucus from the vagina. Non breastfeeding women can become pregnant 3 weeks from delivery.
- Encourage breastfeeding. Reinforce education about lactational amenorrhea, if patient is interested. Pregnancy is possible 3 months after delivery even if fully breastfeeding.
- Refer to the CDC “US Medical Eligibility Criteria for Contraceptive Use 2010: Revised Recommendations for the Use of Contraceptive Methods During the Postpartum Period”, MMWR July 8, 2011 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6026a3.htm.

MATRIX FOR STARTING PP CONTRACEPTION

<table>
<thead>
<tr>
<th>METHOD</th>
<th>NOT BREASTFEEDING</th>
<th>BREASTFEEDING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condoms (Male &amp; Female)</td>
<td>• May use to reduce risk of STI and for pregnancy prevention PP or as a backup when initiating a hormonal contraception</td>
<td>• No effect on breast milk</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• May use to reduce risk of STI and pregnancy prevention PP or as a backup when initiating hormonal contraception</td>
</tr>
<tr>
<td>Cervical Cap, Diaphragm</td>
<td>• 4–6 weeks PP, after cervix and vagina normalized (will need to be refitted PP)</td>
<td>• No effect on breast milk</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• May initiate 4-6 weeks PP, after cervix and vagina normalized (will need to be refitted PP)</td>
</tr>
<tr>
<td>Progestin-Only Methods</td>
<td>• May initiate immediately PP</td>
<td>• May initiate 1 month PP</td>
</tr>
<tr>
<td>• Depo-Provera</td>
<td>• Provide backup method as needed</td>
<td>• No significant impact on milk quality or production but should be informed it may decrease production in some women</td>
</tr>
<tr>
<td>• Progestin-Only Pills</td>
<td></td>
<td>• Breast-fed children of DMPA users grow at normal rate</td>
</tr>
<tr>
<td>• Nexplanon</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combined Hormonal Methods</td>
<td>• Should not be used &lt; 21 days PP</td>
<td>• Should not be used &lt; 21 days PP</td>
</tr>
<tr>
<td>• Pills</td>
<td>• May start 21-41 days PP but must consider risk factor of VTE (such as age ≥ 35 years, previous VTE, immobility, thrombophilia, transfusion at delivery, BMI &gt; 30, postpartum hemorrhage,</td>
<td></td>
</tr>
<tr>
<td>• Patch</td>
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<tr>
<td>• Vaginal Ring</td>
<td></td>
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</tr>
<tr>
<td>Method</td>
<td>Indications</td>
<td>Contraindications</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| **BMI > 30, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking** | • > 42 days, Category 2  
• If risk of VTE, do not use  
• Provide backup method as needed | postcesarean delivery, preeclampsia, or smoking  
• > 42 days, Category 2  
• If risk of VTE, do not use  
• Estrogen can affect the quality and quantity of breast milk. Milk production may be diminished if used prior to establishment of lactation  
• After lactation establishment, these methods have no significant impact but should be informed it may decrease production in some women |
| **IUD:**  
• Copper  
• Levonorgestrel | • Usually await uterine involution to insert (4–6 weeks).  
• May insert Copper or LNG IUD within first 20 minutes after delivery of placenta | No effect on breast milk. ParaGard- same as Progestin only methods  
• Usually await uterine involution to insert (4–6 weeks)  
• May insert Copper or LNG IUD within first 20 minutes after delivery of placenta |
| **Tubal Sterilization (Female)** | • Usually done in first 24–48 hours PP, or await complete uterine involution for interval tubal sterilization (> 6 weeks PP) | No effect on breast milk  
• Usually done in first 24–48 hours PP, or await complete uterine involution for interval tubal sterilization (> 6 weeks PP) |
| **Vasectomy (Male)** | • Anytime | No effect on breast milk |
| **Natural Family Planning or Fertility Awareness Method (FAM)** | • Await resumption of normal menstrual cycles for at least 3 months  
• Provide backup method as needed | No effect on breast milk  
• Await resumption of normal menstrual cycles for at least 3 months  
• Provide backup method as needed |
| **Lactational Amenorrhea Method (LAM)** | • Not applicable | Baby is less than six months old, no menstrual cycle, and baby is exclusively breastfed (with no pacifiers, supplemental bottles, or solid foods) and nurses on demand both day and night  
• May use back up method |

**References:**
2. [www.lalecheleague.org](http://www.lalecheleague.org) or [www.breastfeeding.com](http://www.breastfeeding.com)
3. Breastfeeding Coordinator, WIC Program, Kentucky Department for Public Health
6. CDC US Medical Eligibility Criteria for Contraceptive Use 2010: Revised Recommendations for the Use of Contraceptive Methods During the Postpartum Period, MMWR July 8, 2011 [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6026a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6026a3.htm).
STERILIZATION

Sterilization of persons in federally assisted family planning projects must meet the requirements of Chapter 1 Title 42 Subpart B 50.201 through 50.209 of the Public Health Service Act. Required consent forms for sterilization and “Information for Men” and “Information for Women – Your Sterilization Operation” booklets are available from the U.S. Department of Health and Human Services.

Federally required consent forms:

Programs or projects to which this subpart applies shall perform or arrange for the performance of sterilization of an individual only if the following requirements have been met:

- The individual is at least 21 years old at the time consent is obtained.
- The individual is not mentally incompetent.
- The individual has voluntarily given his/her informed consent.
- At least 30 days but not more than 180 days have passed between the date of informed consent (day one begins the day after consent) and the date of the sterilization procedure, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of a premature delivery or emergency abdominal surgery, if at least 72 hours have passed after the individual gave informed consent to the procedure. The informed consent must have been given at least 30 days before the expected date of delivery. Consent must not be obtained when the patient is:
  → In labor or childbirth;
  → Seeking to obtain or obtaining an abortion; or
  → Under the influence of alcohol or other substances that affect the individual’s state of awareness.

Informed consent does not exist unless the federally required consent form for men or women is completed voluntarily and in accordance with Federal Regulations. A person who obtains informed consent for a sterilization procedure must offer to answer any questions the individual to be sterilized may have regarding the procedure. Provide a copy of the consent form and tell the patient the following:

- Advise that the individual is free to withhold or withdraw consent to the procedure at any time without affecting his/her right to future care or treatment and without loss or withdrawal of any federally funded program benefits;
- A description of available alternative methods of family planning and birth control;
- Advise that the procedure is considered to be irreversible;
- A thorough explanation of the specific procedure;
- A full description of the discomforts and risks that may accompany or follow the procedure; including an explanation of the type and possible side effects of any anesthetic used; and
- A full description of the benefits/advantages of sterilization.
STERILIZATION
(continued)

Sterilizations paid for with funds earmarked for family planning services must first be made available to patients without another source of payment. Spousal consent shall NOT be required for sterilization.

Patients who have had a sterilization either provided or “arranged for” must have a medical record on file showing the date of counseling and consent, the date of the procedure, and any indicated follow-up. The individual patient’s medical record must contain a copy of the completed consent form and the operative report from the physician performing the procedure.

The following definitions are found in the Public Health Services Act, Subpart B – sterilization of persons in Federally Assisted Family Planning Projects – 50.202.

- “Arranged for” means to make arrangements (other than mere referral of an individual to, or the mere making of an appointment for him or her with another healthcare provider) for the performance of a medical procedure on an individual by a healthcare provider other than the program or project.

- “Mentally incompetent individual” means an individual who has been declared mentally incompetent by a Federal, State, or local court of competent jurisdiction for any purpose unless he or she has been declared competent for purposes, which include the ability to consent to sterilization.

References:

Infertility Prevention Project (IPP)
Guidelines for Chlamydia and Gonorrhea Screening
During a Family Planning Visit

All family planning clinics participate in the CDC Infertility Prevention Project within Region IV. The CDC in collaboration with the Office of Population Affairs (OPA) of the Department of Health and Human Services (HHS), supports a national Infertility Prevention Program (IPP) that funds chlamydia screening and treatment services for low-income, sexually active women attending family planning, STD, and other women’s healthcare clinics. Federal funds support screening for and treatment of chlamydia and gonorrhea among sexually-active, low-income women attending public clinics to prevent infertility.

- The STD program will notify Family Planning sites when they demonstrate low positivity for chlamydia or gonorrhea screening.
  - **High positivity**: Females aged 24 years and younger will be routinely screened annually for chlamydia and gonorrhea during their family planning visit.
  - **Low positivity**: Sites identified with low positivity will cease routine screening for females aged 24 years and younger and will then use screening criteria based on symptoms, a new sexual partner or multiple partners within the last 60 days, or exposure to an infected individual.

- Females aged 25 years and older will be offered screening annually for chlamydia and gonorrhea during their family planning visit using screening criteria based on symptoms, a new sexual partner or multiple partners within the last 60 days, or exposure to an infected individual.

References:

1. [http://www.cdc.gov/std/infertility/ipa.htm](http://www.cdc.gov/std/infertility/ipa.htm)
Algorithm for deciding if a Pelvic Exam is necessary during a **Family Planning** Visit

**Family Planning Visit**

- **Yes**
  - **24 and Younger?**
    - **Yes**
      - Perform **Routine** CT/GC Screen
        - Patient reports multiple partners in the last 60 days or exposure to an infected individual.
        - Patient reports symptoms.
        - Pt meets criteria for Pap or HPV testing.
        - **Yes**
          - Perform pelvic exam and indicated STD testing
            - Provide Pap testing or HPV testing as directed by the Women’s Cancer Screening Program criteria
        - **No**
          - Do not Perform Pelvic Exam
    - **No**
      - 24 and Younger? (Repeat)
  - **No**
    - **Yes**
      - Patient reports multiple partners in the last 60 days or exposure to an infected individual.
      - Patient reports symptoms.
      - Pt meets criteria for Pap or HPV testing.
      - **Yes**
        - Perform pelvic exam and indicated STD testing
      - **No**
        - Do not Perform Pelvic Exam
PRECONCEPTION CARE

The following family planning visits require that preconception health care be routinely provided:

- Initial family planning examination visit
- Annual family planning examination visit
- Initial women’s preventive health examination if of childbearing age without a permanent method of contraception (hysterectomy or tubal ligation)
- Pregnancy test visit (only if negative test results)

Preconception interventions may include the following:

- A dialogue regarding the patient’s reproductive life plan and readiness and desire a for pregnancy
- An evaluation of her overall health and opportunities to improve her health
- Education about the significant impact that social, environmental, occupational, behavioral, and genetic factors may have on a future pregnancy
- Identification of women at high risk for an adverse pregnancy outcome with appropriate referrals to a health care professional

Assessment and counseling should be provided only by a qualified provider who has training in risk identification with the ability to provide appropriate counseling and referrals.

Assessment/counseling/referrals of pregnancy related risk factors include:

- Advanced maternal age (pregnancy at or over the age of 35)—poses a higher risk of chromosomal abnormalities in the fetus and medical problems to the mother during pregnancy
- Ethnic backgrounds—a family history that is positive for certain diseases may indicate the need for additional screening
- STD’s—early treatment decreases the risk of transmission to the fetus and preterm delivery
- Vaccination history (Refer to Immunizations Section)
- Chronic disease (hypertension, diabetes, obesity, epilepsy, DVT, depression)
- Alcohol, Tobacco, Other Drugs (ATOD)
- Domestic violence
- Exercise
- Nutrition

References:

FOLIC ACID SUPPLEMENTATION

ALL female patients of childbearing age who have not had a hysterectomy or tubal ligation should be offered one three month supply of a multivitamin containing 0.4 mg folic acid free of charge and should receive individualized folic acid counseling/education with documentation in the medical record to include:

- Description of NTDs and prevention strategies
- Discussion of dietary sources of folic acid
- Provision of educational handouts
- Assessment of folic acid consumption at each visit to the LHD

Nurses (APRN, RN, or LPN), nutritionist, dieticians, health educators and physicians may provide folic acid counseling. Counseling sessions should be an opportunity for the client to ask questions and for the provider to assess the client’s knowledge about the health benefits of folic acid.

Women who have a history of NTD pregnancy:

- **and are NOT pregnant** should be offered one three month supply of a multivitamin containing 0.4 mg folic acid free of charge. These women should be informed of the need to take a prescription dose of 4 mg of folic acid supplements beginning one to three months prior to trying to conceive. These women should also be informed of the need for genetic counseling and medical nutrition therapy if a pregnancy is planned in the future.
- **and are pregnant** should receive a prescription for 4 mg of folic acid supplements. If the patient is taking a multivitamin containing folic acid, the folic acid prescription level supplement should be adjusted to attain the proper dosage as prescribed per health care provider. These women must be referred promptly to a prenatal care provider and should be informed of the need for genetic counseling and medical nutrition therapy.

Women with epilepsy, diabetes, history of gestational diabetes, or obesity are at increased risk of having a NTD pregnancy. These women should be counseled to consult their provider before trying to conceive in order to determine if a larger dose of folic acid is needed.

Notify the Genetic Counselor with the Kentucky Birth Surveillance Registry at 502-564-3756, extension 3768 for any woman identified as having a previous NTD delivery. Be prepared to give the name of the mother (name at time of birth) and name of affected child, stillbirth/live-birth, date of birth of affected child and delivery facility.

References:

Adolescent Clients in the Family Planning Clinic

Adolescents have health care needs that are different from those of other age groups. By improving the quality of care provided to adolescents, we can close the many gaps they experience in care and improve their overall health and well-being.

Youth-friendly provider characteristics include:

- Familiarity with adolescent physiology and development
- Knowledge of appropriate medical options for adolescents according to age and maturity
- Skills to communicate fluently in the youth language
- Effective interpersonal skills
- Ability to relate to youth in a respectful manner
- Skills to honor youth privacy and confidentiality
- Skills to engage in conversation about body image and development, sex, relationships, and contraceptive method options
- Skills to bring myths to the surface, to discuss and dispel them
- Sexual health assessment taken or updated at every visit

Youth-friendly health facility characteristics include:

- Convenient location
- Adequate space
- Counseling areas that provide visual and auditory privacy
- Examination areas that provide visual and auditory privacy
- Comfortable surroundings
- High quality adolescent health materials available, in all the languages that young people in the community speaks and for various reading levels, including low literacy
- Clear and visible information about youth clinic hours and location
- Automated voice messaging on telephones providing information about location, visiting hours, and telephone number for counseling
- Displays of information and health education materials on issues related to adolescent sexual and reproductive health
- Teen-focused magazines and poster displayed on the walls

Special requirements for teen clients receiving family planning services:

1. **Contraceptive counseling that address the client’s contraceptive needs and must include the benefits of abstinence.**

   - Regardless of a patient’s age or previous sexual activity, the provider routinely should address the client’s contraceptive needs, expectations, and concerns.
   - Emergency contraception routinely should be included in discussions about contraception, including access issues.
   - Discussions about contraception should begin with information on the most effective methods first.
   - Long-acting reversible contraceptive (LARC) methods have higher efficacy, higher continuation rates, and higher satisfaction rates compared with short-acting contraceptives. Because LARC methods are safe, they are excellent contraceptive choices for adolescents.
   - Providers should be aware of and be prepared to address the most common misperceptions about contraceptive methods in a way that is age appropriate and compatible with the patient’s health literacy.
   - The initial encounter and follow-up visits should include continual reassessment of sexual concerns, behavior, relationships, prevention strategies, and testing and treatment for sexually transmitted infections (STIs) per the Centers for Disease Control and Prevention’s (CDC) guidelines
• The benefits of abstinence must be discussed with adolescent clients. Benefits include:
  o The only 100% way to prevent STDs and unplanned pregnancy,
  o Allows for more time to focus on school, a job, hobbies and interests,
  o Allows a person to follow their personal, moral or religious beliefs and values, and
  o Helps a person avoid the emotional consequences of a sexual relationship.

2. **Sexual coercion and abuse counseling.**

Coercive sex is defined as a sexual relationship in which a partner possesses an unhealthy dominance that causes submissive behavior, not consensual behavior. Elements of coercion may be deception, bribery, manipulation, violence or threat of violence, which control when, where and how to have sex.

Information and counseling about coercive relationships include:

• General questions about abuse and sexual practices that may be indicative of an abusive or coercive relationship on intake questionnaires that are administered to all clients. This information should be reviewed during the individual education and counseling session with the client and documented in the client’s record. Documentation should also include any referrals and follow-up information.

• Offer adolescents, and other clients, as appropriate, information that presents strategies for avoiding and/or resisting coercive sexual situations.

• Adolescents should be counseled about the potential benefit of involving their parents, caregivers, and/or other appropriate adult family members in supporting their efforts to establish non-coercive sexual relationships.

3. **Encourage family participation in adolescent decision-making.**

Sexual development is a normal part of the teen years. Parents have a strong impact on whether a teenager makes healthy decisions for himself or herself. Research shows that adolescents who talk with parents about topics related to dating, healthy relationships, and pregnancy and STD prevention are more likely to:

• Begin to have sex at a later age.
• Use condoms or other birth control more often if they do have sex.
• Have better communication with romantic partners.
• Have sex less often.

Adolescents who come to the service site alone should be encouraged to talk to their parents or guardians. Providers should encourage and promote communication between the adolescent and his or her parent(s) or guardian(s) about sexual and reproductive health.

Approximately 13% of teenagers state they do not have a trusted adult in their life to talk to about serious problems (2017 KY Youth Risk Behavior Survey). Providers should help these teen clients identify an adult they can trust to talk to about important decisions, such as dating, contraception and healthy relationships.

Resources:

World Health Organization

ACCOG

Family Planning National Training Center

Quality Family Planning (QFP) Guidelines
Follow-up / Internal Tracking / Referral

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**CASE MANAGEMENT**

Follow-up Measures to Ensure Continuity of Care

Internal Tracking

Guidelines for Laboratory/Radiology Follow-Up

Referrals

Referral Sources
Follow-up Measures to Ensure Continuity of Care

Appropriate follow-up measures should be taken to ensure continuity of care for:

1. Patients who have abnormal test results
2. Patients who have been referred to other providers
3. Patients who have missed return appointments
4. Patients who transfer to the LHD from another health care provider must be screened by the LHD protocols and minimal standards of care must be met as outlined. (The LHD may accept documented normal results of screening tests done within the periodicity according to the specific program guidelines).
5. Patients who are pregnant and request services other than prenatal care must be asked if they have a designated prenatal care provider and if prenatal care has been initiated. This information must be documented in the medical record. If the patient does not have a designated prenatal care provider, the health department staff must assist the patient in accessing prenatal care. These efforts must also be documented in the medical record.

Documentation of all return appointments and contacts made or attempted must be in patient’s medical records.

“No Show” should be documented in the medical record when a patient is noncompliant in keeping appointments.

Telephone calls made to or from the patient or the physician regarding the patient’s care should be documented in the patient’s medical record.

This documentation should include:

1. The reason for the call
2. Any problems discussed by the patient/physician
3. Any action taken and advice or instructions given
4. The date and time of the call should be included as well

The specific time frames utilized when providing follow-up will be determined by the professional who initiated the referral, unless further defined by federal or state guidelines or services protocols, and as indicated by the urgency of the situation. (Specific guidelines for abnormal laboratory/radiology follow-up are found at the end of this section).

INTERNAL TRACKING

To ensure appropriate follow-up, all laboratory tests and screenings, i.e., mammograms and Pap tests, that are sent outside the agency for interpretation shall be reviewed, initialed and dated upon return to the LHD by a nurse before it is filed in the patient’s medical record.

Internal Tracking systems must be developed to ensure that emergency, urgent and essential referrals, appointments and return appointments to the health department are made and kept. This system may either be electronic or hard copy. A tracking system will help to keep the timeline for the patient’s condition and achievement of expected outcomes. It will satisfy patient management and needs by avoiding letting patients “slip through the cracks” or stopping short of completing the patient care cycle.
The system will make sure that problems and care are documented and resolved. Mechanisms for follow-up must be sensitive to a patient’s concern for confidentiality and privacy and must be discussed with the patient. An agreed on method for reaching the patient must be determined and noted in the medical record.

A “Tickler File” is one type of internal tracking mechanism. A Tickler is a memorandum book or file that aids in coordinating the patient’s care through the problem management and corrective action tracking. The Tickler helps to monitor the patient’s course successfully. It is easily managed, flexible and may be customized for specific problems.

GUIDELINES FOR LABORATORY/RADIOLOGY FOLLOW-UP

Follow-up on all abnormal laboratory or radiology results are expected. **Patients should be notified within 10 working days** from the LHD receiving report of the abnormal result.

Staff shall make a minimum of three attempts to notify patients of abnormal laboratory or radiology tests as follows:

1. Initial contact may be made by telephone if the number is available and patient has permitted home contact.

2. The second contact should be a regular mailed letter with directions for the patient to contact the LHD for follow-up.

3. The third should be a certified or registered letter with directions for the patient to contact the LHD for follow-up.

4. If the patient cannot be contacted by the above measures, a home visit is strongly recommended for results that are potentially life threatening.

5. If after three attempts are made with no response or three appointments are made and not kept by the patient, the LHD provider should document in the chart that the patient is lost to follow-up care.

6. When the patient is referred to their private medical provider, the follow-up will become the private provider’s responsibility. Exception to this will be the Cancer Program’s follow-up guidelines. See the Cancer Screening/Follow-up Section for specific requirements.

Note: For particular conditions such as abnormal Pap tests, mammograms, newborn screening, and communicable diseases, i.e., TB, HIV, and Hepatitis B, see section program guidelines for required follow-up.
REFERRALS

Referrals are made to assist patients in obtaining services not available on-site. LHD may not coerce patients to undergo any consultation or procedure unwillingly. Referrals may be recommended, arranged for, facilitated and/or paid for by the LHD. When this guide indicates that a referral is recommended, the obligation of the LHD is to recommend that the patient seek care beyond the capability of the LHD. Documentation in the medical record should reflect that the recommendation was made that the patient seeks further care. It is always appropriate to assist the patient in finding a provider and payment source. The significance of the problem will determine whether a referral is an emergency referral, urgent referral, an essential referral, and a discretionary or nonessential referral.

- Emergency – required when a patient’s life is in immediate danger.
- Urgent – required when a patient’s condition or problem needs immediate attention, but the condition is not thought to be immediately life threatening.
- Essential – required when a patient’s condition or problem needs further attention, but waiting for an appointment for the care is either not a problem, or is appropriate.
- Discretionary or Nonessential – those that would benefit the patient, but for which the patient should or could take the initiative.

Written documentation of the outcome, and follow-up of an emergency, urgent or essential referral must be obtained. If the patient refuses this level of referral, documentation in the patient’s record is essential. Documentation of the patient’s history regarding follow-up with discretionary or nonessential referrals is essential.

Patients who are participants in managed care payer systems, such as Health Maintenance Organizations (HMOs) or Medicaid Managed Care may be restricted to certain providers or limitations when needing specialist care. An individual should not be referred to a specialist without knowing whether the primary provider’s authorization is required.

Examples of recommended referrals include: dental referral for children and pregnant women; gynecology referral for women with prenatal Diethylstilbestrol-DES exposure; physician referral for age appropriate adults to obtain colonoscopy, sigmoidoscopy, vision and hearing assessment (beyond the capability of the health department).

Examples of referrals for which the LHD may pay include: physician referral for child with acute condition in need of diagnosis and treatment (first visit); referral for woman who wants an FDA approved contraceptive not available on site; referral of women with an IUD and suspected pelvic inflammatory disease or positive pregnancy test; women with abnormal mammogram or Pap test requiring further diagnosis or treatment.
REFERRAL SOURCES

This list may be used as guide for referral resources. Include other resources that may be available in the local area.

<table>
<thead>
<tr>
<th>Sources</th>
<th>Phone Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kentucky Physician Care Hotline</td>
<td>1-800-633-8100</td>
</tr>
<tr>
<td>Pharmacy Questions Hotline</td>
<td>1-800-633-8100</td>
</tr>
<tr>
<td>Poison Control Hotline</td>
<td>1-800-222-1222</td>
</tr>
<tr>
<td>Kentucky Dental Association</td>
<td>1-502-459-5373</td>
</tr>
<tr>
<td>Statewide First Step Program</td>
<td>1-800-442-0087</td>
</tr>
<tr>
<td>Social Services (Local)</td>
<td></td>
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<tr>
<td>Social Insurance (Local)</td>
<td></td>
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<tr>
<td>Social Security (Local)</td>
<td></td>
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<tr>
<td>Mental Health/Mental Retardation (Comprehensive Care)</td>
<td></td>
</tr>
<tr>
<td>Division of Adult and Child Health</td>
<td>1-800-462-6122</td>
</tr>
</tbody>
</table>

Record Your Local Agencies Numbers
Kentucky Hepatitis C Virus (HCV) Antibody Screening and Confirmation with HCV RNA Quantitative Testing

TABLE OF CONTENTS

Clinical Information and Instructions for Screening and Testing for Hepatitis C Virus (HCV) Infection

Kentucky Adult HCV Screening, Testing and Referral Guidance

Billing for HCV Laboratory Tests

Kentucky HCV RNA Quantitative Testing Patient Information Log.
Clinical Information and Instructions for
Screening and Testing for Hepatitis C Virus (HCV) Infection and Billing for HCV Laboratory Tests

The Kentucky Department for Public Health (KDPH) encourages all Local Health Departments (LHDs) to offer hepatitis C virus (HCV) education, prevention, screening, and testing to all pregnant women and at risk persons. Please offer HCV screening and testing services during all healthcare encounters when persons are identified as being at risk.

Hepatitis C, a blood-borne disease, is primarily spread through intravenous drug use; however, HCV can be contracted in other ways from contaminated blood. Hepatitis C usually is a chronic viral infection with few early symptoms, and danger signs may not appear for decades. Ultimately, patients endure liver scarring, liver cancer, or total liver failure.

HCV is transmitted primarily through large or repeated percutaneous (i.e., passage through the skin) exposures to infectious blood. Populations identified at risk for HCV infections include persons who inject drugs, persons with HIV infection; persons with sexual contact with an infected person; sharing personal items contaminated with infectious blood, such as razors or toothbrushes (rare but can occur); perinatal HCV infection; individuals with a history of incarceration; needle stick injuries in healthcare setting and persons that have experienced unsafe injection practices in healthcare settings. Persons born between 1945 and 1965, i.e., Baby Boomers, are also at high risk for chronic HCV infection and should be tested, [https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm](https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm)

Approximately 15%-20% of persons exposed to HCV clear the virus from their bodies without treatment and do not develop chronic infection; the reasons are not well known. HCV infection becomes chronic in approximately 75%-85% of cases. Chronic infection is the leading indication for liver transplants in the United States. Prior infection with HCV infection does not protect against later infection with the same or different genotypes of the virus. Presently no vaccine for Hepatitis C is available.

Approximately 2.2 to 3.2 million persons are living with chronic HCV infection in the United States. The Center for Disease Control (CDC) has reported that up to 1.2% of Americans have been chronically infected with HCV. In Kentucky, cases of acute hepatitis C have dramatically increased in both rural and urban communities. The reported incidence rate of acute HCV infection was 1.5 cases per 100,000 in 2009 and rose to an alarming 5.1 cases per 100,000 in 2013. In Kentucky, between 2009 and 2013; reported rates of acute hepatitis C increased by 240%.

The hepatitis C epidemic among people who inject drugs continues to spread throughout Kentucky and the US, especially among people in their 20’s. In April 2015, the CDC issued a Health Advisory; Outbreak of Recent HIV and HCV Infections among Persons Who Inject Drugs. In May 2015, the Morbidity and Mortality Weekly Report (MMWR) released a report: “Increases in Hepatitis C Virus Infection Related to Injection Drug Use among Persons Aged ≤30 Years — Kentucky, Tennessee, Virginia, and West Virginia, 2006–2012,” [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6417a2.htm?s_cid=mm6417a2_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6417a2.htm?s_cid=mm6417a2_w).

In April 2018, Governor Bevin amended SB 250 KRS 214.160 to establish that all pregnant women in Kentucky be tested for hepatitis C and recommend testing for children born from a pregnant woman who has a positive hepatitis C test result.
Testing and Diagnosis

Kentucky testing recommendations for hepatitis C infection.
Kentucky hepatitis C infection risk assessment.

Testing for HCV infection begins with a laboratory-conducted assay for HCV antibody in blood. See the Kentucky Adult HCV Screening, Testing and Referral Guidance. The KDPH recommends that Local Health Departments (LHD) use venipuncture to obtain a specimen for HCV Antibody (anti-HCV) testing. Offer the HCV Rapid test only for offsite HCV Outreach Programs or in Syringe Exchange programs. Refer to the 2-Screening and Referral Guidance for Hepatitis C Virus (HCV) Infection among High Risk Individuals and 3-Outreach or Syringe Exchange Programs: Hepatitis C Virus (HCV) Rapid Test and Follow Up Guidance. A nonreactive HCV antibody result indicates no HCV antibody detected.

A reactive result indicates one of the following: 1) current HCV infection, 2) past HCV infection that has resolved, or 3) false positivity. A reactive result should be followed by a HCV confirmation test using HCV RNA Quantitative tests to detect amount (viral load) of the virus. That confirmation test is done automatically (i.e., reflex testing) for HCV tests submitted to the Division of Laboratory Services.

If HCV RNA is detected, that indicates current HCV infection. If HCV RNA is not detected, that indicates either a past, resolved HCV infection, or false positive HCV antibody. A table on the interpretation of results of tests for Hepatitis C Virus (HCV) infection and further actions is available at: http://www.cdc.gov/hepatitis/HCV/PDFs/hcv_graph.pdf. CDC has not expressed a preference for which HCV infection test to use.

How soon after exposure to HCV can anti-HCV be detected?

HCV infection can be detected by anti-HCV screening tests (enzyme immunoassay) four to ten weeks after infection. Anti-HCV can be detected in >97% of persons by 6 months after exposure.

How soon after exposure to HCV can HCV RNA be detected?

HCV RNA appears in blood and can be detected as early as two to three weeks after infection.

For more information about the CDC HCV recommendations, see the “Testing for HCV infection: An Update of Guidance for Clinicians and Laboratorians-
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6218a5.htm
Local Health Department Guidance for HCV Screening & Testing:

1. Local Health Departments seeking to participate in the Kentucky HCV antibody Screening and Testing with HCV RNA Quantitative Confirmation Program should email the KY AVHPC Program to advise about participation and contact KY Division of Lab Services (DLS) dphlabkits@ky.gov to order PPT tubes and shipping/collection information and shipping materials.

HCV Rapid Testing

The KDPH recommends HCV Rapid test only for offsite HCV Outreach Programs or in Syringe Exchange programs. Training on the HCV Rapid can be arranged by contacting the rapid test manufacturer. Call the KY DLS for the contact information. HCV Rapid testing should not start until this training has occurred. Any Syringe Exchange Program using the HCV rapid test must have a Quality Control (QC) Plan. QC Plans can be reviewed by the DLS. Test kits and controls have a defined shelf life and must not be used beyond their expiration dates. The rapid tests have defined storage and temperature guidelines that must be followed.

2. Identify Linkage to Care in your region to ensure referrals for further evaluation for those with HCV RNA positive test results. Local Health Departments should confirm these providers have the capability to provide medical evaluation and treatment for individuals with HCV infection.

3. Identify HCV screening, educating, and testing healthcare personnel at your LHD who will provide HCV screening and testing services. The KY Adult Viral Hepatitis Prevention and Control Program is available to provide HCV Introductory Training upon request. The HCV Introductory Training will include screening, collection and handling, data and epidemiology data surveillance reporting and analysis, and appropriate counseling messages, with referral and linkage to care guidance.

4. LHD’s identified healthcare staff should follow recommended guidance in this document for HCV testing; this includes: Confidentiality; Staff training on identifying who is at risk for HCV infection, and the ability to provide screening, education, and testing; HCV Epidemiology Data Analysis using the Kentucky HCV RNA Quantitative Testing Patient Information Log with the ability to report and email the KY AVHPC the data analysis monthly; HCV Counseling and Referral tracking to HCV diagnostic testing, care, treatment and other supportive services. LHDs should request data management assistance from their Regional Epidemiologist.

Referral for HCV Management and Treatment

What should be done for a patient with confirmed HCV infection?

HCV-positive persons should be evaluated (by referral or consultation, if appropriate) for presence of chronic liver disease, including assessment of liver function tests, evaluation for severity of liver disease and possible treatment, and determination of the need for Hepatitis A and Hepatitis B vaccination.
Hepatitis A and hepatitis B vaccines are recommended for persons with HCV infection to prevent additional damage to the liver that infections from these other hepatitis viruses may cause.

**When might a specialist be consulted in the management of HCV-infected persons?**

Any physician or medical provider who manages a person with Hepatitis C should be knowledgeable and current on all aspects of the care of a person with Hepatitis C; this can include specialists such as infectious disease physicians, gastroenterologists, or hepatologists.

Referral appointments can be tracked to ensure follow through by the client. Linkage agreement/MOU can include specific language on the process for tracking referrals to ensure efficient tracking of referrals. LHDs should obtain a signed release of information from individuals to ensure that they may obtain all necessary information from the referral provider.
Counseling Patients

What topics should be discussed with individuals who have HCV infection?

- Individuals should be informed about the risk for transmission to sex partners.
- Sharing personal items that might have blood on them, such as toothbrushes or razors, can pose a risk to others.
- Cuts and sores on the skin should be covered to keep from spreading infectious blood or secretions.
- Donating blood, organs, tissue, or semen can spread HCV to others.
- HCV is not spread by sneezing, hugging, holding hands, coughing, sharing eating utensils or drinking glasses, or through food or water.
- Individuals may benefit from a joining a local HCV support group.

What should HCV-infected persons be advised to do to protect their livers from further harm?

- HCV-positive persons should be advised to avoid alcohol because it can accelerate cirrhosis and end-stage liver disease.
- Viral hepatitis patients should also check with a health professional before taking any new prescription pills, over-the-counter drugs (such as non-aspirin pain relievers), or supplements, as these can potentially damage the liver.

Pregnancy and HCV Infection

On April 10, 2018, Governor Bevin amended SB 250 KRS 214.160 to establish that all pregnant women be tested for hepatitis C and recommend testing for children born from a pregnant woman who has a positive hepatitis C result. Refer to 4- Hepatitis C (HCV) Infection Screening and Referral Guidance for Pregnant Women. HCV infection in pregnant women and infants born to mothers with hepatitis C is reportable to public health officials. Complete the EPID 394 Kentucky Reportable Disease Form and fax to 502-564-4760.

What is the risk that an HCV-infected mother will spread HCV to her infant during birth?

Approximately 6 of every 100 infants born to HCV-infected mothers become infected with the virus. Transmission occurs at the time of birth, and no prophylaxis is available to prevent it. The risk is increased by the presence of maternal HCV viremia at delivery and also is two to three times greater if the woman is co-infected with HIV. Most infants infected with HCV at birth have no symptoms and do well during childhood. More research is needed to find out the long-term effects of perinatal HCV infection.

There is no evidence that breastfeeding spreads HCV. However, HCV-positive mothers should consider abstaining from breastfeeding if their nipples are cracked or bleeding.
Infants born to mothers with HCV infection

On April 10, 2018, Governor Bevin amended SB 250 KRS 214.160 to recommend testing for children born from a pregnant woman who has a positive hepatitis C test result. The KDPH recommends HCV RNA testing for Infants born to mothers infected with HCV at the infant's well-child visit at age two months or four months. HCV RNA testing should then be repeated at a subsequent visit in four to six months, independent of the initial HCV RNA test result if the first test is reported as negative.

An infant born to mothers with HCV infection is reportable to public health officials in Kentucky. Complete the EPID 394 Kentucky Reportable Disease Form and fax to 502-564-4760. An alternative anti-HCV antibody test (anti-HCV) can be offered no sooner than age 18 months because anti-HCV from the mother might last until this age. See the 5-Screening and Referral Guidance for Infants Born to Mothers with Hepatitis C Virus (HCV) Infection. Refer children with positive HCV test results to identified HCV pediatric specialists in your region. For questions on referral, contact the KY Adult Viral Hepatitis Prevention and Control Coordinator.

HCV Testing Provided at LHDs

Perform HCV high risk screening and offer HCV testing to individuals identified high risk by LHD personnel. LHDs should refer an individual identified with HCV risk factors whose health insurance coverage will cover the cost of HCV testing to a private provider for HCV testing and follow up. If the individual is uninsured or has insurance that will not pay for the cost of the HCV test, the LHD personnel qualified in venipuncture will collect and submit a specimen to the Kentucky Division of Lab Services (DLS) following guidance from 1-Hepatitis C Virus (HCV) Antibody and HCV RNA Quantitative Specimen Collection and Handling Guidance. The process includes:

- Email dphlabkits@ky.gov to obtain PPT tubes from DLS (Division of Laboratory Services)
- Collect a specimen from the patient using one 8.5mL PPT tube. Spin tube within 6 hours of collection. For sites lacking a centrifuge contact DLS at dphlabkits@ky.gov. Specimen should be at least 3mL plasma
- Send spun PPT tube to DLS using ice packs. Specimens collected on Friday should be frozen over the weekend and sent the following workday to DLS on ice packs or dry ice. When possible, send specimens using overnight mailing system to ensure that the specimens meet the shipping guidelines. Specimens will be stable refrigerated for 72 hours and if frozen, 6 weeks.
- DLS will perform the HCV antibody testing. If the antibody testing is positive, DLS will automatically reflex to Quantitative HCV RNA testing for confirmation. No second specimen is needed.

Simply collect the specimens using PPT tubes, spin them down, and ship to DLS using ice packs. If you have any questions about specimen collection and/or shipping, please contact DLS at dphlabkits@ky.gov. Please do not send DLS whole blood for the HCV antibody testing.

Please note that confirmatory testing will be performed by HCV RNA Quantitative testing. If you need assistance interpreting the HCV RNA Quantitative test results, please contact the DLS Supervisor of the Virology Section at 502-564-4446.
ADMINISTRATIVE REFERENCE SECTION
Coding on the HCV Screening and Testing Record & Coding on the Patient Encounter Form (PEF).

Medicaid Preventive Fee Schedule:
86803- Hepatitis C Antibody test, ..................................................................................$19.42
87522- Hepatitis C, Quantification, includes
    reverse transcription when performed .................................................................$58.29

99201- Office/ Outpatient Visit New .................................................................$39.86
99202- Office/ Outpatient Visit New .................................................................$68.99
99203- Office/ Outpatient Visit New .................................................................$100.39
99204- Office/ Outpatient Visit New .................................................................$155.31
99205- Office/ Outpatient Visit New .................................................................$194.18
99211- Office/ Outpatient Visit Established (EST) .........................................$18.28
99212- Office/ Outpatient Visit EST .................................................................$40.17
99213- Office/ Outpatient Visit EST .................................................................$67.93
99214- Office/ Outpatient Visit EST .................................................................$100.55
99215- Office/ Outpatient Visit EST .................................................................$135.11

Partnerships with local substance abuse service providers
LHDs are encouraged to work with local substance abuse services that treat IDUs to develop anti-HCV testing services for their clients. A current list of Kentucky Opioid Treatment programs can be found at:
**Kentucky Adult HCV Screening, Testing and Referral Guidance**

<table>
<thead>
<tr>
<th>Identify Individuals</th>
<th>HCV Pre-Test Counseling</th>
<th>HCV Testing</th>
<th>HCV RNA Confirmation &amp; Referral</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Identify Individuals for Testing - See KY DPH Hepatitis C Virus (HCV) Risk Assessment Form:</strong></td>
<td>Pre-test HCV counseling</td>
<td>Option 1 - Local Health Department</td>
<td>HCV RNA Quantitative Test Results</td>
</tr>
<tr>
<td>1). Baby boomers (born between 1945 and 1965)</td>
<td>1). Discuss CDC testing recommendations</td>
<td>HCV Antibody Test for Screening Individuals</td>
<td>If positive HCV RNA Quantitative results:</td>
</tr>
<tr>
<td>2). High Risk Factors Identified:</td>
<td>-Prevalence</td>
<td>B). Receive test results</td>
<td>B). Recommend follow up to either:</td>
</tr>
<tr>
<td>- Currently or ever injected drugs, including those who injected/ intranasal once or a few times many years ago</td>
<td>-Ways to prevent spread</td>
<td></td>
<td>-Primary care provider</td>
</tr>
<tr>
<td>- Unregulated body piercing and/ or tattoos</td>
<td>-Prognosis: Curable disease with appropriate management</td>
<td></td>
<td>-HCV Provider Specialist</td>
</tr>
<tr>
<td>- Household contact with a known HCV-positive person</td>
<td>3). Assess for, and if needed, recommend HIV and HBV testing</td>
<td></td>
<td>-Hepatologist</td>
</tr>
<tr>
<td>- History of high risk sexual behavior</td>
<td>4). Assess for, and if needed, recommend HepA &amp; HepB vaccinations</td>
<td></td>
<td>-Gastroenterologist</td>
</tr>
<tr>
<td>- History of sexually transmitted infection</td>
<td>5). Discuss HCV testing process and timing:</td>
<td></td>
<td>-Infectious Disease Specialist</td>
</tr>
<tr>
<td></td>
<td>Option 1: HCV antibody test</td>
<td></td>
<td>If negative HCV RNA Quantitative results:</td>
</tr>
<tr>
<td></td>
<td>Option 2: HCV rapid test</td>
<td></td>
<td>A). Provide test results and counseling</td>
</tr>
<tr>
<td></td>
<td>If positive results: HCV RNA Quantitative confirmation</td>
<td></td>
<td>B). Counsel regarding meaning of test results</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C). Counsel regarding HCV transmission and ways to prevent spread</td>
</tr>
</tbody>
</table>
Have certain medical conditions, including persons:
- who received clotting factor concentrates produced before 1987
- who were ever on long-term hemodialysis
- who have HIV infection
- who have Hepatitis B infection

<table>
<thead>
<tr>
<th>Option 2 - Syringe Exchange Programs</th>
<th>HCV RNA Quantitative Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>2). HCV Rapid Test for Screening Individuals</td>
<td>If positive HCV RNA Quantitative results:</td>
</tr>
<tr>
<td>1). Conduct onsite rapid HCV test</td>
<td>A). Provide HCV RNA test results. Counsel regarding meaning of test results, avoiding transmission to others and next steps of follow up</td>
</tr>
<tr>
<td>2). Receive test results</td>
<td>B). Recommend follow up to either:</td>
</tr>
<tr>
<td>HCV Rapid test</td>
<td>-Primary care provider</td>
</tr>
<tr>
<td>If Positive HCV antibody results:</td>
<td>-HCV Provider Specialist</td>
</tr>
<tr>
<td>1.) Provide on-site rapid test results and counseling</td>
<td>-Hepatologist</td>
</tr>
<tr>
<td>2). During same visit or later visit, draw blood for HCV RNA Quantitative testing using the “HCV Antibody and HCV RNA Quantitative Specimen Collection and Handling Guidance”</td>
<td>-Gastroenterologist</td>
</tr>
<tr>
<td>3). Receive lab results from lab</td>
<td>-Infectious Disease Specialist</td>
</tr>
<tr>
<td>If Negative HCV rapid results:</td>
<td>If negative HCV RNA Quantitative results:</td>
</tr>
<tr>
<td>A). Provide test results and counseling</td>
<td>A). Provide test results and counseling</td>
</tr>
<tr>
<td>B). Counsel regarding meaning of test results</td>
<td>B). Counsel regarding meaning of test results and</td>
</tr>
<tr>
<td>C). Counsel regarding HCV transmission and ways to prevent spread</td>
<td>C). Counsel regarding HCV transmission and ways to prevent spread</td>
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</tbody>
</table>
HIV

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CLINICAL PROTOCOLS

Requirements for HIV Pre/Post-Test Counseling

Reporting HIV/AIDS Cases
## HIV Testing – Initial Visit

### Conventional Testing (venipuncture)

<table>
<thead>
<tr>
<th>Before the Test</th>
</tr>
</thead>
</table>
| • *Step 1*: Introduce and orient client to session.  
  o Discuss confidentiality;  
  o Provide test information (possibility of up to 3 months after exposure before antibody detection; type of test; process to get results; and meaning of positive, negative, and indeterminate results);  
  o Get informed consent to be tested;  
  o Explain NO phone results given;  
  o Must have ID number to obtain anonymous test results;  
  o Written results will not be provided for test done anonymously.  
|  
| • *Step 2*: Identify client’s risk behaviors and circumstances.  
  • *Step 3*: Identify safer goal behaviors that are acceptable to the client.  
  • *Step 4*: Assist the client in developing their action plan to reduce risks.  
  • *Step 5*: Make referrals and provide support.  
  o Review symptoms of other STDs, offer screening services;  
  o Condom and syringe availability; and  
  o Review risks for viral hepatitis and review immunization history for hepatitis A and hepatitis B vaccines. Refer for immunizations, if needed.  
|  
| • *Step 6*: Summarize and close session.  
|  
| Complete administrative tasks.  
  o Initiate HIV Counseling and Testing Report Form, available at [http://chfs.ky.gov/forms](http://chfs.ky.gov/forms);  
  o Give appointment for Post-Test Counseling and results in two weeks with same provider. Note date (mm/dd/yy) on Local Use Field (L1) on HIV Counseling and Testing Report Form.  |

### Rapid Testing (fingerstick or oral swab)

<table>
<thead>
<tr>
<th>Before the Test</th>
</tr>
</thead>
</table>
| • *Step 1*: Introduce and orient client to session.  
  o Discuss confidentiality.  
  o Provide test information (possibility of up to 3 months after exposure before antibody detection; type of test; process to get results; and meaning of positive, negative, invalid, and indeterminate results).  
  o Get informed consent to be tested.  
|  
| Collect sample and perform rapid test per instructions on TRAIN (see course 1052459 for Clearview, course 1052460 for OraQuick), continue counseling:  
  • *Step 2*: Identify client’s risk behaviors and circumstances.  
  • *Step 3*: Identify safer goal behaviors that are acceptable to the client.  
  • *Step 4*: Assist the client develop an action plan to reduce risks.  |

### Assess Client Readiness and Interpret Rapid Test Results

<table>
<thead>
<tr>
<th>Preliminary Positive</th>
<th>Negative</th>
</tr>
</thead>
</table>
| • Show results;  
  • Assess coping ability; and  
  • Review need for confirmatory testing.  
  • *Step 5*: Make referrals and provide support.  
  o Draw blood for confirmatory testing and set an appointment for the confirmatory results;  
  o Review symptoms of other STDs, offer screening services;  
  o Review condom and syringe availability; and  
  o Review risks for viral hepatitis and review immunization history for hepatitis A and hepatitis B vaccines. Refer for immunizations, if needed.  
|  
| • *Step 6*: Summarize and close session.  
|  
| Initiate HIV Counseling and Testing Report Form,  
  |  
| • Show results;  
  • Assess coping ability;  
  • Explanation of no immunity to HIV; and  
  • Advise retest a minimum of 3 months from last exposure incident.  
  • *Step 5*: Make referrals and provide support.  
  o Review symptoms of other STDs, offer screening services;  
  o Condom and syringe availability; and  
  o Review risks for viral hepatitis and review immunization history for hepatitis A and hepatitis B vaccines. Refer for immunizations, if needed.  
|  
| • *Step 6*: Summarize and close session.  
|  
| Initiate HIV Counseling and Testing Report Form,  
  |
How to Collect sample and send to lab

- Submit 7-10 ml red stopper tube of whole blood to Virology Section of DLS. A numbered sticker which corresponds to the number of the lab slip must be placed on the blood tube.
- Confidential Test: Name and ID number on lab form and specimen tube.
- Anonymous Test: ID number only on lab form and specimen tube.
- Court-Ordered Test: Name and ID number on lab form and specimen tube. Send Administrative Order of the Courts Form 499 to DLS with specimen.

Follow Up Visit for HIV Test Results

<table>
<thead>
<tr>
<th>Post-Test Counseling Visit for Negative Results</th>
<th>Post-Test Counseling Visit for Positive Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Show results;</td>
<td>• Show results;</td>
</tr>
<tr>
<td>• Explanation of no immunity to HIV;</td>
<td>• Assess coping ability;</td>
</tr>
<tr>
<td>• Advise retest at minimum of 3 months from last exposure incident;</td>
<td>• Refer to Kentucky HIV Care Coordinator Program;</td>
</tr>
<tr>
<td>• Review risk factor reduction;</td>
<td>• Refer to area STD Program Supervisor for counseling assistance and partner services;</td>
</tr>
<tr>
<td>• Review symptoms of other STDs and offer screening services;</td>
<td>• Encourage anonymously-tested clients to agree to confidential services;</td>
</tr>
<tr>
<td>• Review condom and syringe availability;</td>
<td>• Refer for nutritional counseling;</td>
</tr>
<tr>
<td>• Review risks for viral hepatitis and review immunization history for hepatitis A and hepatitis B vaccines. Refer for immunizations, if needed;</td>
<td>• TB risk assessment and TB skin test (if not already done);</td>
</tr>
<tr>
<td>• Complete HIV Counseling and Testing Report Form* (sections for “Test Result,” “Result Provided,” and “If Results NOT provided, why?”).</td>
<td>• Review symptoms of other STDs and offer screening services;</td>
</tr>
</tbody>
</table>

*Submit copy of completed form to Kentucky HIV/AIDS Branch after giving results to patient. If patient does not return within two months for results, complete and submit the HIV Test Form to the HIV/AIDS Branch. Retain original copy at local site for at least one year in case the patient returns (in which case, update and resubmit form).

* CDC recommends: www.effectiveinterventions.org
Reporting HIV/AIDS Cases

Report either by phone or mail. When mailing, please place case forms inside of two (2) sealed envelopes, both marked CONFIDENTIAL.

Adult and pediatric case report forms can be downloaded from our website at: http://chfs.ky.gov/forms. Please use this form when mailing in case reports. Please do not fax any confidential information.

For reports from Jefferson, Henry, Oldham, Bullitt, Spencer, Shelby and Trimble counties:
Reporting by Phone:
Susan Delph at 502-574-6574

Reporting by Mail:
Louisville Metro Public Health and Wellness
Attn: Susan Delph
400 East Gray St. Rm 317
Louisville, KY 40202

For reports from the other 113 counties:
Reporting by Phone:
Julie Nakayima
at (866) 510-0008

Reporting by Mail:
Kentucky Department for Public Health
Attn: Julie Nakayima
275 E. Main Street HS2E-C
Frankfort, KY 40621

Additional information on the state regulation regarding reporting is available on our website at http://chfs.ky.gov/dph/epi/hivais.htm or by calling 866-510-0008.

Please note that the EPID 200 is NOT to be used for reporting of HIV/AIDS cases.
## Immunizations

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†Several manufacturers; for complete listing, see:
https://www.cdc.gov/vaccines/terms/USVaccines.html

*Dash (-) indicates: products that are supplied in their final form by the manufacturer and do not require mixing or reconstitution by user; slash (/) indicates: products that are mixed or reconstituted by user.

These protocols are based on the recommendations of the Advisory Committee for Immunization Practices (ACIP),
http://www.cdc.gov/vaccines/hcp/acip-recs/index.html
**Vaccine Information Statements (VIS):**
Vaccine Information Statements (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain to vaccine recipients, their parents, or their legal representative both the benefits and risks of administering certain vaccines. Federal law requires that VISs be handed out (before each dose) whenever certain vaccines are given.

Copies of the latest VISs, may be obtained from the CDC Website, https://www.cdc.gov/vaccines/hcp/vis/index.html, or on the Immunize.org Website, [http://www.immunize.org/vis/](http://www.immunize.org/vis/), or from within the Kentucky Immunization Registry.

**ACIP Recommended Immunization Schedules:**
The current editions of the ACIP “Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger,” catch-up immunization schedules for children and adolescents, and the ACIP “Recommended Immunization Schedule for Adults, Aged 19 Years or Older,” are available online from the CDC at [http://www.cdc.gov/vaccines/schedules/index.html](http://www.cdc.gov/vaccines/schedules/index.html).
Pediatric-type Diphtheria and Tetanus Toxoids (DT) Vaccine

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunization.

Recommended Schedule
DT vaccine can be given to children less than 7 years old, to complete the vaccination series if a child has a valid contraindication to pertussis vaccine or if parents refuse pertussis vaccine.

DT vaccine can be given concurrently with other vaccines.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Recommended Ages for routine vaccination</th>
<th>Schedule for catch-up vaccination (minimum intervals between doses)</th>
<th>Booster doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>DT</td>
<td>Dose #1 beginning &lt;12 months of age:</td>
<td>Dose #2 and dose #3 may be given four weeks after previous dose</td>
<td>Give booster dose (Td vaccine) at 11 through 12 years of age if 5 years have elapsed since last dose.</td>
</tr>
<tr>
<td></td>
<td>Give to children at 2m, 4m, 6m, 15 through 18m, 4 through 6yrs of age</td>
<td>Dose #4 may be given 6m after dose #3 but not before 12m of age</td>
<td>Give booster dose (Td vaccine) every ten years thereafter</td>
</tr>
<tr>
<td></td>
<td>Use schedule for catch-up vaccination</td>
<td>If dose #4 is given before 4th birthday, wait at least 6m for dose #5 (4 through 6 yrs of age)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>If dose #4 is given after 4th birthday, dose #5 is not needed.</td>
<td></td>
</tr>
<tr>
<td>DT</td>
<td>Dose #1 beginning ≥12 months of age:</td>
<td>Dose #2 may be given four weeks after previous dose</td>
<td>Give booster dose (Td vaccine) at 11-12 years of age if 5 years have elapsed since last dose.</td>
</tr>
<tr>
<td></td>
<td>Use schedule for catch-up vaccination</td>
<td>Dose #3 may be given 6-12m after dose #2</td>
<td>Give booster dose (Td vaccine) every ten years thereafter</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If dose #3 is given before 4th birthday, wait at least 6m for dose #4 (4-6yrs of age)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>If dose #3 is given after 4th birthday, dose #4 is not needed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dose #5 is not needed.</td>
<td></td>
</tr>
</tbody>
</table>

Adult-type tetanus and diphtheria toxoids (Td) vaccine should be used for all those aged 7 years and older and for whom pertussis vaccine is specifically contraindicated. (See Td/Tdap protocol)

- Tetanus disease does NOT confer immunity because of the very small amount of toxin required to produce illness.

Dosage and Route
Give DT vaccine 0.5 mL intramuscularly (IM).

Shake the vial well to distribute the suspension uniformly before withdrawing for administration. (Do not use if resuspension does not occur with vigorous shaking)
Always check the package insert prior to administration of any vaccine.

Anatomical Site

In children younger than 1 year (i.e., infants), the anterolateral aspect of the thigh is the preferred site of injection. In older children, the deltoid muscle is usually large enough for IM injection. The vaccine should not be injected into the gluteal area or areas where there is a major nerve trunk.

Precautions

- Moderate to severe illness, with or without fever (temporary precaution)
- Individuals who experience Arthus-type hypersensitivity reactions following a prior dose of tetanus toxoids usually have high serum tetanus antitoxin levels and should not be given further routine or even emergency doses of Td vaccine more frequently than every 10 years, even if they have a wound that is neither clean nor minor.
- As with other intramuscular injections, use with caution in patients on anticoagulant therapy.

Contraindications

Individuals with:

- Anaphylactic reaction to a previous dose of DT, latex, or any other component of the vaccine (see package insert for specific components)
- This vaccine is not recommended for persons aged 7 years and older.

Adverse Events

- See the product’s package insert
- See Adverse Events Following Vaccinations page of this section

Storage and Handling

- Store in refrigerator at 36°F – 46°F (2°C – 8°C)
DO NOT FREEZE; discard if product has been frozen.
Diphtheria and Tetanus Toxoids and Acellular Pertussis (DTaP) Vaccine Adsorbed

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunization.

Recommended Schedule
DTaP is indicated for active immunization against diphtheria, tetanus and pertussis in infants and children 6 weeks through 6 years of age (prior to seventh birthday).

DTaP should not be administered to any infant before the age of 6 weeks or to individuals aged 7 years or older.

DTaP Schedule for Children < 7 Years of Age, Unless a Contraindication

<table>
<thead>
<tr>
<th>Dose</th>
<th>Vaccine</th>
<th>Recommended Age</th>
<th>Accelerated Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DTaP</td>
<td>2 months</td>
<td>&gt; 6 weeks of age</td>
</tr>
<tr>
<td>2</td>
<td>DTaP</td>
<td>4 months</td>
<td>&gt; 1 month after 1st dose</td>
</tr>
<tr>
<td>3</td>
<td>DTaP</td>
<td>6 months</td>
<td>&gt; 1 month after 2nd dose</td>
</tr>
<tr>
<td>4</td>
<td>DTaP</td>
<td>15 through 18 months</td>
<td>&gt; 6 months after 3rd dose</td>
</tr>
<tr>
<td>5</td>
<td>DTaP</td>
<td>4 through 6 years</td>
<td>&gt; 6 months after 4th dose</td>
</tr>
<tr>
<td>Additional Boosters</td>
<td>Tdap/Td</td>
<td>11 through 12 years of age, if &gt;5 years since 5th dose, then every 10 years</td>
<td>1st booster &gt;5 years after the 5th dose, then every 10 years</td>
</tr>
</tbody>
</table>

Diphtheria and Tetanus Toxoids Adsorbed (For Pediatric Use), DT, is indicated only for children less than 7 years of age and for whom pertussis vaccine is specifically contraindicated. (See DT protocol)

Dosage and Route
Give DTaP vaccine 0.5 mL intramuscularly (IM) according to the recommended schedule.
Do NOT administer this product intravenously or subcutaneously.

See protocols for Tdap and Td vaccines.

Always check the package insert prior to administration of any vaccine.
Anatomical Site

Administer IM vaccines at a 90° angle with a 22- to 25-gauge needle.

- For infants < 12 months of age, administer into the anterolateral aspect of the thigh with a 7/8- to 1-inch needle. (For newborn and or low birth weight infants only, a 5/8” needle may be considered.)
- For children ≥12 months of age, administer into the anterolateral aspect of the thigh or deltoïd muscle, using a 7/8- to 1¾-inch needle.
- As with other intramuscular injections, use with caution in patients on anticoagulant therapy.

Precautions

- Moderate to severe illness, with or without fever (temporary precaution)
- Temperature of 105° F (40.5° C) or higher within 48 hours after previous dose of DTaP or, DTP unexplained by any other cause
- Seizures or convulsions, with or without fever, within 72 hours after previous dose of DTaP or DTP
- Collapse or shock-like state (e.g., hypotonic hyporesponsive episode) within 48 hours after previous dose of DTaP or DTP
- Persistent, inconsolable crying lasting 3 hours or longer within 48 hours of previous dose of DTaP or DTP
- Guillain-Barré syndrome (GBS) within 6 weeks after a dose of DTaP or DTP
- Underlying unstable neurologic disorders (including seizure disorders cerebral palsy, and developmental delay)

Contraindications

Individuals with:

- Anaphylactic reaction to previous dose of DTaP, latex, or any other component of the vaccine (see package insert for specific components) should not receive DTaP
- Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not due to another identifiable cause within 7 days of previous dose of DTP or DTaP
- Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy – defer DTaP until neurologic status clarified and stabilized

Adverse Events

- See the product’s package insert
- See Adverse Events Following Vaccinations page of this section

Storage and Handling

- Store in refrigerator at 36°F – 46°F (2°C – 8°C)
- DO NOT FREEZE; discard if product has been frozen.
Other Important Notes

- Administer DTaP vaccine simultaneously with all other vaccines indicated according to the recommended schedule and the patient’s current vaccine status.
- DTaP and DT should not be given to individuals aged 7 years and older.
- The fourth dose of DTaP may be administered as early as 12 months of age, provided 6 months have elapsed since the third dose and the child is unlikely to return at age 15 through 18 months.
- The fifth dose of DTaP is not necessary if the fourth dose was given on or after the 4th birthday.
Diphtheria Tetanus Acellular Pertussis-Inactivated Poliovirus (DTaP-IPV) Combination Vaccine (KINRIX®)

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunization.

Indications and Usage:
KINRIX® is indicated for active immunization against diphtheria, tetanus, pertussis, and poliomyelitis.
KINRIX® (DTaP-IPV) is approved for the fifth dose in the DTaP vaccine series and the fourth dose in the IPV series in children 4 through 6 years of age whose previous vaccine doses have been with INFANRIX® (DTaP) and/or PEDIARIX® (DTaP-HepB-IPV) for the first three doses and INFANRIX® for the fourth dose.

Recommended Schedule
Give a single dose in children 4 through 6 years of age who meet eligibility requirements.
The minimum interval from dose 4 to dose 5 should be at least 6 months to provide an optimum booster response.

Dosage
KINRIX® is to be administered as a single 0.5 mL dose by intramuscular (IM) injection. KINRIX® is available in 0.5 mL single dose vials and in prefilled TIP-LOK syringes.

Preparation for Administration
Shake vigorously to obtain a homogeneous, turbid, white suspension. DO NOT USE if resuspension does not occur with vigorous shaking.

Anatomical Site
The preferred site of administration is the deltoid muscle of the upper arm.
Do not administer KINRIX® intravenously, intradermally or subcutaneously.

Precautions
If Guillain-Barré syndrome occurs within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give any tetanus toxoid-containing vaccine, including KINRIX®, should be based on careful
consideration of the potential benefits and possible risks. When a decision is made to withhold tetanus toxoid, other available vaccines should be given as indicated.

The tip cap and the rubber plunger of the needleless prefilled syringes contain dry natural latex rubber that may cause allergic reactions in latex sensitive individuals. The vial stopper is latex-free.

**Contraindications**

Individuals with:

- An anaphylactic reaction to previous dose of any diphtheria toxoid, tetanus toxoid, pertussis or poliovirus-containing vaccine, or to any component of KINRIX®, including neomycin and polymyxin B (see package insert). Because of the uncertainty as to which component of the vaccine might be responsible, no further vaccination with any of these components should be given. Alternatively, such individuals may be referred to an allergist for evaluation if immunization with any of these components is considered.
- Encephalopathy within 7 days of administration of a previous dose of a pertussis containing vaccine.
- Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy is a contraindication of any pertussis-containing vaccine.

**Adverse Events**

- See the product’s package insert
- See Adverse Events Following Vaccinations page of this section

**Storage and Handling**

- Store in refrigerator at 36°F – 46°F (2°C – 8°C)
- DO NOT FREEZE; discard if product has been frozen.

**Additional Information:**

- "**Indications and Guidance for Use:** DTaP-IPV (KINRIX®) is indicated for use as the fifth dose of DTaP and fourth dose of IPV in children aged 4 through 6 years who received DTaP (INFANRIX) and/or DTaP-Hepatitis B-IPV (PEDIARIX) as the first 3 doses and DTaP (INFANRIX) as the fourth dose (1,2). This vaccine should not be administered to children aged less than 4 years or aged 7 years and older; however, if DTaP-IPV (KINRIX®) is inadvertently administered for an earlier dose of the DTaP and/or IPV series, the dose should be counted as valid and does not need to be repeated provided minimum interval requirements have been met (5). Data are limited on the safety and immunogenicity of interchanging DTaP vaccines from different manufacturers (6). ACIP recommends that, whenever feasible, the same manufacturer’s DTaP vaccines should be used for each dose in the series; however, vaccination should not be deferred because the type of DTaP previously administered is unavailable or unknown.” (MMWR October 3, 2008 / 57(39);1078-1079)
• Vaccine Information Statements -- There is no specific Vaccine Information Statement (VIS) for KINRIX®. When administering a combination vaccine, the VIS for the individual component vaccines must be supplied.

• CPT 90696

• ACIP has clarified the poliovirus vaccination schedule to be used for specific combination vaccines. When DTaP-IPV/Hib (Pentacel) is used to provide 4 doses at ages 2, 4, 6, and 15 through 18 months, an additional booster dose of age-appropriate IPV-containing vaccine (IPV [IPOL] or DTaP-IPV (KINRIX®)) should be administered at age 4 through 6 years. This will result in a 5-dose IPV vaccine series, which is considered acceptable by ACIP. DTaP-IPV/Hib (Pentacel) is not indicated for the booster dose at age 4 through 6 years. ACIP recommends that the minimum interval from dose 4 to dose 5 should be at least 6 months to provide an optimum booster response. In accordance with existing recommendations, if a child misses an IPV dose at age 4 through 6 years, the child should receive a booster dose as soon as feasible (MMWR August 7, 2009/ 58(30); 830).
Diphtheria Tetanus Acellular Pertussis-Inactivated Poliovirus (DTaP-IPV) Combination Vaccine (QUADRACEL®)

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunization.

Indications and Usage
QUADRACEL® is indicated for active immunization against diphtheria, tetanus, pertussis, and poliomyelitis. QUADRACEL® (DTaP-IPV) is approved for the fifth dose in the DTaP vaccine series and the fourth or fifth dose in the IPV series in children 4 through 6 years of age who have received four doses of DTaP-IPV-Hib (PENTACEL®) and/or DTaP (DAPTACEL®) vaccine.

Recommended Schedule
Give a single dose in children 4 through 6 years of age who meet eligibility requirements. The minimum interval from dose 4 to dose 5 should be at least 6 months to provide an optimum booster response. Note that the final dose in the IPV series must be administered at age ≥4 years regardless of the number of previous doses, and with a minimum interval of 6 months from the previous dose.

Dosage
QUADRACEL® is to be administered as a single 0.5 mL dose by intramuscular (IM) injection. QUADRACEL® is available in suspension for injection, supplied in single dose (0.5 mL) vials.

Preparation for Administration
Shake the vial well, until a uniform, white, cloudy suspension results before use. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the product should not be administered.

Anatomical Site
The preferred site of administration is the deltoid muscle of the upper arm.
Do not administer QUADRACEL® intravenously, intradermally, or subcutaneously.

Precautions
If Guillain-Barré syndrome occurs within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give any tetanus toxoid-containing vaccine, including QUADRACEL®, should be based on careful consideration of the potential benefits and possible risks.

Carefully consider benefits and risks before administering QUADRACEL® to persons with a history of:

- Fever 40.5° C or higher (105° F or higher), hypotonic-hyporesponsive episode (HHE) or persistent, incolsolable crying lasting 3 hours or longer within 48 hours after a previous pertussis-containing vaccine.
- Seizures with/without fever within 3 days after a previous pertussis-containing vaccine.
**Contraindications**

Individuals with:
- Anaphylactic reaction to previous dose of any diphtheria toxoid, tetanus toxoid, pertussis, or poliovirus-containing vaccines, or to any component of QUADRACEL<sup>®</sup>.
- Encephalopathy within 7 days of administration of a previous dose of a pertussis containing vaccine with no other identifiable cause.
- Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy is a contraindication of any pertussis-containing vaccine.

**Adverse Events**
- See the product’s package insert.
- See Adverse Events Following Vaccinations page of this section.

**Storage and Handling**
- Store in refrigerator at 35°F - 46°F (2°C - 8°C).
- DO NOT FREEZE; discard if product has been frozen.
- Do not use after expiration date on label.

**Additional Information**
- “Indications and Guidance for Use: DTaP-IPV (QUADRACEL<sup>®</sup>) is indicated for use as the fifth dose of DTaP and fourth or fifth dose of IPV in children aged 4 through 6 years who received four doses of PENTACEL<sup>®</sup> and/or DAPTACEL<sup>®</sup> vaccine. This vaccine should not be administered to children aged less than 4 years of age 7 years and older; however, if DTaP-IPV (QUADRACEL<sup>®</sup>) is inadvertently administered for an earlier dose of the DTaP and/or IPV series, the dose should be counted as valid and does not need to be repeated provided minimum interval requirements have been met (5). Note that the final dose in the IPV series must be administered at age ≥4 years regardless of the number of previous doses, and with a minimum interval of 6 months from the previous dose. **Data are limited on the safety and immunogenicity of interchanging DTaP vaccines from different manufacturers** (6). ACIP recommends that, whenever feasible, the same manufacturer’s DTaP vaccines should be used for each dose in the series; however, vaccination should not be deferred because the type of DTaP previously administered is unavailable or unknown.” (*MMWR Morb Mortal Wkly Rep.* 2015 Sep 4;64(34):948-9).
- Vaccine Information Statements – There is no specific Vaccine Information Statement (VIS) for QUADRACEL<sup>®</sup>. When administering a combination vaccine, the VIS for the individual component vaccines must be supplied.
- ACIP has clarified the poliovirus vaccination schedule to be used for specific combination vaccines. When DTaP-IPV/Hib (PENTACEL<sup>®</sup>) is used to provide 4 doses at ages 2, 4, 6, and 15 through 18 months, an additional booster dose of age-appropriate IPV-containing vaccine (IPV [IPOL] or DRAp-IPV (KINRIX® [or QUADRACEL<sup>®</sup>])) should be administered at age 4 through 6 years. This will result in a 5-dose IPV vaccine series, which is considered acceptable by ACIP. DTaP-IPV/Hib (PENTACEL<sup>®</sup>) is not indicated for the booster dose at age 4 through 6 years. ACIP recommends that the minimum interval from dose 4 to dose 5 should be at least 6 months to provide an optimum booster response. In accordance with existing recommendations, if a child misses an IPV dose at age 4 through 6 years, the child should receive a booster dose as soon as feasible (*MMWR Morb Mortal Wkly Rep.* August 7, 2009/58(30); 830).
References


QUADRACEL® Package Insert (dated 03/2015)
DTaP-HepB-IPV Combination Vaccine (PEDIARIX®)

**Precautions and Contraindications**
Screen all patients for precautions and contraindications to immunization.

**Recommended Schedule**
DTaP-HepB-IPV is approved for the primary series routinely given at 2, 4 and 6 months of age. The recommended interval between doses is 6 to 8 weeks (preferably 8 weeks).

DTaP-HepB-IPV is approved for use in children aged 6 weeks through 6 years (prior to the 7th birthday). A child who is behind schedule can still receive DTaP-HepB-IPV as long as it is given for doses 1, 2 or 3 of the series and the child is less than 7 years of age.

DTaP-HepB-IPV can be used to complete the primary series in infants who have begun with the separate vaccines.

Children who have received DTaP-HepB-IPV can also receive TriHIBit® (DTaP-Hib) to complete the 4th dose of the DTaP and *Haemophilus influenzae* type b (Hib) series -- as long as it is the final dose in the Hib series, and the child has received at least one prior dose of Hib vaccine.

DTaP-HepB-IPV can be administered simultaneously with other vaccines given at separate injection sites, including Hib and pneumococcal conjugate (PCV7 is listed in the latest package insert) vaccines. Please refer to the section below on **Adverse Events** for additional information.

**Minimum Ages and Intervals**
- The recommended minimum age and interval for each dose are equivalent to the oldest age or longest interval recommended for any of the individual components for that dose. For example, the minimum age for dose #1 is 6 weeks (the same as DTaP and IPV), while the minimum age for the third dose is 24 weeks (the same as HepB).
- If an accelerated schedule is used, the minimum interval between the 1st and 2nd doses is 6 weeks; and between the 2nd and 3rd doses is 8 weeks, but the 3rd dose should not be given before age 24 weeks. Please refer to the table below.

<table>
<thead>
<tr>
<th>Dose</th>
<th>Minimum Age</th>
<th>Minimum Interval from Previous Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6 weeks</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>10 weeks</td>
<td>6 weeks</td>
</tr>
<tr>
<td>3</td>
<td>24 weeks</td>
<td>8 weeks*</td>
</tr>
</tbody>
</table>

*And not before 24 weeks of age

Children who have fallen out of the regular schedule may also receive PEDIARIX® for the primary series up to the age of 7 years.
**Dosage and Route**

Give **PEDIARIX** vaccine 0.5 mL intramuscularly (IM).

Always check the package insert prior to administration of any vaccine.

**Anatomical Site**

The preferred sites are the anterolateral aspects of the thigh or into the deltoid muscle. The vaccine should not be injected into the gluteal area or areas where there is a major nerve trunk.

**Precautions**

- Moderate to severe illness, with or without fever (temporary precaution)
- **PEDIARIX** should be given with caution in children with bleeding disorders such as hemophilia or thrombocytopenia, with steps taken to avoid the risk of hematoma following injection.
- As with other intramuscular injections, use with caution in patients on anticoagulant therapy.
- As with any vaccine, if administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the expected immune response may not be obtained. See package insert about immunosuppressive therapies.
- While the single dose vial is latex-free, the tip cap and rubber plunger of the needle-less, pre-filled syringes contains dry natural rubber latex that may cause allergic reactions in latex sensitive individuals.

**Contraindications**

Individuals with:

- Anaphylactic reaction to previous dose of this vaccine or with any component of this vaccine (see package insert).
- Hypersensitivity to any component of the vaccine, including yeast, neomycin, and polymyxin B, is a contraindication.
- This vaccine is not recommended for persons before the age of 6 week or for those persons 7 years of age and older.
- The contraindications and precautions for DTaP-HepB-IPV are the same as they would be for any of its individual component vaccines. Please refer to the package insert for a complete list of contraindications and precautions and to immunization protocols for individual component vaccines.
- Encephalopathy within 7 days of administration of a previous dose of a pertussis containing vaccine
- Evolving neurologic disease, including infantile spasms, epilepsy or progressive encephalopathy

**Adverse Events**

- See the product’s package insert
- See Adverse Events Following Vaccinations page of this section

**Storage and Handling**

- Store in refrigerator at 36°F – 46°F (2°C – 8°C)
- DO NOT FREEZE; discard if product has been frozen.
Additional Information

- Vaccine Information Statements
  There is not a specific Vaccine Information Statement (VIS) for PEDIARIX®. When administering a combination vaccine, the VISs for the individual component vaccines must be supplied. DTaP-HepB-IPV may be used interchangeably with other pertussis-containing or HepB vaccines.

- DTaP-HepB-IPV is considered preservative-free. However, a trace amount of thimerosal (<0.0125 mcg/0.5 mL) is present.

References:

Package Insert – PEDIARIX (Dated 10/2016),
https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing Information/Pediarix/pdf/PEDIARIX.PDF.
Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated
Poliovirus and *Haemophilus* b Conjugate
(Tetanus Toxoid Conjugate) Vaccine
DTaP-IPV/Hib Combination Vaccine (PENTACEL®)

**Precautions and Contraindications**
Screen all patients for precautions and contraindications to immunization.

**Indications and Usage:**
PENTACEL® vaccine is indicated for active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to *Haemophilus influenzae* type b. PENTACEL® vaccine is approved for use in children 6 weeks through 4 years of age (prior to fifth birthday).

**Recommended Schedule**

<table>
<thead>
<tr>
<th>Administration of PENTACEL®, DTaP-IPV/Hib</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose</strong></td>
</tr>
<tr>
<td>One (1), or any dose</td>
</tr>
<tr>
<td>Two (2)</td>
</tr>
<tr>
<td>Three (3)</td>
</tr>
<tr>
<td>Four (4)</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

*Use of the minimum age and minimum intervals for vaccine administration in the first 6 months of life are recommended only if the vaccine recipient is at risk for imminent exposure to circulating poliovirus.

<table>
<thead>
<tr>
<th>Dose</th>
<th>Maximum age for PENTACEL® Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Dose</td>
<td>4 years, 364 days (i.e., do not administer at age 5 years or older.)</td>
</tr>
</tbody>
</table>
MMWR dated December 19, 2007 CDC recommended that PedvaxHIB, a Hib capsular polysaccharide polyribosylribitol phosphate [PRP]), be used for vaccinating American Indian/Alaska Native (AI/AN) children due to the increased risk of developing Hib disease in the first six months of life; therefore, PENTACEL® IS NOT RECOMMENDED FOR USE IN THE AI/AN POPULATION.

PENTACEL® vaccine is approved for administration as 4-dose series routinely given at 2, 4, and 6 months, and 15 through 18 months of age. The first dose may be given as early as 6 weeks of age.

- Four doses of PENTACEL® vaccine constitute a primary immunization course against pertussis.
- Three doses of PENTACEL® vaccine constitute a primary immunization course against diphtheria, tetanus, H influenzae type b invasive disease, and poliomyelitis.
- The fourth dose of PENTACEL® constitutes a booster vaccination against diphtheria, tetanus, H influenzae type b invasive disease and poliomyelitis.

If a decision is made to withhold pertussis vaccine, vaccination against diphtheria, tetanus, poliomyelitis and invasive disease due to H influenzae type be should be provided with brands of vaccines other than PENTACEL®.

Children who have completed a four-dose series with PENTACEL® should receive a fifth dose of DTaP vaccine at 4 through 6 years of age. Because the pertussis antigens in DAPTACEL® brand DTaP vaccine are the same as those in PENTACEL®, these children should receive DAPTACEL® vaccine as their fifth dose of DTaP.

Data are not available to evaluate the safety of DAPTACEL® vaccine following four previous doses of PENTACEL® vaccine [See the product’s package insert].

ACIP has clarified the poliovirus vaccination schedule to be used for specific combination vaccines. When DTaP-IPV/Hib (PENTACEL®) is used to provide 4 doses at ages 2, 4, 6, and 15 through 18 months, an additional booster dose of age-appropriate IPV-containing vaccine (IPV [IPOL] or DTaP-IPV (KINRIX®)) should be administered at age 4 through 6 years. This will result in a 5-dose IPV vaccine series, which is considered acceptable by ACIP.

DTaP-IPV/Hib (PENTACEL®) is not indicated for the booster dose at age 4 through 6 years. ACIP recommends that the minimum interval from dose #4 to dose #5 should be at least 6 months to provide an optimum booster response. In accordance with existing recommendations, if a child misses an IPV dose at age 4 through 6 years, the child should receive a booster dose as soon as feasible (MMWR August 7, 2009/ 58(30); 830).

Children Previously Vaccinated with One or More Doses of DAPTACEL® Vaccine: PENTACEL® vaccine may be used to complete the first 4 doses of the DTaP series in infants and children who have received one or more doses of DAPTACEL® and are also scheduled to receive the other antigens of PENTACEL® vaccine, however, the safety and efficacy of PENTACEL® vaccine in such infants have not been evaluated [See the product’s package insert]

Children Previously Vaccinated with One or More Doses of IPV: PENTACEL® vaccine may be used in the 4 dose IPV series in infants and children who have received 1 or more doses of another licensed IPV vaccine and are also scheduled to receive the other antigens of PENTACEL® vaccine, however, the safety and efficacy of PENTACEL® in such infants have not been evaluated [See the product’s package insert]. PENTACEL® is not indicated for the booster dose at age 4 through 6 years.
Children Previously Vaccinated with One or More Doses of *Haemophilus b* Conjugate Vaccine:
PENTACEL® may be used to complete the vaccination series in infants and children previously vaccinated with one or more doses of a *Haemophilus b* conjugate vaccine (either separately administered or as part of another combination vaccine), who are also scheduled to receive the other antigens of PENTACEL® vaccine, however, the safety and efficacy of PENTACEL® vaccine in such infants have not been evaluated [See the product’s package insert]. If different brands of *Haemophilus b* conjugate vaccines are administered to complete the series, three primary immunizing doses are needed, followed by a booster dose.

**Dosage and Route**

Give PENTACEL® vaccine 0.5 mL intramuscularly (IM).

Always check the package insert prior to administration of any vaccine.

**Anatomical Site**

The preferred sites are the anterolateral aspects of the thigh or into the deltoid muscle. The vaccine should not be injected into the gluteal area or areas where there is a major nerve trunk.

**Preparation for Administration:**

PENTACEL® vaccine should be inspected visually for extraneous particulate matter and/or discoloration before administration. If these conditions exist, PENTACEL® vaccine should not be administered.

**Reconstitution of Freeze-Dried Product and Withdrawal from Stoppered Vial:**

- Gently shake the vial of DTaP-IPV component
- Withdraw the entire liquid content
- Insert the syringe needle through the stopper of the vial of lyophilized ActHIB vaccine component and inject the liquid into the vial.
- Shake vial thoroughly
- After reconstitution, immediately withdraw 0.5 mL of PENTACEL® vaccine and administer intramuscularly
- PENTACEL® should be used immediately after reconstitution

The contraindications and precautions for DTaP-IPV/Hib are the same as they would be for any of its individual component vaccines. Please refer to the package insert for a complete list of contraindications and precautions and to the other immunization protocols for the individual component vaccines.

**Precautions**

- Before administration, a patient’s health status and medical history should be reviewed to determine whether any contraindications exist and to assess the benefits and risks.
- For infants or children at higher risk for seizures than the general population an appropriate antipyretic may be administered at the time of vaccination of any acellular pertussis containing vaccine, including PENTACEL®, and for the following 24 hours.
- If PENTACEL® is administered to immunocompromised persons, including persons receiving immunosuppressive therapy, the expected immune response may not be obtained.
Contraindications to the Administration of PENTACEL®

- A severe allergic reaction (e.g., anaphylaxis) after a previous dose of PENTACEL® vaccine, any ingredient of this vaccine, or any other tetanus toxoid, diphtheria toxoid, pertussis-containing vaccine, inactivated poliovirus vaccine or H influenzae type b vaccine (see PENTACEL® package insert)
- PENTACEL® vaccine is not recommended for persons before the age of 6 weeks or for those persons 5 years of age and older.
- The following medical events are contraindications to administration of any pertussis-containing vaccine, including PENTACEL® vaccine.
  - Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of administration of a previous dose of a pertussis containing vaccine that is not attributable to another identifiable cause
  - Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy. Pertussis vaccine should not be administered to individuals with such conditions until the neurologic status is clarified and stabilized.

Adverse Events

- See the product’s package insert
- See Adverse Events Following Vaccinations page of this section

Storage and Handling

- Store in refrigerator at 36°F – 46°F (2°C – 8°C)
- DO NOT FREEZE; discard PENTACEL® vaccine that has been frozen
- PENTACEL® vaccine should be used immediately after reconstitution

Additional Information:

- Vaccine Information Statements (VIS) -- No specific VIS is available for PENTACEL®
- CPT Code 90698
- Concomitant Administration with Other Vaccines: In clinical trials (See package insert), PENTACEL® was administered concomitantly, at separate sites, with pneumococcal conjugate vaccine (PCV7), hepatitis B vaccine, measles, mumps, rubella (MMR) vaccine, and varicella vaccine.
- Different lot numbers for the different components of DTaP-IPV/Hib are included on the DTaP-IPV vial and on the Hib powder vial. Providers should record lot numbers separately for the DTaP-IPV and Hib components, as stated in the MMWR dated October 3, 2008.
Protocol for Administration of Hepatitis A (HepA) Vaccine

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunization.

Indications (Pre-exposure)*
ACIP recommends HepA vaccination for pre-exposure protection from hepatitis A virus (HAV) infection for the following previously unvaccinated persons:

- **Routine vaccination:** All children aged 12 through 23 months
- **Catch-up vaccination** of unvaccinated children aged two through 18 years
- All persons aged 19 years and older seeking protection from hepatitis A virus (HAV) infection.
- **Persons in special populations** at increased risk for HAV infection, including:
  - Persons traveling to or working in countries that have high or intermediate endemicity of infection *;  
  - Men having sex with men;  
  - Persons who use injection and non-injection illicit drugs;  
  - Persons with clotting-factor disorders;  
  - Persons with chronic liver disease; and  
  - Persons working with HAV-infected primates or with HAV in a research laboratory;  
  - Persons who anticipate close personal contact (e.g., household contact or regular babysitting) with an international adoptee from a country of high or intermediate endemicity during the first 60 days following arrival of the adoptee in the United States.  
  - Food service workers who work in areas where community-wide hepatitis A outbreaks are occurring and where state and local health authorities or private employers determine that such vaccination is cost-effective

* Countries outside the US other than Canada, Australia, New Zealand, Japan, and Western Europe should be considered to have high or intermediate endemicity for hepatitis A virus.

Recommended Schedule for Single-Antigen Hepatitis A Vaccine Formulations
- All children should receive hepatitis A vaccine (HepA) at **one year of age** (i.e., 12 through 23 months of age). The two doses in the series should be administered at least six to 18 months apart.
- Children who have received one dose of HepA vaccine before age 24 months should receive a second dose six to 18 months after the first dose.
- Children aged 24 months through 18 years should receive a primary dose with one booster dose six to 18 months later.
- Adults aged 19 years and older should receive a primary dose with one booster dose six to 18 months later.
• Close contacts of an international adoptee should receive the first dose of the 2-dose HAV series as soon as adoption is planned, ideally two or more weeks before the arrival of the adoptee in the United States.

**Dosage and Route**

• 0.5-mL, intramuscular (IM) - Infants and children (Pediatric / Adolescent formulation - 12 months through 18 years of age)
• 1-mL intramuscular (IM) – Adults, 19 years of age and older (Adult formulation)

**HAVRIX** (HepA vaccine manufactured by GlaxoSmithKline) is available in two formulations, which differ according to the person’s age:

  o Persons aged 12 months through 18 years, should receive 720 EL.U. per dose (0.5-mL) in a 2-dose schedule
  o Persons aged 19 years and older should receive 1,440 EL.U. per dose (1-mL) in a 2-dose schedule.

**VAQTA** (HepA vaccine manufactured by Merck & Co., Inc) is licensed in two formulations, which differ according to the person’s age:

  o Persons aged 12 months through 18 years should receive 25 U per dose (0.5-mL) in a 2-dose schedule;
  o Persons aged 19 years and older should receive 50 U per dose (1-mL) in a 2-dose schedule.

The pediatric formulations of either **HAVRIX** or **VAQTA** are not FDA approved for administration to adults, aged 19 years and older.

**Anatomical Site**

• In children and adolescents (i.e., persons aged 12 months through 18 years), the deltoid muscle can be used if the muscle mass is adequate
• The needle size for children and adolescents can range from 22 to 25 gauge and from 7/8 to 1 ¾ inches, on the basis of the size of the muscle
• For toddlers, the anterolateral thigh can be used, but the needle is usually 1 inch. For adults (i.e., persons aged 19 years and older) the deltoid muscle is recommended for routine intramuscular vaccinations. The anterolateral thigh can be used. The suggested needle size is 1-1½ inches and 22-25 gauge.
• In adults (i.e., persons aged 19 years and older), the deltoid muscle can be used if the muscle mass is adequate

**Precautions**

• **Pregnancy:** The safety of HepA vaccination during pregnancy has not been determined; however, because HepA vaccine is produced from inactivated hepatitis A virus (HAV), the theoretical risk to the developing fetus is expected to be low. The risk associated with vaccination should be weighed against the risk for hepatitis A in women who may be at high risk for exposure to HAV
• Prior to administering the vaccine, obtain a vaccination history to determine any reactions to any vaccine including HepA vaccine.

**See precautions in package insert** for administration to individuals with a history of bleeding disorders such as hemophilia or thrombocytopenia or to individuals on anticoagulant therapy.

• Persons with immunodeficiency (may have a suboptimal response)
• Latex allergy – **See WARNINGS in package insert** for information about any latex components in the vial stopper and / or prefilled syringes for the particular brand of hepatitis A vaccine being used.

**Contraindications**
Individuals with:

• **Allergy to vaccine components**
  Anaphylactic reaction to the vaccine or a constituent of the vaccine
• **Acute, moderate or severe illness with or without fever**

**Adverse Events**

• See the product’s package insert
• See Adverse Events Following Vaccinations page of this section

**Storage and Handling**

• Store in refrigerator at 36°F – 46°F (2°C – 8°C)
• DO NOT FREEZE; discard if product has been frozen.

**Other Important Notes** --If administered concomitantly with immune globulin (IG), use a separate syringe and different anatomical site, preferably a different limb, for the administration of HepA vaccine.

**ADDITIONAL INFORMATION**

Preventing the spread of Hepatitis A virus to others:

• Educate on careful hand washing techniques and good hygiene
• Vaccination with hepatitis A is recommended for persons at increased risk for HAV infection or its consequences

**Post Exposure Prophylaxis** (e.g. During Hepatitis A outbreaks or as part of a contact investigation):
Persons who have recently been exposed to HAV and who have not been previously vaccinated should receive post exposure prophylaxis (PEP) as soon as possible and within two weeks of HAV exposure.

Options for Hepatitis A PEP, updated in 2017, include:

• Single antigen HepA vaccine is preferred for healthy persons aged 12 months through 40 years
• Immune globulin (IG) (new dose of 0.1 mL/kg).
IG (0.1 mL/kg) should be used for children less than 12 months of age, immunocompromised persons, persons who have chronic liver disease, and persons for whom HepA vaccine is contraindicated.

- IG is preferred for persons aged 41 years and older, however HepA vaccine can be used if IG is not available
- IG may be used for persons eligible to be vaccinated, who elect not to receive HepA vaccine

- Both single antigen HepA vaccine and IG: Persons administered IG for whom HepA vaccine is also recommended for other reasons should receive a dose of vaccine simultaneously with IG. For persons who receive HepA vaccine the second dose to complete the series should be administered according to the licensed schedule.

**Preexposure Prophylaxis for International Travel**

HepA vaccine at the age-appropriate dose is preferred to IG (see page 1) for many people.

Travelers who elect not to receive HepA vaccine, who are aged <12 months, or who are allergic to a component of HepA vaccine should receive a single dose of IG before travel.

For travel that will begin in ≤2 weeks to countries with high or intermediate hepatitis A endemicity *, older adults, immunocompromised persons, and persons with chronic liver disease or other chronic medical conditions may receive IG simultaneously with HepA vaccine at a separate anatomic injection site.

The following doses of IG (updated in 2017) are recommended for preexposure prophylaxis:

<table>
<thead>
<tr>
<th>Length of Stay</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 1 month</td>
<td>0.1 mL/kg</td>
</tr>
<tr>
<td>Up to 2 months</td>
<td>0.2 mL/kg</td>
</tr>
<tr>
<td>More than 2 months</td>
<td>0.2 mL/kg  (repeat every 2 months)</td>
</tr>
</tbody>
</table>

* Countries outside the US other than Canada, Australia, New Zealand, Japan, and Western Europe should be considered to have high or intermediate endemicity for hepatitis A virus.

**References:**

New Recommendations to Increase the Dose of GamaSTAN S/D (Immune Globulin [Human]) When Used for Prophylaxis for Hepatitis A,


DOI: [http://dx.doi.org/10.15585/mmwr.mm6636a5](http://dx.doi.org/10.15585/mmwr.mm6636a5)
MMWR: Advisory Committee on Immunization Practices Recommended Immunization Schedules for Persons Aged 0 Through 18 Years — United States, 2017,


Recommended Adult Immunization Schedule,

http://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html

Recommended Childhood Immunization Schedule,

http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

Package Insert: HAVRIX® (manufactured by GlaxoSmithKline) (Dated 05/2016)


Package Insert: VAQTA® (manufactured by Merck & Co., Inc) (Dated 02/2014)

Hepatitis A/B Vaccine (TWINRIX®)

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunization.

Indications
TWINRIX® brand hepatitis A/B vaccine is indicated for active immunization against hepatitis A virus (HAV) and hepatitis B virus (HBV) infection for the following eligible groups:

- Any person 18 years of age or older with an indication for both hepatitis A and hepatitis B vaccination
- Patients with chronic liver disease
- Injection drug users
- Men who have sex with men
- Persons with clotting factor disorders who receive therapeutic blood products
- International travelers under certain circumstances
  - Hepatitis A vaccine is recommended for travelers to areas of high or intermediate hepatitis A endemicity
  - Hepatitis B vaccine is recommended for travelers to areas of high or intermediate hepatitis B endemicity who plan to stay for six or more months and have frequent close contact with the local population.
- Persons at increased risk due to occupational exposure
- Hepatitis A vaccine is recommended for unvaccinated persons who anticipate close personal contact (e.g., household contact or regular babysitting) with an international adoptee from a country of high or intermediate endemicity during the first 60 days following arrival of the adoptee in the United States. Countries outside the US other than Canada, Australia, New Zealand, Japan, and Western Europe should be considered to have high or intermediate endemicity for hepatitis A virus.

Recommended Schedule
- Persons 18 years of age or older
- For persons, 18 years of age and older, recommended for Hepatitis A vaccine because of close contact with an international adoptee, the first three doses of the 4-dose series (i.e., the accelerated schedule) should be completed as soon as adoption is planned, ideally 2 or more weeks before the arrival of the adoptee. The fourth dose (i.e., the booster dose) in the accelerated schedule is needed to assure long-term immunity. Alternatively, TWINRIX® can be given with the regular dosing schedule with proper planning in anticipation of the adoption, so that all three doses are completed before the arrival of the adoptee.

Dosage and Route
- TWINRIX® should be administered by intramuscular injection. Do not inject intravenously, intradermally, or subcutaneously.
- Primary immunization for adults consists of three doses, given on a 0-, 1-, and 6-month schedule.
- Accelerated dosing schedule:
4-dose schedule, given on days 0, 7 and 21 to 30 followed by a booster dose 12 months after the first dose.

**Anatomical Site** (ACIP and the AAFP recommendations for intramuscular injections)
- For adults (persons 18 years of age and older) the deltoid muscle is recommended for routine intramuscular vaccinations. The suggested needle size is 1-1½ inches and 22-25 gauge.

**Precautions**
- See precautions in package insert
- Latex allergy – See WARNINGS in package insert for information about any latex components in the prefilled syringes being used. The vial stopper is latex-free.
- It is not known whether the vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This vaccine should only be given to a pregnant woman only if clearly indicated.
- It is not known whether this vaccine is excreted in human milk, caution should be exercised when administered to a nursing woman.
- As with other intramuscular injections, use with caution in patients on anticoagulant therapy

**Contraindications**

Individuals with:
- Allergy to vaccine components
- Allergy to Neomycin sulfate
- Allergy to Yeast protein
- Anaphylactic reaction to the vaccine or a constituent of the vaccine
- Acute, moderate or severe illness with or without fever

**Adverse Events**
- See the product’s package insert
- See Adverse Events Following Vaccinations page of this section

**Storage and Handling**
- Store in refrigerator at 36°F – 46°F (2°C – 8°C)
- DO NOT FREEZE; discard if product has been frozen.

**Other Important Notes**
- If administered concomitantly with immune globulin (IG), use a separate syringe and different site.
- Postexposure prophylaxis (PEP) during hepatitis A outbreaks or as part of a contact investigation. TWINRIX® vaccine should not be used for hepatitis A PEP. Use single antigen hepatitis A vaccine for hepatitis A PEP, when hepatitis A vaccine is indicated. See the Hepatitis A vaccine protocol for additional details.
Hepatitis B (HepB) Vaccine (Recombinant)

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunization.

Indications
Hepatitis B vaccination is indicated for the following eligible groups for active immunization against infection caused by all known subtypes of hepatitis B virus (HBV):

- All infants, children, and adolescents as part of the routine infant, child, and adolescent immunization schedule
- Catch-up vaccination of unvaccinated children aged 4 months through 18 years
- Persons at risk for infection by sexual exposure
  - Sex partners of hepatitis B surface antigen (HBsAg)-positive persons
  - Sexually active persons who are not in a long-term mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months)
  - Persons seeking evaluation or treatment for a sexually transmitted infection
  - Men who have sex with men
- Persons at risk for infection by percutaneous or mucosal exposure to blood
  - Current or recent injection-drug users
  - Household contacts of HBsAg-positive persons
  - Residents and staff of facilities for developmentally disabled persons.
  - Health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids.
  - Hemodialysis patients and predialysis, peritoneal dialysis, and home dialysis patients
  - Persons with diabetes aged 19 through 59 years;
  - Persons with diabetes aged 60 years and older at the discretion of the treating clinician or medical provider. Decisions to vaccinate these adults should incorporate consideration of the patient’s likelihood of acquiring HBV infection, including the risk posed by an increased need for assisted blood-glucose monitoring in long term care facilities, the likelihood of experiencing chronic sequelae if infected with HBV, and the declining immunologic responses to vaccines that are associated with frailty, a geriatric syndrome characterized by decreased physiologic reserve and increased vulnerability, leading to early mortality in older adults.
    - When a medical provider sends an order to a Local Health Department (LHD) or gives a prescription for HepB vaccine to the adult diabetic patient aged 60 years and older, the vaccine may be administered.
- When a LHD nurse assesses that an adult diabetic patient aged 60 years and older meets criteria listed above, an order for HepB vaccine may be obtained from the LHD medical provider or private medical provider.

- Others
  - International travelers to regions with high or intermediate levels of endemic HBV infection (i.e., HBsAg-positive prevalence of 2% or greater). See country specific travel recommendations for HepB vaccine on CDC’s Travelers’ Health Website, [https://wwwnc.cdc.gov/travel](https://wwwnc.cdc.gov/travel).
  - Persons with hepatitis C virus infection
  - Persons with chronic liver disease (including, but not limited to, persons with cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, and an alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal
  - Persons with HIV infection
  - Incarcerated persons
  - All other persons seeking protection from HBV infection

**Recommended Schedule**

**Hepatitis B Vaccination Schedule for Infants and Children Younger than 11 Years of Age**
(see Table on page 5 for additional dosing schedules)

<table>
<thead>
<tr>
<th>Dose</th>
<th>Vaccine</th>
<th>Recommended Age</th>
<th>Schedule if the Birth Dose WAS NOT Given or Catch-up Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HepB</td>
<td>Birth *</td>
<td>Birth (or elected date)</td>
</tr>
<tr>
<td>2</td>
<td>HepB</td>
<td>1 to 2 months, at least four weeks after dose 1</td>
<td>4 weeks after #1 dose</td>
</tr>
<tr>
<td>3</td>
<td>HepB</td>
<td>6 through 18 months, at least 8 weeks after dose 2 and at least 16 weeks after dose 1</td>
<td>Dose #3 must be:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- At least 8 weeks after dose 2, and</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- At least 16 weeks after dose 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- At 24 weeks of age or older</td>
</tr>
</tbody>
</table>

*PEDIARIX® can be given at 2, 4 and 6 months to infants who received a birth dose of HepB Vaccine (total of 4 doses). See CDC’s Pink Book 13th Edition, pg. 162.
**HepB vaccine and hepatitis B immune globulin (HBIG) at birth:**

- Administer monovalent (single-antigen) hepatitis B vaccine to all newborns within 24 hours of birth.
- For infants born to HBsAg-negative mothers, administer monovalent (single-antigen) HepB vaccine within 24 hours of birth.
- For infants born to HBsAg- positive mothers, administer HepB vaccine and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. These infants should be tested for both HBsAg and quantitative anti-HBs (i.e., antibody to HBsAg) 1 to 2 months after completion of the HepB series, at age 9 through 18 months (generally at the next well-child visit).
- If mother’s HBsAg status is unknown, within 12 hours of birth administer HepB vaccine to all infants regardless of the birth weight. For infants weighing < 2,000 grams, administer HBIG in addition to HepB vaccine within 12 hours of birth. Determine mother’s HBsAg status as soon as possible and, if she is HBsAg-positive, also administer HBIG for infants weighing ≥ 2,000 grams (no later than age 1 week).
- Infants born to women for whom HBsAg testing results during pregnancy are not available but other evidence suggestive of maternal HBV infection exists (e.g., presence of HBV DNA, HBeAg-positive, or mother known to be chronically infected with HBV) should be managed as if born to an HBsAg-positive mother. The infant should receive both HepB vaccine and HBIG within 12 hours of birth.
- If it is not possible to determine the mother's HBsAg status (e.g., when a parent or person with lawful custody safely surrenders an infant confidentially shortly after birth), the vaccine series should be completed according to a recommended schedule for infants born to HBsAg-positive mothers. The final dose in the series should not be administered before age 24 weeks (164 days). These infants should receive postvaccination serologic testing at age 9-12 months, and revaccination if necessary.

**HepB vaccine doses following the birth dose:**

- Administer monovalent (single-antigen) hepatitis B vaccine for doses administered before age 6 weeks.
- The second dose should be administered at age 1 or 2 months.
- Infants who did not receive a birth dose should receive three doses of a HepB containing vaccine on a schedule of 0, 1 to 2 months, and 6 months starting as soon as feasible.
- The minimum interval between dose 1 and dose 2 is 4 weeks and between dose 2 and dose 3 is 8 weeks. The final (third or fourth) dose in the HepB vaccine series should be administered no earlier than age 24 weeks and at least 16 weeks after the first dose.
- Administration of a total of 4 doses of HepB vaccine is recommended when a combination vaccine containing HepB is administered after the birth dose.
## Hepatitis B Vaccination Schedule for Children and Adolescents

<table>
<thead>
<tr>
<th>Age</th>
<th>Schedule&lt;sup&gt;1,6&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children (1 through 10 years)</td>
<td>0, 1, and 6 months&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>0, 2, and 4 months&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>0, 1, 2, and 12 months&lt;sup&gt;2,4&lt;/sup&gt;</td>
</tr>
<tr>
<td>Adolescents (11 through 18 years)</td>
<td>0, 1, and 6 months&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>0, 1, and 4 months&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>0, 2, and 4 months&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>0, 12, and 24 months&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>0 and 4 through 6 months&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>0, 1, 2, and 12 months&lt;sup&gt;2,4&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>0, 7 days, 21 through 30 days, 12 months&lt;sup&gt;5&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

*Table Notes:*

1. Children and adolescents may be vaccinated according to any of the schedules indicated, except as noted. Selection of a schedule should consider the need to optimize compliance with vaccination.

2. Pediatric/adolescent formulation.

3. A two-dose schedule of **RECOMBIVAX HB**<sup>®</sup> Adult Formulation is (10 micrograms) is licensed for adolescents aged 11 through 15 years. When scheduled to receive the second dose, adolescents aged more than 15 years should be switched to a three-dose series, with dose 2 and dose 3 consisting of the pediatric formulation administered on an appropriate schedule.

4. A four-dose schedule of ** ENGERIX-B**<sup>®</sup> is licensed for all age groups.

5. **TWINRIX**<sup>®</sup> can be administered to persons 18 years of age or older before travel or any other potential exposure on an accelerated schedule at 0, 7, and 21 to 30 days, followed by a booster dose 12 months after the first dose.

6. Use of brand names is not meant to preclude the use of other comparable US licensed vaccines.
Interrupted schedules and minimum dosing intervals

- When the HepB vaccine schedule is interrupted, the vaccine series does not need to be restarted. If the series is interrupted after the first dose, the second dose should be administered as soon as possible, and the second and third doses should be separated by an interval of at least eight weeks. If only the third dose has been delayed, it should be administered as soon as possible.
- The final dose of vaccine must be administered at least eight weeks after the second dose and should follow the first dose by at least 16 weeks; the minimum interval between the first and second doses is four weeks. Inadequate doses of Hepatitis B vaccine or doses received after a shorter than recommended dosing interval should be re-administered, using the correct dosage or schedule.
- Vaccine doses administered 4 days or less before the minimum interval or age are considered valid. Because of the unique accelerated schedule for TWINRIX® the four-day guideline does not apply to the first three doses of this vaccine when administered on a 0 day, 7 day, 21 to 30 day, and 12 month schedule.
- In infants, administration of the final dose is not recommended before age 24 weeks (164 days).

Hepatitis B Vaccination Schedule for Healthcare Personnel (HCP)

The Occupational Safety and Health Administration mandates that employers offer HepB vaccination to all employees who have occupational risk and that post exposure prophylaxis be available following an exposure.

- Healthcare Personnel who perform tasks that may involve exposure to blood or body fluids should receive a 3-dose series of hepatitis B vaccine at 0-, 1- and 6-month intervals. Test for antibody to hepatitis B surface antigen (i.e., quantitative anti-HBs) to document immunity 1 to 2 months after dose #3.
  - If anti-HBs is 10 mIU/mL or more (positive), the patient is immune. No further serologic testing or HepB vaccination is recommended.
  - If anti-HBs is less than 10 mIU/mL (negative), the patient is unprotected from hepatitis B virus (HBV) infection; revaccinate with a second complete 3-dose series. Retest (i.e., quantitative anti-HBs) 1 to 2 months after dose #3 of the second 3-dose series (i.e., after a total of 6 doses of HepB vaccine).
    - If anti-HBs is 10 mIU/mL or more (positive), the patient is immune. No further testing or HepB vaccination is recommended.
    - If anti-HBs is less than 10 mIU/mL (negative), after 6 doses of HepB vaccine, patient is a non-responder.
- Wounds and skin sites that have been in contact with blood or body fluids should be washed with soap and water: mucous membranes should be flushed with water. Using antiseptics (e.g., 2%-4% chlorhexidine) for wound care or expressing fluid by squeezing the wound further have not been shown to reduce the risk for HBV transmission; however, the use of antiseptics is not contraindicated. The application of caustic agents (e.g., bleach) or the injection of antiseptics or disinfectants into the wound is not recommended.

  o **For non-responders:** HCP who are non-responders should be considered susceptible to HBV and should be counseled regarding precautions to prevent HBV infections and the need to obtain HBIG prophylaxis for any known or probably parenteral exposure to hepatitis B surface antigen (HBsAg)-positive blood. It is also possible that non-responders are people who are HBsAg positive. Testing should be considered. HCP found to be HBsAg positive should be counseled and medically evaluated.

**Note:** Anti-HBs testing is not recommended routinely for previously vaccinated HCP (who have written documentation of a complete HepB vaccine series) and were not tested 1 to 2 months after their original vaccine series. These HCP should be tested for anti-HBs and the source patient (if known) should be tested for HBsAg as soon as possible after exposure. Anti-HBs testing should be performed using a method that allows detection of the protective concentration of anti-HBs (≥ 10 mIU/mL). Testing the source patient and the HCP should occur simultaneously; testing the source patient should not be delayed while waiting for the HCP anti-HBs test results and likewise testing the HCP should not be delayed while waiting for the source patient’s HBsAg results. See figure 3.


TABLE 5. Postexposure management of health care personnel after occupational percutaneous or mucosal exposure to blood or body fluids, by health care personnel HepB vaccination and response status

<table>
<thead>
<tr>
<th>HCP status</th>
<th>Source patient (HBsAg)</th>
<th>HCP testing (anti-HBs)</th>
<th>HBIG</th>
<th>Vaccination</th>
<th>Postvaccination serologic testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documented responder after complete series</td>
<td>Positive/unknown</td>
<td>_*</td>
<td>No action needed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documented nonresponder after two complete series</td>
<td>Positive/unknown</td>
<td>_*</td>
<td>HBIG x2 separated by 1 month</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>_</td>
<td>_</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Response unknown after complete series</td>
<td>Positive/unknown</td>
<td>&lt;10 mIU/mL</td>
<td>HBIG x1</td>
<td>Initiate revaccination</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>&lt;10 mIU/mL</td>
<td>None</td>
<td>Initiate revaccination</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Any result</td>
<td>≥10 mIU/mL</td>
<td>None</td>
<td>No action needed</td>
<td></td>
</tr>
<tr>
<td>Unvaccinated/incompletely vaccinated or vaccine refusers</td>
<td>Positive/unknown</td>
<td>_</td>
<td>HBIG x1</td>
<td>Complete vaccination</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>_</td>
<td>None</td>
<td>Complete vaccination</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Abbreviations: anti HB = antibody to hepatitis B surface antigen; HBIG = hepatitis B immune globulin; HBsAg = hepatitis B surface antigen; HCP = health care personnel; N/A = not applicable.

*Not indicated.
**TABLE 6. Postexposure management after distinct nonoccupational percutaneous or mucosal exposure to blood or body fluids**

<table>
<thead>
<tr>
<th>Exposure*</th>
<th>Unvaccinated person</th>
<th>Previously vaccinated person</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg-positive source</td>
<td>HepB vaccine series and HBIG</td>
<td>HepB vaccine dose</td>
</tr>
<tr>
<td>HBsAg status unknown for source</td>
<td>Hep B vaccine series</td>
<td>No management</td>
</tr>
</tbody>
</table>

**Abbreviations:** HepB = hepatitis B; HBsAg = hepatitis B surface antigen; HBIG = hepatitis B immune globulin.

* Exposures include percutaneous (e.g., bite or needlestick) or mucosal exposure to blood or body fluids, sex or needle-sharing contact, or victim of sexual assault/abuse
See Figure 3 for “Preexposure evaluation for health care personnel previously vaccinated with complete, ≥3-dose HepB vaccine series who have not had postvaccination serologic testing”
Catch-Up Schedule

- Unvaccinated persons should complete a 3-dose series.
- A 2-dose series (doses separated by at least 4 months) of adult formulation RECOMBIVAX HB® is licensed for use in adolescents aged 11 through 15 years.
- For other catch-up guidance from ACIP, see “Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind —United States, 2018,” [http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf](http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf).

Booster Doses

- Booster doses are not recommended for persons with normal immune status who were vaccinated as infants, children, adolescents, or adults. Serologic testing is not recommended to assess antibody concentrations in any age group, except in certain circumstances (see “Postvaccination Serologic Testing (PVST)” below).
- For hemodialysis patients, the need for booster doses should be assessed by annual anti-HBs testing. A booster dose should be administered when anti-HBs levels decline to <10 mIU/mL.
- For other immunocompromised persons (e.g., HIV-infected persons, hematopoietic stem cell transplant recipients and persons receiving chemotherapy), the need for booster doses has not been determined. When anti-HBs levels decline to <10 mIU/mL, annual anti-HBs testing and booster doses should be considered for immunocompromised persons with an ongoing risk for exposure.

Postvaccination Serologic Testing is NOT Routinely Recommended for Most Persons

- Not routinely recommended following vaccination of infants, children, adolescents, or most adults.
- Routine postvaccination testing is not recommended for persons at low risk of exposure, such as public safety workers and healthcare personnel without direct patient contact.

Postvaccination Serologic Testing is Routinely Recommended for Selected Individuals:

- **When indicated, postvaccination serologic testing (i.e., quantitative anti-HBs) should be performed 1 to 2 months after completion of the HepB vaccine series**
- Persons determined to have anti-HBs concentrations of ≥10 mIU/mL after receipt of the primary HepB vaccine series are considered immune, and the result should be documented.
- Postvaccination serologic testing is routinely recommended for:
  - Healthcare personnel who have contact with patients or blood
  - Infants born to HBsAg-positive women *See Immunizations/Perinatal Hepatitis B Prevention Program and Case Management Protocol in the CSG.*
  - Sex partners of HBsAg-positive persons
  - Persons with HIV infection
o Chronic hemodialysis patients
o Other immunocompromised persons (e.g., hematopoietic stem-cell transplant recipients or persons receiving chemotherapy)

Management of Nonresponse to Hepatitis B Vaccine

- A seroprotective (adequate) level of anti-HBs after completion of a HepB vaccination series is defined as anti-HBs ≥10 mIU/mL; a response < 10 mIU/mL is inadequate and is not a reliable indicator of protection.
- Persons for whom postvaccination serologic testing is recommended but did not adequately respond to the first HepB vaccine series should complete a second three-dose HepB vaccine series. The second HepB vaccine series should be given on the usual schedule of 0, 1, and 6 months.
- Retest (i.e., quantitative anti–HBs) 1 to 2 months after completing the second HepB vaccine series
- An alternative, though less practical option, is to conduct serologic testing after each additional dose of HepB vaccine or after one or more doses of HepB vaccine.
- Persons who do not have a protective concentration of anti–HBs (≥10 mIU/mL) after revaccination (i.e., after receiving a total of 6 HepB doses) should be tested for HBsAg and anti–HBc to determine their hepatitis B virus infection status.

Dosage and Route

- **Pediatric Vaccination Schedule (infants and children younger than 11 years of age):** The HepB vaccine series has three 0.5 mL doses – intramuscular (IM).
  - Administer 0.5 mL (5 mcg) of pediatric or adult formulation **RECOMBIVAX HB** ® (Merck) or
  - Administer 0.5 mL (10 mcg) of pediatric **INGERIX-B** ® (GlaxoSmithKline)

- **Adolescent Schedule (11 through 19 years of age):** The HepB vaccine series has three doses – intramuscular (IM).
  - For adolescents aged 11 through 19 years, administer 0.5 mL (5 mcg) of the pediatric or adult formulation of **RECOMBIVAX HB** ® (Merck) or
  - Administer 0.5 mL (10 mcg) of the pediatric formulation of **INGERIX-B** ® (GlaxoSmithKline).
  - The adult formulation of **INGERIX-B** ® may be used in adolescents, but the approved dose is 1 mL (20 mcg).

- **Alternative Adolescent Vaccination Schedule (11 through 15 years of age only):** The HepB vaccine series has two 1 mL (10 mcg) doses – intramuscular (IM). Administer 1 mL (10 mcg) only using the pediatric or adult formulation of **RECOMBIVAX HB** ® when using this schedule.
• **Adult Schedule (20 years of age and older):** The HepB vaccine series has three 1 mL doses – intramuscular (IM).
  o For adults aged 20 years and older, administer 1 mL (10 mcg) of pediatric or adult formulation **RECOMBIVAX HB®** (Merck) or
  o Administer 1 mL (20 mcg) of adult formulation **INGERIX-B®** (GlaxoSmithKline). The pediatric formulation of **INGERIX-B®** is not approved for use in adults.
  o Alternative adult schedules for single antigen HepB vaccine are 0, 1, and 6 months, 0, 1, and 4 months, and 0, 2, and 4 months for both HepB vaccine brands. An adult schedule of 0, 1, 2, and 12 months is FDA approved for **INGERIX-B®**. See the HepB vaccine package insert.

• **Adult patients receiving hemodialysis, predialysis patients, or with other immunocompromising conditions:**
  o The HepB vaccine series has three 1 mL doses – intramuscular (IM) of the **RECOMBIVAX HB®** Dialysis Formulation (40 mcg/mL) administered on a 3-dose schedule at 0, 1, and 6 months, or
  o The HepB vaccine series has four 2 mL (40 mcg/2 mL) doses of adult formulation **INGERIX-B®**– intramuscular (IM) administered on a 0, 1, 2, and 6 month schedule. Each dose in the series can be given as a single 2 mL dose or as two 1-mL doses in one visit.
  o **RECOMBIVAX HB®** Dialysis Formulation (40 μg/mL) is not provided by the Kentucky Vaccine Program (KVP) but may be ordered with Local Health Department funds. **RECOMBIVAX HB®** Dialysis Formulation may be available at private provider offices and specialty clinics.
  o Serologic testing of hemodialysis patients and other immunocompromised persons is recommended 1–2 months after administration of the final dose of the primary HepB vaccine series to determine the need for revaccination (see Postvaccination Testing for Serologic Response). In addition, booster doses of vaccine might be needed. For hemodialysis patients, the need for booster doses should be assessed by annual anti-HBs testing. A booster dose should be administered when anti-HBs levels decline to <10 mIU/mL.

**Anatomical Site** (ACIP and the AAFP recommendations for intramuscular injections)

• In children and adolescents (persons 12 months through 19 years of age), the deltoid muscle can be used if the muscle mass is adequate. The needle size can range from 22 to 25 gauge and from 7/8 to 1¼ inches, based on the size of the muscle. For infants and toddlers, the anterolateral thigh can be used, but the needle should be longer, usually 1 inch.
• For adults (persons 20 years of age and older) the deltoid muscle is recommended for routine intramuscular vaccinations. The anterolateral thigh can be used. The suggested needle size is 1-1½ inches and 22-25 gauge.

**Precautions**

• See precautions in package insert.
• Latex allergy – See WARNINGS and/or PRECAUTIONS in the package insert for information about any latex components in the vial stopper and or prefilled syringes for the particular brand of hepatitis B vaccine being used.
• As with other intramuscular injections, use with caution in patients on anticoagulant therapy.

**Contraindications**

• Allergy to vaccine components
• Anaphylactic reaction to the vaccine or a constituent of the vaccine
• Acute, moderate or severe illness with or without fever

**Adverse Events**

• See the product’s package insert
• See Adverse Events Following Vaccinations page of this section

**Storage and Handling**

• Store in refrigerator at 36°F – 46°F (2°C – 8°C)
• DO NOT FREEZE; discard if product has been frozen.

**Other Important Notes**

• If HepB vaccine is administered concomitantly with hepatitis B immune globulin (HBIG), use a separate syringe and a different site, preferably a different limb.
• Exposed unvaccinated persons should receive the HepB vaccine series with the first dose administered as soon as possible after exposure, preferably within 24 hours. The vaccine series should be completed according to the vaccination schedule.
References:


Immunization Action Coalition (IAC): Needle Tips; ACIP Votes to Update Recommendations for HPV, Tdap, MenB and HepB Vaccines; Volume 26-Number 4; December 2016 http://www.immunize.org/nt/

ACIP VFC Resolution 2/17-1, “Vaccines to Prevent Hepatitis B”


CDC. Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, United States, 2018, http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html

CDC. Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States, 2018, http://www.cdc.gov/vaccines/schedules/hcp/adult.html


HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use HEPLISAV-B® safely and effectively. See full prescribing information for HEPLISAV-B.

HEPLISAV-B [Hepatitis B Vaccine (Recombinant), Adjuvanted] Solution for Intramuscular Injection
Initial US Approval: 2017

-----------INDICATIONS AND USAGE-----------
HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus. HEPLISAV-B is approved for use in adults 18 years of age and older. (1)

-----------DOSAGE AND ADMINISTRATION-----------
For intramuscular administration
Administer two doses (0.5 mL each) of HEPLISAV-B intramuscularly one month apart. (2.1, 2.2)

-----------DOSE FORMS AND STRENGTHS-----------
HEPLISAV-B is a solution for injection supplied as a single-dose vial and prefilled syringe. A single dose of HEPLISAV-B is 0.5 mL. (3)

---------CONTRAINDICATIONS---------
Severe allergic reaction, such as anaphylaxis, after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV-B, including yeast. (4)

---------ADVERSE REACTIONS ---------
The most common local reaction was injection site pain (23% - 39%). The most common systemic reactions were fatigue (11% - 17%) and headache (8% - 17%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Dynavax at 1-844-889-8753 or VAERS at 1-800-822-7967 and www.vaers.hhs.gov.

---------USE IN SPECIFIC POPULATIONS---------
A pregnancy registry is available for HEPLISAV-B. Women who receive HEPLISAV-B during pregnancy are encouraged to contact 1-844-443-7734. (8.1)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 03/2018

FULL PRESCRIBING INFORMATION: CONTENTS*

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2 DOSAGE AND ADMINISTRATION

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

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July 2019
FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus. HEPLISAV-B is approved for use in adults 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular administration.

2.1 Dose and Regimen

Administer two doses (0.5 mL each) of HEPLISAV-B one month apart.

2.2 Administration

HEPLISAV-B is a clear to slightly opalescent, colorless to slightly yellow solution.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

Administer HEPLISAV-B by intramuscular injection in the deltoid region using a sterile needle and syringe.

3 DOSAGE FORMS AND STRENGTHS

HEPLISAV-B is a sterile solution for injection available in 0.5 mL single-dose vials and prefilled syringes. [see How Supplied/Storage and Handling (16.1)].

4 CONTRAINDICATIONS

Do not administer HEPLISAV-B to individuals with a history of severe allergic reaction (e.g. anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV-B, including yeast [see Description (11)].

5 WARNINGS AND PRECAUTIONS

5.1 Managing Allergic Reactions

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of HEPLISAV-B.

5.2 Immunocompromised Individuals

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to HEPLISAV-B.

5.3 Limitations of Vaccine Effectiveness

Hepatitis B has a long incubation period. HEPLISAV-B may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

A total of 9597 individuals 18 through 70 years of age received at least 1 dose of HEPLISAV-B in 5 clinical trials conducted in the United States, Canada, and Germany. Data from three of these trials are provided below.
Study 1 in Subjects 18 through 55 Years of Age

Study 1 was a randomized, observer-blind, active-controlled, multicenter study in Canada and Germany in which 1810 subjects received at least 1 dose of HEPLISAV-B and 605 subjects received at least 1 dose of Engerix-B® [Hepatitis B Vaccine (Recombinant)]. Enrolled subjects had no history of hepatitis B vaccination or infection. HEPLISAV-B was given as a 2-dose regimen at 0 and 1 month followed by saline placebo at 6 months. Engerix-B was given at 0, 1, and 6 months. In the total study population, the mean age was 40 years; 46% of the subjects were men; 93% were white, 2% black, 3% Asian and 3% Hispanic; 26% were obese, 10% had hypertension, 8% had dyslipidemia, and 2% had diabetes mellitus. These demographic and baseline characteristics were similar in both vaccine groups.

Solicited Local and Systemic Adverse Reactions
Subjects were monitored for local and systemic adverse reactions using diary cards for a 7-day period starting on the day of vaccination. The percentages of subjects who reported local and systemic reactions are shown in Table 1.

<table>
<thead>
<tr>
<th>Reaction</th>
<th>HEPLISAV-B %</th>
<th>Engerix-B %</th>
<th>Post-Dose*</th>
<th>Post-Dose*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local</td>
<td></td>
<td></td>
<td>Post-Dose*</td>
<td>Post-Dose*</td>
</tr>
<tr>
<td>Injection Site Pain</td>
<td>38.5</td>
<td>34.8</td>
<td>33.6</td>
<td>24.7</td>
</tr>
<tr>
<td>Injection Site Redness†</td>
<td></td>
<td></td>
<td>4.1</td>
<td>2.9</td>
</tr>
<tr>
<td>Injection Site Swelling‡</td>
<td></td>
<td></td>
<td>2.3</td>
<td>1.5</td>
</tr>
<tr>
<td>Systemic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>17.4</td>
<td>13.8</td>
<td>16.7</td>
<td>11.9</td>
</tr>
<tr>
<td>Headache</td>
<td>16.9</td>
<td>12.8</td>
<td>19.2</td>
<td>12.3</td>
</tr>
<tr>
<td>Malaise</td>
<td>9.2</td>
<td>7.6</td>
<td>8.9</td>
<td>6.5</td>
</tr>
<tr>
<td>Fever†</td>
<td></td>
<td></td>
<td>1.1</td>
<td>1.5</td>
</tr>
</tbody>
</table>

Note: only subjects having data are included. Clinical trial number: NCT010435812

*HEPLISAV-B was given as a 2-dose regimen at 0 and 1 month followed by saline placebo at 6 months. Engerix-B was given at 0, 1, and 6 months
† Redness and swelling ≥ 2.5 cm.
‡ Oral temperature ≥ 100.4°F (38.0°C).

Unsolicited Adverse Events:
Unsolicited adverse events within 28 days following any injection, including placebo, were reported by 42.0% of HEPLISAV-B recipients and 41.3% of Engerix-B recipients.

Serious Adverse Events (SAEs)
Subjects were monitored for serious adverse events for 7 months after the first dose of vaccine. The percentage of subjects reporting serious adverse events was 1.5% in the HEPLISAV-B group and 2.1% in the Engerix-B group. No acute myocardial infarctions were reported. No deaths were reported.
Potentially Immune-mediated Adverse Events
Potentially immune-mediated adverse events that occurred within 7 months of the first dose of vaccine were reported in 0.2% (n = 4) of HEPLISAV-B recipients and 0.7% (n = 4) of Engerix-B recipients. The following events were reported in the HEPLISAV-B group in one subject each: granulomatosis with polyangiitis, lichen planus, Guillain-Barré syndrome, and Grave’s disease. The following events were reported in the Engerix-B group in one subject each: Bell’s palsy, Raynaud’s phenomenon, and Grave’s disease. One additional Engerix-B recipient with a history of mixed connective tissue disease had p-ANCA-positive vasculitis.

Study 2 in Subjects 40 through 70 Years of Age
Study 2 was a randomized, observer-blind, active-controlled, multicenter study in Canada and the United States in which 1968 subjects received at least 1 dose of HEPLISAV-B and 481 subjects received at least 1 dose of Engerix-B. HEPLISAV-B was given as a 2-dose regimen at 0 and 1 month followed by saline placebo at 6 months. Enrolled subjects had no history of hepatitis B vaccination or infection. Engerix-B was given at 0, 1, and 6 months. In the total population, the mean age was 54 years; 48% of subjects were men; 82% were white, 15% black, 1% Asian and 6% Hispanic; 44% were obese, 30% had hypertension, 30% had dyslipidemia, and 8% had diabetes mellitus. These demographic and baseline characteristics were similar in both vaccine groups.

Solicited Local and Systemic Adverse Reactions
Subjects were monitored for local and systemic adverse reactions using diary cards for a 7-day period starting on the day of vaccination. The percentages of subjects who experienced local and systemic reactions are shown in Table 2.

<table>
<thead>
<tr>
<th>Reaction</th>
<th>HEPLISAV-B %</th>
<th>Engerix-B %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Post-Dose a</td>
<td>Post-Dose a</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Local</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection Site Pain</td>
<td>23.7</td>
<td>22.8</td>
</tr>
<tr>
<td>Injection Site Redness†</td>
<td>0.9</td>
<td>0.7</td>
</tr>
<tr>
<td>Injection Site Swelling†</td>
<td>0.9</td>
<td>0.6</td>
</tr>
<tr>
<td>Systemic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>12.6</td>
<td>10.8</td>
</tr>
<tr>
<td>Headache</td>
<td>11.8</td>
<td>8.1</td>
</tr>
<tr>
<td>Malaise</td>
<td>7.7</td>
<td>7.0</td>
</tr>
<tr>
<td>Myalgia</td>
<td>8.5</td>
<td>6.4</td>
</tr>
<tr>
<td>Fever†</td>
<td>0.6</td>
<td>0.6</td>
</tr>
</tbody>
</table>

Note: only subjects having data are included. Clinical Trial Number: NCT01005407
*HEPLISAV-B was given as a 2-dose regimen at 0 and 1 month followed by saline placebo at 6 months. Engerix-B was given at 0, 1, and 6 months
† Redness and swelling ≥2.5 cm
‡ Oral temperature ≥ 100.4°F (38.0°C).

Unsolicited Adverse Events:
Unsolicited adverse events within 28 days following any injection, including placebo, were reported by 35.4% of HEPLISAV-B recipients and 36.2% of Engerix-B recipients.

Serious Adverse Events
Subjects were monitored for serious adverse events for 12 months after the first dose of vaccine. The percentage of subjects reporting serious adverse events was 3.9% in the HEPLISAV-B group and 4.8% in the Engerix-B group. Acute myocardial infarction occurred in 0.1% (n=2) of HEPLISAV-B recipients and 0.2% (n=1) of Engerix-B recipients.

Autoimmune Adverse Events
Subjects were monitored for the occurrence of new-onset potentially immune-mediated adverse events
for 12 months after the first dose of vaccine. Events were adjudicated as to whether they were autoimmune by an external group of experts blinded to treatment assignment. As determined by the adjudicators, new-onset autoimmune adverse events were reported in 0.2% (n=3) of HEPLISAV-B recipients: two subjects with hypothyroidism and one subject with vitiligo. None of these events was considered related to vaccination by the expert group. No new-onset autoimmune adverse events were reported in the Engerix-B group. Although not referred to the external group of experts, one HEPLISAV-B recipient was determined to have Tolosa-Hunt syndrome which is presumed to have an immune-mediated etiology. This event was not considered related to vaccination.

Deaths
One subject (0.05%) died of a pulmonary embolism in the HEPLISAV-B group and 1 subject (0.2%) died of heart failure in the Engerix-B group. Neither death was considered related to vaccination.

Study 3 in Subjects 18 through 70 Years of Age

Study 3 was a randomized, observer-blind, active-controlled, multicenter study in the United States in which 5587 subjects received at least 1 dose of HEPLISAV-B and 2781 subjects received at least 1 dose of Engerix-B. Enrolled subjects had no history of hepatitis B vaccination or infection. HEPLISAV-B was given as a 2-dose regimen at 0 and 1 month followed by saline placebo at 6 months. Engerix-B was given at 0, 1, and 6 months. In the total study population, the mean age was 50 years; 51% were men; 71% were white, 26% black, 1% Asian, and 9% Hispanic; 48% were obese, 36% had hypertension, 32% had dyslipidemia, and 14% had type 2 diabetes mellitus. These demographic and baseline characteristics were similar in both vaccine groups.

Unsolicited Medically-Attended Adverse Events
Subjects were monitored for unsolicited medically-attended adverse events, those for which a subject sought medical care, for 13 months after the first dose of vaccine. Overall, medically-attended adverse events were reported in 46.0% of HEPLISAV-B recipients and 46.2% of Engerix-B recipients. Herpes zoster was reported in 0.7% of HEPLISAV-B recipients and 0.3% of Engerix-B recipients. Unsolicited medically-attended adverse events within 28 days following any injection, including placebo, were reported by 20.1% of both HEPLISAV-B and Engerix-B recipients.

Serious Adverse Events
Subjects were monitored for serious adverse events for 13 months after the first dose of vaccine. The percentage of subjects who reported serious adverse events was 6.2% in the HEPLISAV-B group and 5.3% in the Engerix-B group. Acute myocardial infarction (AMI) was reported in 0.25% (n=14) of HEPLISAV-B recipients and 0.04% (n=1) of Engerix-B recipients. An analysis of serious adverse events likely representing myocardial infarction (MI) was conducted using the standard Medical Dictionary for Regulatory Activities (MedDRA) query (SMQ) for MI. This analysis identified a total of 19 HEPLISAV-B subjects (0.3%) and 3 Engerix-B subjects (0.1%) with events included in the SMQ for MI (these events include the 15 reports of AMI). Additional evidence, including information on temporal relationship and baseline risk factors, does not support a causal relationship between HEPLISAV-B administration and AMI. Among the 19 events identified as MI in HEPLISAV-B recipients, three occurred within 14 days, nine occurred within 53-180 days, and seven occurred more than 180 days following any dose of HEPLISAV-B. Among the three events identified as MI in Engerix-B recipients, one each occurred 13, 115, and 203 days following any dose. All 19 HEPLISAV-B recipients and 3 Engerix-B recipients reported one or more baseline risk factors for cardiovascular disease.

Autoimmune Adverse Events
Subjects were monitored for the occurrence of new-onset potentially immune-mediated adverse events for 13 months after the first dose of vaccine. Events were adjudicated as to whether they were autoimmune by an external group of experts who were blinded to treatment assignment. As determined by the adjudicators, new-onset autoimmune adverse events were reported in 0.1% (n=4) of HEPLISAV-B recipients [one each of: alopecia areata, polymyalgia rheumatica, ulcerative colitis, and autoimmune thyroiditis (with concurrent diagnosis of papillary thyroid carcinoma)]. None of these events was considered to be related to vaccination by the external experts. No new-onset autoimmune adverse events were reported in the Engerix-B group.
Deaths
During the study death was reported in 25 subjects (0.4%) in the HEPLISAV-B group and 7 subjects (0.3%) in the Engerix-B group. No death was considered related to vaccination.

7 DRUG INTERACTIONS

7.1 Use with Immune Globulin
There are no data to assess the concomitant use of HEPLISAV-B with immune globulin. When concomitant administration of HEPLISAV-B and immune globulin is required, they should be given with different syringes at different injection sites.

7.2 Interference with Laboratory Tests
Hepatitis B surface antigen (HBsAg) derived from hepatitis B vaccines has been transiently detected in blood samples following vaccination. Serum HBsAg detection may not have diagnostic value within 28 days after receipt of HEPLISAV-B.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Pregnancy Exposure Registry
There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to HEPLISAV-B during pregnancy. Women who receive HEPLISAV-B during pregnancy are encouraged to contact 1-844-443-7734.

Risk Summary
All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In clinically recognized pregnancies in the US general population, the estimated background risk of major birth defects is 2% to 4% and of miscarriage is 15% to 20%.

There are no clinical studies of HEPLISAV-B in pregnant women. Available human data on HEPLISAV-B administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a developmental toxicity study, 0.3 mL of a vaccine formulation containing 2.5 mcg HBsAg and 3000 mcg cytosine phosphoguanine (CpG) 1018 adjuvant was administered to female rats prior to mating and during gestation. These animal studies revealed no evidence of harm to the fetus due to this vaccine formulation [see Data].

Data
Animal data
Developmental toxicity studies were conducted in female rats. Animals were administered 0.3 mL of a vaccine formulation containing 2.5 mcg HBsAg and 3000 mcg CpG 1018 adjuvant twice prior to mating, and on gestation days 6 and 18 (a single human dose of HEPLISAV-B contains 20 mcg HBsAg and 3000 mcg CpG 1018 adjuvant). No adverse effects on pre-natal and post-natal development up to the time of weaning were observed. There were no vaccine-related fetal malformations or variations observed.

8.2 Lactation
Risk Summary
It is not known whether HEPLISAV-B is excreted in human milk. Data are not available to assess the effects of HEPLISAV-B on the breastfed infant or on milk production/excretion.

The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for HEPLISAV-B and any potential adverse effects on the breastfed child from HEPLISAV-B or from the underlying maternal condition. For preventive vaccines, the underlying condition is susceptibility to disease prevented by the vaccine.

8.3 Pediatric Use
Safety and effectiveness of HEPLISAV-B have not been established in individuals less than 18 years of age.
8.4 Geriatric Use
Clinical trials included 909 adults 65 through 70 years of age who received HEPLISAV-B.

Among subjects who received HEPLISAV-B, a seroprotective level of antibody to HBsAg was achieved in 90% of those 65 through 70 years of age compared to 96% of those aged 18 through 64 years of age.

Safety and effectiveness of HEPLISAV-B in adults older than 70 years of age were extrapolated from findings in subjects younger than 70 years of age.

8.5 Adults on Hemodialysis
Safety and effectiveness of HEPLISAV-B have not been established in adults on hemodialysis.

11 DESCRIPTION
HEPLISAV-B [Hepatitis B Vaccine (Recombinant), Adjuvanted] is a sterile solution for intramuscular injection.

The HBsAg is expressed in a recombinant strain of Hansenula polymorpha yeast. The fermentation process involves growth of the recombinant H. polymorpha on chemically-defined fermentation media containing vitamins and mineral salts.

The HBsAg is expressed intra-cellularly in the yeast cells. It is released from the yeast cells by cell disruption and purified by a series of physicochemical steps. Each dose may contain residual amounts of yeast protein (≤5.0% of total protein), yeast DNA (<20 picogram), and deoxycholate (<0.9 ppm) from the HBsAg manufacturing process.

HEPLISAV-B is prepared by combining the purified HBsAg together with the CpG 1018 adjuvant, a 22-mer phosphorothioate linked oligodeoxynucleotide in a phosphate buffered saline (sodium chloride, 9.0 mg/mL; sodium phosphate, dibasic dodecahydrate, 1.75 mg/mL; sodium phosphate, monobasic dihydrate, 0.48 mg/mL; and polysorbate 80, 0.1 mg/mL).

Each 0.5-mL dose is formulated to contain 20 mcg of HBsAg and 3000 mcg of CpG 1018 adjuvant.

HEPLISAV-B is available in vials and prefilled syringes. The tip caps and stoppers of the prefilled syringes and vial stoppers are not made with natural rubber latex.

HEPLISAV-B is formulated without preservatives. [see How Supplied/Storage and Handling (16)].

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
Infection with hepatitis B virus can have serious consequences including acute massive hepatic necrosis and chronic active hepatitis. Chronically infected persons are at increased risk for cirrhosis and hepatocellular carcinoma.

Antibody concentrations ≥10 mIU/mL against HBsAg are recognized as conferring protection against hepatitis B virus infection.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
HEPLISAV-B has not been evaluated for carcinogenicity, mutagenic potential or male infertility in animals. Vaccination of female rats with a vaccine formulation containing 2.5 mcg HBsAg and 3000 mcg CpG 1018 adjuvant had no effect on fertility [see Use in Specific Populations (8)].

14 CLINICAL STUDIES
14.1 Evaluation of Seroprotection
The immunogenicity of HEPLISAV-B was evaluated in comparison with a licensed hepatitis B vaccine (Engerix-B) in 3 randomized, active controlled, observer-blinded, multi-center Phase 3 clinical trials of
adults. HEPLISAV-B was given as a 2-dose regimen at 0 and 1 months followed by saline placebo at 6 months. Engerix-B was given at 0, 1, and 6 months.

The trials compared the seroprotection rates (% with antibody concentration ≥ 10 mIU/mL) induced by HEPLISAV-B and Engerix-B. Noninferiority was met if the lower bound of the 95% confidence interval of the difference in seroprotection rates (HEPLISAV-B minus Engerix-B) was greater than -10%.

**Study 1: Seroprotection in Adults 18 through 55 Years of Age**

In Study 1, the immunogenicity population comprised 1511 participants who received HEPLISAV-B and 521 who received Engerix-B. The mean age was 40 years for both groups. The primary analysis compared the seroprotection rate at Week 12 for HEPLISAV-B with that at Week 28 for Engerix-B. Non-inferiority of the seroprotection rate induced by HEPLISAV-B compared to Engerix-B was demonstrated (Table 3).

<table>
<thead>
<tr>
<th>Timepoint</th>
<th>HEPLISAV-B N = 1511</th>
<th>Engerix-B N = 521</th>
<th>Difference in SPRs (HEPLISAV-B minus Engerix-B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 12 (HEPLISAV-B)</td>
<td>SPR (95% CI)</td>
<td>SPR (95% CI)</td>
<td>Difference (95% CI)</td>
</tr>
<tr>
<td>Week 28 (Engerix-B)</td>
<td>95.0% (93.9, 96.1)</td>
<td>81.3% (77.8, 84.6)</td>
<td>13.7% (10.4, 17.5)*</td>
</tr>
</tbody>
</table>

CI = confidence interval; N = number of subjects in the analysis population in the group; SPR = seroprotection rate (% with anti-HBs ≥ 10 mIU/mL).

* Noninferiority was met because the lower bound of the 95% confidence interval of the difference in SPRs was greater than -10%.
Clinical trial number: NCT00435812

**Study 2: Seroprotection in Adults 40 through 70 Years of Age**

In Study 2, the immunogenicity population comprised 1121 subjects who received HEPLISAV-B and 353 subjects who received Engerix-B. The mean age was 54 years for both groups. The primary analysis compared the seroprotection rate at Week 12 for HEPLISAV-B with that at Week 32 for Engerix-B. Non-inferiority of the seroprotection rate induced by HEPLISAV-B compared to Engerix-B was demonstrated (Table 4).

<table>
<thead>
<tr>
<th>Timepoint</th>
<th>HEPLISAV-B N = 1121</th>
<th>Engerix-B N = 353</th>
<th>Difference in SPRs (HEPLISAV-B minus Engerix-B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 12 (HEPLISAV-B)</td>
<td>SPR (95% CI)</td>
<td>SPR (95% CI)</td>
<td>Difference (95% CI)</td>
</tr>
<tr>
<td>Week 32 (Engerix-B)</td>
<td>90.1% (88.2, 91.8)</td>
<td>70.5% (65.5, 75.2)</td>
<td>19.6% (14.7, 24.8)*</td>
</tr>
</tbody>
</table>

CI = confidence interval; N = number of subjects in the analysis population in the group; SPR = seroprotection rate (% with anti-HBs ≥ 10 mIU/mL).

* Noninferiority was met because the lower bound of the 95% confidence interval of the difference in SPRs was greater than -10%.

The SPR following HEPLISAV-B was statistically significantly higher than following Engerix-B (lower bound of the 95% confidence interval of the difference in SPRs was greater than 0%).

Clinical trial number: NCT01005407

**Study 3: Seroprotection in Adults 18 through 70 Years of Age Including those with Type 2 Diabetes Mellitus**

In Study 3, the immunogenicity population comprised 4537 subjects who received HEPLISAV-B and 2289 subjects who received Engerix-B. The mean age was 51 years and 14% of subjects had type 2 diabetes mellitus (defined as having a clinical diagnosis of type 2 diabetes and taking at least an oral or non-insulin injectable hypoglycemic agent and/or insulin).

The primary analysis compared the seroprotection rate at Week 28 for HEPLISAV-B (n= 640) with that at Week 28 for Engerix-B (n = 321) in subjects with type 2 diabetes mellitus. Non-inferiority of the seroprotection rate induced by HEPLISAV-B compared to Engerix-B was demonstrated (Table 5).
Table 5

<table>
<thead>
<tr>
<th>Timepoint</th>
<th>Study 3: Seroprotection Rate of HEPLISAV-B and Engerix-B (subjects with type 2 diabetes mellitus ages 18 through 70 years)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HEPLISAV-B N = 640</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Engerix-B N = 321</td>
<td></td>
</tr>
<tr>
<td>Week 28</td>
<td>SPR (95% CI)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>90.0% (87.4, 92.2)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Difference in SPRs (HEPLISAV-B minus Engerix-B)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>24.9% (19.3, 30.7)*</td>
<td></td>
</tr>
</tbody>
</table>

CI = confidence interval; N = number of subjects in the analysis population in the group; SPR = seroprotection rate (% with anti-HBs ≥ 10 mIU/mL).

* Noninferiority was met because the lower bound of the 95% confidence interval of the difference in SPRs was greater than -10%.

The SPR following HEPLISAV-B was statistically significantly higher than following Engerix-B (lower bound of the 95% confidence interval of the difference in SPRs was greater than 0%).

Clinical trial number: NCT02117934

A secondary analysis compared the seroprotection rate at Week 24 for HEPLISAV-B with that at Week 28 for Engerix-B in the total study population. Non-inferiority of the seroprotection rate induced by HEPLISAV-B compared to Engerix-B was demonstrated (Table 6).

Table 6

<table>
<thead>
<tr>
<th>Timepoint</th>
<th>Study 3: Seroprotection Rate of HEPLISAV-B and Engerix-B (total study population ages 18 through 70 years)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HEPLISAV-B N = 4376</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Engerix-B N = 2289</td>
<td></td>
</tr>
<tr>
<td>Week 24 (HEPLISAV-B)</td>
<td>SPR (95% CI)</td>
<td></td>
</tr>
<tr>
<td>Week 28 (Engerix-B)</td>
<td>95.4% (94.8, 96.0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>81.3% (79.6, 82.8)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Difference in SPRs (HEPLISAV-B minus Engerix-B)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>14.2% (12.5, 15.9)*</td>
<td></td>
</tr>
</tbody>
</table>

CI = confidence interval; N = number of subjects in the analysis population in the group; SPR = seroprotection rate (% with anti-HBs ≥ 10 mIU/mL).

*Noninferiority was met because the lower bound of the 95% confidence interval of the difference in SPRs was greater than -10%. The SPR following HEPLISAV-B was statistically significantly higher than following Engerix-B (lower bound of the 95% confidence interval of the difference in SPRs was greater than 0%).

Another secondary analysis compared the seroprotection rate at Week 24 for HEPLISAV-B with that at Week 28 for Engerix-B, by age group. For each age stratum non-inferiority of the seroprotection rate induced by HEPLISAV-B compared to Engerix-B was demonstrated (Table 7).

Table 7

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Study 3: Seroprotection Rates of HEPLISAV-B and Engerix-B (ages 18 - 70 years)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HEPLISAV-B*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>SPR (95% CI)</td>
</tr>
<tr>
<td>18-29</td>
<td>174</td>
<td>100.0% (97.9, 100.0)</td>
</tr>
<tr>
<td>30-39</td>
<td>832</td>
<td>98.9% (97.7, 99.6)</td>
</tr>
<tr>
<td>40-49</td>
<td>974</td>
<td>97.2% (96.0, 98.2)</td>
</tr>
<tr>
<td>50-59</td>
<td>1439</td>
<td>95.2% (94.0, 96.3)</td>
</tr>
<tr>
<td>60-70</td>
<td>1157</td>
<td>91.6% (89.9, 93.1)</td>
</tr>
</tbody>
</table>

CI = confidence interval; N = number of subjects in the analysis population in the group; SPR = seroprotection rate (% with anti-HBs ≥ 10 mIU/mL).

*Week 24 for HEPLISAV-B and Week 28 for Engerix-B

Clinical trial number: NCT02117934

*Noninferiority was met because the lower bound of the 95% confidence interval of the difference in SPRs was greater than -10%. The SPR following HEPLISAV-B was statistically significantly higher than following Engerix-B (lower bound of the 95% confidence interval of the difference in SPRs was greater than 0%).
16  HOW SUPPLIED/STORAGE AND HANDLING

16.1  How Supplied

- Vial, 1 dose (0.5 mL) - (NDC number: 43528-002-01)
- Package of 5 single dose vials - (NDC number: 43528-002-05)
- Prefilled syringe, 1 dose (0.5 mL) - (NDC number: 43528-003-01)
- Package of 5 single dose prefilled syringes - (NDC number: 43528-003-05)

The tip caps and stoppers of the prefilled syringes and vial stoppers are not made with natural rubber latex.

16.2  Storage Conditions

Store in a refrigerator at 2°C to 8°C (35°F to 46°F). Do not freeze; discard if the vaccine has been frozen.

Do not use the vaccine after the expiration date shown on the vial or prefilled syringe label.

17.  PATIENT COUNSELING INFORMATION

- Inform vaccine recipient of the potential benefits and risks associated with vaccination, as well as the importance of completing the immunization series.
- Emphasize that HEPLISAV-B contains non-infectious purified HBsAg and cannot cause hepatitis B infection.
- Advise vaccine recipient to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 and www.vaers.hhs.gov.
- Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

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Manufactured by:
Dynavax Technologies Corporation Berkeley, CA 94710 USA
US-18-00-00015
Haemophilus influenzae Type b (Hib) Conjugate Vaccine

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunizations.

Vaccine Information Statements
Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide a non-English speaking patient with a copy of the VIS in their native language, if one is available and desired; these VISs can be found at http://www.immunize.org/vis.

FDA Approved Indications and Usage (See Package Insert for ActHIB®, current version dated 12/2015)
- ActHIB® is a vaccine indicated for the prevention of invasive disease caused by Haemophilus influenza type b. ActHIB® vaccine is approved for use as a four-dose series in infants and children 2 months through 5 years of age.

FDA Approved Indications and Usage (See Package Insert for PedvaxHIB®, current version dated 12/2010)
- PedvaxHIB® is indicated for routine vaccination against invasive disease caused by Haemophilus influenza type b in infants and children 2 to 71 months of age.

Recommended Schedule
ActHIB® (PRP-T)

Hib Vaccine Schedule for Unimmunized Children Without Any Previous Doses

<table>
<thead>
<tr>
<th>Age Receiving 1st Dose</th>
<th>Dose</th>
<th>Recommended Age</th>
<th>Accelerated Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 6 months</td>
<td>1</td>
<td>2 months</td>
<td>≥ 6 weeks of age</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>4 months</td>
<td>≥ 1 month after dose #1</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>6 months</td>
<td>≥ 1 month after dose #2</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>12 through 15 months</td>
<td>≥2 months after previous dose and ≥12 months of age</td>
</tr>
<tr>
<td>7 – 11 months</td>
<td>1</td>
<td>-</td>
<td>1st visit</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>-</td>
<td>≥ 1 month after dose #1</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>-</td>
<td>≥2 months after previous dose and between 12 through 15 months of age</td>
</tr>
<tr>
<td>12 – 14 months</td>
<td>1</td>
<td>-</td>
<td>1st visit</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>-</td>
<td>≥ 2 months after previous dose</td>
</tr>
<tr>
<td>15 – 59 months</td>
<td>1</td>
<td>-</td>
<td>1st visit</td>
</tr>
</tbody>
</table>

1 When feasible, use same vaccine for doses 1 – 3.

2 When feasible, use same vaccine for doses 1 – 2.
Hib Vaccine Schedule (All Hib Formulations) for Partially-Immunized Children,
Not Up-To-Date

<table>
<thead>
<tr>
<th>Age at Presentation</th>
<th>Previous Vaccination History</th>
<th>Recommended Regimen</th>
</tr>
</thead>
</table>
| 7 through 11 months | 1 dose of PRP-T, or PRP-OMP ¹  
2 doses of PRP-T | 1 dose of conjugate at 7 through 11 months with a booster dose given at least 2 months later, at 12 through 15 months ²  
Same as above |
| 12 through 14 months | 2 doses before 12 months of PRP-T or PRP-OMP ¹ | 1 dose of any licensed conjugate ³ |
| 12 through 14 months | 1 dose before 12 months of PRP-T or PRP-OMP ¹ | 2 additional doses of any licensed conjugate, with a minimum interval of 2 months ³ |
| 15 through 59 months | Any incomplete schedule | 1 dose of any licensed conjugate ³ |

¹ PRP-T (ActHIB), PRP-OMP (PedvaxHIB).

² For the dose given at 7 through 11 months, when feasible, the same vaccine should be used for the dose given at 2 through 6 months. At > 12 months of age, any licensed conjugate can be used.

³ For children 12 through 59 months of age with an underlying condition predisposing them to Hib disease who are not immunized or who have received only 1 dose of conjugate vaccine before 12 months, 2 additional doses of a licensed conjugate vaccine (separated by 2 months) are recommended. If they have received 2 doses before 12 months, only 1 dose is recommended.

PedvaxHIB® (PRP-OMP) Schedules for Unimmunized Children Without Any Previous Doses

<table>
<thead>
<tr>
<th>Age Receiving 1ˢᵗ Dose</th>
<th>Dose</th>
<th>Recommended Age</th>
<th>Accelerated Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 through 7 months</td>
<td>1 ¹</td>
<td>2 months</td>
<td>≥ 6 weeks of age</td>
</tr>
<tr>
<td></td>
<td>2 ¹</td>
<td>4 months</td>
<td>≥ 1 month after dose #1</td>
</tr>
<tr>
<td></td>
<td>3 ²</td>
<td>12 through 15 months</td>
<td>≥ 2 months after previous dose and ≥ 12 months of age</td>
</tr>
<tr>
<td>7 through 11 months</td>
<td>1 ²</td>
<td>-</td>
<td>1ˢᵗ visit</td>
</tr>
<tr>
<td></td>
<td>2 ²</td>
<td>-</td>
<td>≥ 1 months after dose #1</td>
</tr>
<tr>
<td></td>
<td>3 ³</td>
<td>-</td>
<td>≥ 2 months after previous dose and between 12 through 15 months of age</td>
</tr>
<tr>
<td>12 through 14 months</td>
<td>1 ³</td>
<td>-</td>
<td>1ˢᵗ visit</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>-</td>
<td>2 months after the previous dose</td>
</tr>
<tr>
<td>15 through 59 months</td>
<td>1</td>
<td>-</td>
<td>1ˢᵗ visit</td>
</tr>
</tbody>
</table>

¹ When feasible, use the same vaccine for doses 1 – 2.
Routine vaccination

- Administer a 2- or 3-dose Hib vaccine primary series and a booster dose (dose 3 or 4 depending on vaccine used in primary series) at age 12 through 15 months to complete a full Hib vaccine series.
- The primary series with ActHIB®, HIBERIX®, MENHIBRIX®, or PENTACEL® consists of three doses and should be administered at 2, 4, and 6 months of age. The primary series with PedvaxHIB® or COMVAX® consists of 2 doses and should be administered at 2 and 4 months of age; a dose at age 6 months is not indicated.
- One booster dose (dose 3 or 4 depending on vaccine used in primary series) of any Hib vaccine should be administered at age 12 through 15 months.
- Licensed monovalent Hib conjugate vaccines are considered interchangeable for the primary as well as the booster doses (dose 3 or 4, depending on vaccine type used for primary series), [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm).
- Data on the interchangeability of [Hib] combination [conjugate] vaccines with other [Hib] combination [conjugate] vaccines or with monovalent [Hib conjugate] vaccines are limited. Whenever feasible, the same [Hib] combination [conjugate] vaccine should be used for the subsequent doses; however, if a different brand is administered, the dose should be considered valid and need not be repeated, [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm).

NOTE: Haemophilus influenzae type b (Hib) conjugate vaccine. (Minimum age: 6 weeks for PRP-T [ACTHIB, DTaP-IPV/Hib (PENTACEL®), HIBERIX® and Hib-MenCY (MENHIBRIX®)], PRP-OMP [PedvaxHIB® or COMVAX®].

Recommendations for Routine Vaccination
[http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm)

- ACIP recommends routine administration of a conjugate Hib vaccine series (monovalent vaccine [PedvaxHIB® (PRP-OMP) or HIBERIX® or ActHIB®, (PRP-T)] or Hib vaccine in combination with HepB [COMVAX®], DTaP/IPV [PENTACEL®], or MenCY [MENHIBRIX®]) beginning at age 2 months.
- Infants aged 2 through 6 months should receive a 3-dose series of Hib (PRP-T as ActHIB®, PENTACEL®, HIBERIX® or MENHIBRIX®) or a 2-dose series of Hib (PRP-OMP as PedvaxHIB® or COMVAX®). The first dose can be administered as early as age 6 weeks.
- A booster dose (which will be dose 3 or 4 depending on vaccine type used in primary series) of any licensed conjugate Hib vaccine (monovalent vaccine [PedvaxHIB® (PRP-OMP), ActHIB® (PRP-T), or HIBERIX® (PRP-T)] or Hib vaccine in combination with HepB [COMVAX®] or DTaP/IPV [PENTACEL®] or MenCY [MENHIBRIX®]) is recommended at age 12 through 15 months and at least 8 weeks after the most recent Hib vaccination).

Guidance for Routine Vaccination
[http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm)

- Doses for either primary series (2-dose or 3-dose) should be administered 8 weeks apart; however, if necessary, an interval of 4 weeks between doses is acceptable.
- If a PRP-OMP vaccine (PedvaxHIB® or COMVAX®) is administered for both doses in the primary series, a third primary dose is not indicated.
• If a PRP-OMP vaccine (PedvaxHIB® or COMVAX®) is not administered for both doses in the primary series or there is uncertainty about which products were administered previously, a third primary series dose of a Hib conjugate vaccine is needed to complete the primary series.

• Any monovalent or combination Hib conjugate vaccine is acceptable for the booster dose (dose 3 or 4 depending on vaccine type used in primary series), regardless of the product used for the primary series.

**Catch-up schedule**

• If dose 1 was administered at ages 12 through 14 months, administer a second (final) dose at least 8 weeks after dose 1, regardless of Hib vaccine used in the primary series.

• If the first 2 doses were PRP-OMP (PedvaxHIB® or COMVAX®), and were administered at age 11 months or younger, the third (and final) dose should be administered at age 12 through 15 months and at least 8 weeks after the second dose.

• If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a third (and final) at age 12 through 15 months or 8 weeks after second dose, whichever is later, regardless of Hib vaccine used for first dose.

• If the first dose administered is at younger than 12 months of age and second dose administered is between 12 through 14 months of age, a third (and final) dose should be administered 8 weeks later.

• For unvaccinated children aged 15 months or older, administer only one dose.

**Vaccination of children with high-risk conditions** (Patients with functional or anatomic asplenia, HIV infection, immunoglobulin deficiency including Immunoglobulin G2 subclass deficiency, or early component complement deficiency, recipients of a hematopoietic stem cell transplant (HSCT), and those receiving chemotherapy for malignant neoplasms, [http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/02-13-2-hib.pdf](http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/02-13-2-hib.pdf)

• Children aged 12 through 59 months who are at increased risk for Hib disease, including chemotherapy recipients and those with anatomic or functional asplenia (including sickle cell disease), human immunodeficiency virus (HIV) infection, immunoglobulin deficiency, or early component complement deficiency, who have received either no doses or only 1 dose of Hib vaccine before 12 months of age, should receive 2 additional doses of Hib vaccine 8 weeks apart; children who received 2 or more doses of Hib vaccine before 12 months of age should receive 1 additional dose.

• For patients younger than 5 years of age undergoing chemotherapy or radiation treatment who received a Hib vaccine dose(s) within 14 days of starting therapy or during therapy, repeat the dose(s) at least 3 months following therapy completion.

• Recipients of hematopoietic stem cell transplant (HSCT) should be revaccinated with a 3-dose regimen of Hib vaccine starting 6 to 12 months after successful transplant, regardless of vaccination history; doses should be administered at least 4 weeks apart.

• A single dose of any Hib-containing vaccine should be administered to unimmunized* children and adolescents 15 months of age and older undergoing an elective splenectomy; if possible, vaccine should be administered at least 14 days before procedure.

• Hib vaccine is not routinely recommended for patients 5 years or older. However, 1 dose of Hib vaccine should be administered to unimmunized* persons aged 5 years or older who have anatomic or functional asplenia (including sickle cell disease) and unvaccinated persons 5 through 18 years of age with human immunodeficiency virus (HIV) infection.
* Patients who have not received a primary series and booster dose or at least one dose of Hib vaccine after 14 months of age are considered unimmunized. [http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html](http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html)

**Vaccination of adults with high-risk conditions**

- One dose of Hib vaccine should be administered to persons who have functional or anatomic asplenia or sickle cell disease or are undergoing elective splenectomy if they have not previously received Hib vaccine.
  - Hib vaccination 14 or more days before splenectomy is suggested.
- Recipients of a hematopoietic stem cell transplant should be vaccinated with a 3-dose regimen 6 to 12 months after a successful transplant, regardless of vaccination history; at least 4 weeks should separate doses
- **Hib vaccine is not recommended** for adults with HIV infection since their risk for Hib infection is low.

**Hib vaccine is indicated for the following groups**

- All infants and children, six weeks of age to less than 59 months of age. The number of doses needed is dependent on the age of the child when the vaccine series is initiated and the type of vaccine given;
- **PedvaxHIB** (PRP-OMP) is indicated for routine vaccination against invasive disease caused by *Haemophilus influenzae* type b in infants and children 2 to 71 months of age.
- Unimmunized children, **aged 5 years and older**, with sickle-cell disease, HIV infection, AIDS, severe non-HIV immunosuppressive condition and treatments, functional or anatomic asplenia, renal failure and diabetes;
- Adults with severe non-HIV immunosuppression, after organ transplantation, with functional or anatomic asplenia and chronic immunosuppressive therapy.

**Dosage and Route**

- See the package insert for reconstitution instructions if the **ActHIB** brand of Hib vaccine is being administered.
- See the package insert for reconstitution instructions if the **HIBERIX** brand of Hib vaccine is being administered.
- Administer Hib vaccine 0.5 mL intramuscularly (IM) according to the recommended schedule. **Always check the package insert prior to administration of any vaccine.** Administer IM vaccines at a 90° angle with a 22- to 25-gauge needle.

**Anatomical Site**

- Outer aspect of the deltoid of the upper arm or in the higher anterolateral area of the thigh.

**Precautions**

- Prior to administering the vaccine, obtain a vaccination history to determine any reactions to any vaccine.
- **Moderate to severe illness with or without fever** (temporary precaution)
- As with other intramuscular injections, use with caution in patients on anticoagulant therapy.
Contraindications

- **DO NOT** administer Hib vaccine to individuals with an anaphylactic reaction to a previous dose of Hib, latex (*PedvaxHIB* and the vial of diluent for *ActHIB*) or to any other component of the vaccine (see package insert for specific components)

Adverse Events

- See the product’s package insert
- See Adverse Events Following Vaccinations page of this section

Storage and Handling

- Store in refrigerator at 36°F – 46°F (2°C – 8°C).
- DO NOT FREEZE; discard if product has been frozen.

Other Important Notes

- *ActHIB* vaccine must be used ≤24 hours after reconstitution, or be discarded.

References


Haemophilus influenzae Type b (Hib)

Tetanus Toxoid Conjugate Vaccine - HIBERIX®

Precautions and Contraindications

Screen all patients for precautions and contraindications to immunization.

Vaccine Information Statements

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide a non-English speaking patient with a copy of the VIS in their native language, if one is available and desired; these VISs can be found at http://www.immunize.org/vis.

FDA Approved Indications and Usage (See Package Insert, current version dated 01/2016)

- HIBERIX® is a vaccine indicated for active immunization for the prevention of invasive disease caused by Haemophilus influenzae type b.
- HIBERIX® is approved for use in children aged 6 weeks through 4 years of age (prior to fifth birthday).

Recommended Schedule

- HIBERIX® is recommended for children aged 2 months through 4 years of age (prior to fifth birthday).
  
  HIBERIX® is administered as a 4-dose series
  o Primary series (3 doses): One dose each at 2, 4, and 6 months of age.
  o Booster dose: One dose administered at 15 through 18 months of age.
- HIBERIX® and other Hib conjugate vaccines can be administered as early as 6 weeks of age, in accordance with Hib vaccination schedules for routine and catch-up immunization.
- Licensed monovalent Hib conjugate vaccines are considered interchangeable for the primary as well as the booster doses (dose 3 or 4, depending on vaccine type used for primary series), http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm.

**Dosage and Route**
- Administer HIBERIX® vaccine 0.5 mL intramuscularly (IM) after reconstitution.
- Administer IM vaccines at a 90° angle.
- Always check the package insert prior to administration of any vaccine.

**Anatomical Site**
- The preferred sites are the anterolateral aspects of the thigh or into the deltoid muscle. 
- The vaccine should not be injected into the gluteal area or areas where there is a major nerve trunk.

**Do not administer intravenously, intradermally, or subcutaneously.**

**Preparation for Administration**
- **Reconstitution Instructions**
  - HIBERIX® vaccine is to be reconstituted only with the accompanying saline diluent. The reconstituted vaccine should be a clear and colorless solution.
  - See the package insert for reconstitution instructions for HIBERIX® vaccine.
  - HIBERIX® vaccine should be inspected visually for particulate matter and discoloration prior to administration.
  - After reconstitution, withdraw 0.5 mL of reconstituted vaccine into the syringe.
  - Administer by intramuscular injection.
  - If not administered promptly, HIBERIX® should be refrigerated between 36° and 46°F (2° and 8°C) and administered within 24 hours. If the vaccine is not administered promptly, shake the solution vigorously before injection.

**Warnings and Precautions**
- Prior to administering the vaccine, obtain a vaccination history to determine any possible vaccine hypersensitivity.
- Moderate to severe illness with or without fever (temporary precaution).
- As with other intramuscular injections, use with caution in patients on anticoagulant therapy.
- If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give any tetanus toxoid-containing vaccine, including HIBERIX®, should be based on careful consideration of the potential benefits and possible risks.
- If HIBERIX® is administered to immunosuppressed children, including children receiving immunosuppressive therapy, the expected immune response may not be obtained.
- Urine antigen detection may not have a diagnostic value in a suspected disease due to *H. influenzae* type b within 1 to 2 weeks after receipt of a *H. influenzae* type b-containing vaccine, including HIBERIX®.
- Immunization with HIBERIX® does not substitute for routine tetanus immunization.
Contraindications

- A severe allergic reaction (e.g., anaphylaxis) after a previous dose of any *H. influenzae* type b- or tetanus toxoid-containing vaccine or any component of the vaccine.
- Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including HIBERIX®, to infants born prematurely should be based on consideration of the individual infant’s medical status, and the potential benefits and possible risks of vaccination.

Adverse Events

- See the product’s package insert
- See Adverse Events following vaccinations page of this section

Storage and Handling

- Before reconstitution:
  - Store refrigerated between 36° and 46°F (2° and 8°C).
  - Protect vials from light.
  - DO NOT FREEZE; discard HIBERIX® vaccine that has been frozen.

- After reconstitution:
  - Store refrigerated between 36° and 46°F (2° and 8°C).
  - HIBERIX® should be administered within 24 hours of reconstitution.
  - Discard the reconstituted vaccine if not used within 24 hours.
  - DO NOT FREEZE; discard if the vaccine has been frozen.

Comment

HIBERIX® does not contain thimerosal or other preservatives.

References


Protocol for Human Papillomavirus 9-valent Vaccine, Recombinant
(9vHPV Vaccine, GARDASIL®9)

Precautions and Contraindications
Screen all patients for precautions and contraindications prior to immunization.

FDA Approved Indications and Usage (See Package Insert, current version dated 1/2017)

Girls and Women:
- The 9-valent human papillomavirus (9vHPV) vaccine IS INDICATED in girls and women aged 9 through 26 years of age for the prevention of the following diseases caused by human papillomavirus (HPV) types included in the vaccine:
  - Genital warts (condyloma acuminata) caused by HPV types 6 and 11.
  - Cervical, vulvar, vaginal, and anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58.

And [for the prevention of] the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:
  - Cervical intraepithelial neoplasia (CIN) grade 2/3 and cervical adenocarcinoma in situ (AIS).
  - Cervical intraepithelial neoplasia (CIN) grade 1.
  - Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3.
  - Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3.
  - Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3.

Boys and Men:
- The 9-valent human papillomavirus (9vHPV) vaccine IS INDICATED in boys and men aged 9 through 26 years of age for the prevention of the following diseases:
  - Genital warts (condyloma acuminata) caused by HPV types 6 and 11.
  - Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58.

And [for the prevention of] the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:
  - Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3.

Advisory Committee on Immunization Practices (ACIP) Recommended Schedule*
- ROUTINE VACCINATION: 9vHPV vaccine IS RECOMMENDED in a 2-dose series for females aged 11 or 12 years or when initiating at ages 9 through 14 years.
- ROUTINE VACCINATION: 9vHPV vaccine is RECOMMENDED in a 2-dose series for males aged 11 or 12 years or when initiating at ages 9 through 14 years. CATCH-UP VACCINATION: 9vHPV vaccine IS RECOMMENDED for girls and women aged 13 through 26 years, who have not been vaccinated previously or who have not completed the 2-dose series (if initiated at ages 9 through 14 years) or completed the 3-dose series (if initiated at age 15 years or older)
- CATCH-UP VACCINATION: 9vHPV vaccine IS RECOMMENDED for boys and men aged 13 through 21 years, who have not been vaccinated previously or who have not completed the 2-dose series (if initiated at ages 9
through 14 years) or completed the 3-dose series (if initiated at age 15 years or older). Males aged 22 through 26 years of age may be vaccinated.

- **OTHER VACCINATION:**
  - The vaccine series may be started at age 9 years for both females and males.
  - Administer HPV vaccine beginning at age 9 years to children with a history of sexual abuse or assault who have not initiated or completed the series.
- The 9vHPV vaccine **IS RECOMMENDED** in a 3-dose series for immunocompromised persons (as a result of infection [including HIV], disease, or medications) aged 9 through 26 years for those who have not been vaccinated previously or who have not completed the 3-dose series.
- The 9vHPV vaccine **IS RECOMMENDED** for men who have sex with men (MSM) through age 26 years for those who have not been vaccinated previously or who have not completed the series.
- The 9vHPV vaccine **IS RECOMMENDED** for transgender persons as for all adolescents, and initiation of vaccination through age 26 years for those who were not adequately vaccinated previously.
- Eligible females and males (aged 9 through 14 years) given 9vHPV vaccine for routine or catch-up vaccinations should complete a 2-dose series with the following schedule:
  - 1st dose: At elected date
  - 2nd dose: 6 through 12 months after the first dose
- Eligible females and males (aged 15 through 26 years of age and immunocompromised persons aged 9 through 26 years) given 9vHPV vaccine for routine or catch-up vaccinations should complete a 3-dose series with the following schedule (Note that this schedule is the same for the 4vHPV vaccine):
  - 1st dose: At elected date
  - 2nd dose: 1 through 2 months after the first dose
  - 3rd dose: 6 months after the first dose

*ACIP recommends completion of the HPV 3-dose series regardless of the patient’s age (i.e., even if the patient is older than age 26 years) as long as the HPV series was started at age 26 years or younger, [http://www.immunize.org/askexperts/experts_hpv.asp](http://www.immunize.org/askexperts/experts_hpv.asp).

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**Minimum age and minimum (min.) intervals for 9vHPV vaccine**

**2 doses: Initiating vaccination for children aged 9 through 14 years:**

<table>
<thead>
<tr>
<th>Minimum age</th>
<th>Min. Interval between</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 years old</td>
<td>Dose 1 and 2</td>
</tr>
<tr>
<td></td>
<td>5 months</td>
</tr>
</tbody>
</table>

If a second dose is administered at a shorter interval, a third dose should be administered a minimum of 12 weeks after the second dose and a minimum of 5 months after the first dose.
3 doses: Initiating vaccination for adolescents and adults aged 15 through 26 years and for immunocompromised persons aged 9 through 26 years:

<table>
<thead>
<tr>
<th>Minimum age</th>
<th>Min. Interval between Dose 1 and 2</th>
<th>Min. Interval between Dose 2 and 3</th>
<th>Min. Interval between Dose 1 and 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 years old</td>
<td>4 weeks</td>
<td>12 weeks</td>
<td>24 weeks</td>
</tr>
</tbody>
</table>

*Doses received after a shorter than recommended dosing interval should be re-administered after another minimum interval has been met since the most recent dose.

Persons vaccinated previously.

- Persons who initiated vaccination with 9vHPV, 4vHPV, or 2vHPV before their 15th birthday, and received 2 doses of any HPV vaccine at the recommended dosing schedule (0, 6–12 months), or 3 doses of any HPV vaccine at the recommended dosing schedule (0, 1–2, 6 months), are considered adequately vaccinated.
- Persons who initiated vaccination with 9vHPV, 4vHPV, or 2vHPV on or after their 15th birthday, and received 3 doses of any HPV vaccine at the recommended dosing schedule, are considered adequately vaccinated.
- 9vHPV may be used to continue or complete a vaccination series started with 4vHPV or 2vHPV.
- For persons who have been adequately vaccinated with 2vHPV or 4vHPV, there is no ACIP recommendation regarding additional vaccination with 9vHPV.

Interrupted Vaccine Schedules: There is no maximum interval between doses of 9vHPV vaccine. If the vaccine schedule is interrupted, the vaccine series does not need to be restarted. The number of recommended doses is based on age of administration of the first dose.

- In 2 dose series: The first and second doses should be separated by an interval of six to twelve months with a minimum interval of at least 5 months between doses.
- In 3 dose series: The first and second doses should be separated by an interval of at least one month. The second and third doses should be separated by an interval of at least 3 months, with a minimum interval of 6 months between the first and third doses.

Interchangeability of HPV vaccine products (i.e., manufacturer’s brand)

Girls and Women: It was previously recommended that the HPV vaccine series for girls and women be completed with the same HPV vaccine product (i.e., same manufacturer’s brand) whenever possible, as no clinical trials or studies have been published on the efficacy and protection afforded after interchanging HPV vaccine products. After May 2017, only 9vHPV vaccine will be available in LHDs for administration to girls and women.

If vaccination providers do not know the brand of HPV vaccine administered, or do not have available the 2vHPV vaccine or 4vHPV vaccine product previously administered, 9vHPV vaccine product may be used to continue or complete a HPV vaccine series for females.

- The 2vHPV vaccine provided protection only against two HPV types, i.e., types 16 and 18.
• The 4vHPV vaccine provided protection against four HPV types, i.e., types 6, 11, 16, and 18.
• The 9vHPV vaccine provides protection against nine HPV types, i.e., types 6, 11, 16, 18, 31, 33, 45, 52, and 58.

**Interchangeability of HPV vaccine products (i.e., manufacturer’s brand) - Continued**

**Boys and Men:**

After May 2017, only 9vHPV vaccine will be available in LHDs for administration to boys and men.

• Only 4vHPV or 9vHPV vaccine is FDA approved for administration to boys or men to initiate, continue, or complete the HPV vaccine series.
• If vaccination providers do not know the brand of HPV vaccine administered or do not have available the 4vHPV vaccine product previously administered, 9vHPV vaccine product may be used to continue or complete a HPV vaccine series for males.

**Dosage and Route**

• 0.5-mL
• Intramuscular (IM)
• **GARDASIL 9®** is a suspension for intramuscular administration and is available in 0.5-mL single dose vials and prefilled syringes

**Anatomical Site**

• Administer in outer aspect of the deltoid of the upper arm or in the higher anterolateral area of the thigh. As with other intramuscular injections, use with caution in patients on anticoagulant therapy.

**Precautions**

• Prior to administering the vaccine, obtain a vaccination history to determine any reactions to any HPV vaccine including the 9vHPV vaccine.
• Safety of **GARDASIL 9®** has not been shown in pregnant women.
  • A pregnancy registry is available. Health care providers are encouraged to register women exposed to **GARDASIL 9®** around the time of conception or during pregnancy by calling 1-800-986-8999
• Pregnancy – the 9vHPV vaccine is not recommended for use in pregnant women. However, pregnancy testing is not needed before vaccination. Receiving HPV vaccine when pregnant is not a reason to consider terminating the pregnancy.
  • Initiation of the vaccine series should be delayed until after completion of the pregnancy.
  • If a woman is found to be pregnant after initiating the vaccination series, the remainder of the 3-dose series should be delayed until after completion of the pregnancy.
  • If a vaccine dose has been administered during pregnancy, no intervention is needed.
• Nursing Mothers
  o Note: The ACIP recommendations, the contents in the 9vHPV vaccine VIS (dated 03/31/2016) and HPV vaccine VIS (dated 12/02/2016) recommend “Women who are breastfeeding may be vaccinated.” [http://www.immunize.org/vis/hpv_gardasil_9.pdf]; differ from the GARDASIL 9® Package Insert contents, i.e., “It is not known whether GARDASIL 9 is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when GARDASIL 9® is administered to a nursing woman.”
• Immunocompromised individual’s response to GARDASIL 9® may be diminished.
• Immunosuppression and immunosuppressive therapies – 9vHPV vaccine is not a live vaccine. The 9vHPV vaccine can be administered to females and males who are immunosuppressed by diseases or are receiving immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses). However, the immune response and vaccine efficacy might be less than that in persons who are immunocompetent.

Warnings

Observation for 15 minutes after administration of the 9vHPV vaccine is recommended because some persons may develop syncope, sometimes resulting in falling with injury. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position.

Contraindications

DO NOT administer 9vHPV vaccine to individuals with:

• A true hypersensitivity, including severe allergic reactions, to common baker’s yeast.
• A history of hypersensitivity or anaphylactic reactions after receiving a previous dose of 4vHPV vaccine or a previous dose of 9vHPV vaccine.
• An allergy to Amorphous Aluminum Hydroxyphosphate Sulfate.
• An allergy to Polysorbate 80.

Adverse Events

• See the product’s package insert.
• See Adverse Events Following Vaccinations page of this section.
• Report suspected adverse reactions by contacting Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231 or VAERS at 1-800-822-7967 or [http://www.vaers.hhs.gov]

Storage and Handling

• Store in refrigerator at 36°F to 46°F (2°C to 8°C) and Do Not Freeze.
• Protect from light.
• Administer 9vHPV vaccine as soon as possible after being removed from refrigeration.
• 9vHPV vaccine can be out of refrigeration (at temperatures at or below 77°F / 25°C) for a total time of not more than 72 hours.
• Shake well before use. Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine. After thorough agitation, 9vHPV vaccine is a white, cloudy liquid.
• Do not use 9vHPV vaccine if particulates are present or it appears discolored.
• 9vHPV vaccine should not be diluted or mixed with other vaccines.

Other Important Notes
• Inform the patient, parent, or guardian that administration of GARDASIL 9® vaccine does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening.
• Recipients of GARDASIL 9® vaccine should not discontinue anal cancer screening if it has been recommended by a health care provider.
• GARDASIL 9® has not been demonstrated to provide protection against disease from vaccine HPV types to which a person has previously been exposed through sexual activity.
• GARDASIL 9® has not been demonstrated to protect against diseases due to HPV types other than 6, 11, 16, 18, 31, 22, 45, 52, and 58.
• GARDASIL 9® is not intended to be used for treatment of active external genital lesions, cervical, vulvar, vaginal, and anal cancers, CIN, VIN, VaIN, or AIN.
• Not all vulvar, vaginal, and anal cancers are caused by HPV, and GARDASIL 9® protects only against those vulvar, vaginal, and anal cancers caused by HPV types 16, 18, 31, 22, 45, 52, and 58.
• Vaccination with GARDASIL 9® may not result in protection in all vaccine recipients.
• 9vHPV vaccine can be administered to persons with minor acute illnesses. Vaccination of persons with moderate or severe acute illnesses should be deferred until after the patient improves.
• 9vHPV vaccine does not contain preservatives (e.g., thimerosal) or antibiotics.

References:
Advisory Committee on Immunization Practices, Vaccines for Children Program, Vaccines to Prevent Human Papillomavirus. VFC Resolution No. 10/16-2

https://www.cdc.gov/mmwr/volumes/65/wr/mm6549a5.htm.

Centers for Disease Control and Prevention. Supplemental information and guidance for vaccination providers regarding use of 9-valent HPV vaccine (November 2016).

http://jamanetwork.com

Advisory Committee on Immunization Practices, Vaccines for Children Program, Vaccines to Prevent Human Papillomavirus. VFC Resolution No. 02/15-2

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a3.htm


GARDASIL® Package Insert (Dated 1/2017)

Protocol for Administration of
Inactivated Influenza Vaccine (IIV)

All Local Health Department staff who administer influenza immunizations should review the package label and the package insert for influenza vaccines in stock to assure that influenza vaccine for the current influenza season is being administered.

- Administer influenza vaccines as soon as locally available.
- Continue to offer influenza vaccine until the vaccine expiration date.

During annual influenza vaccination campaigns, please review the pneumococcal vaccine status for all adults & children, aged 2 years and older, with medical conditions that put them at higher risk for invasive pneumococcal disease or its complications. Review the protocols for pneumococcal vaccines (i.e., PCV13 and PPSV23) in the Clinical Services Guide and administer recommended age-appropriate pneumococcal vaccine doses, when indicated.

Indications and Usage

Inactivated influenza vaccines (IIVs) will be available in both trivalent (IIV3) and quadrivalent (IIV4) formulations. IIV is indicated for active immunization of persons against influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.

- Brands of IIV are FDA licensed for particular age groups. See the package insert for the IIV brands being used in the Local Health Department to determine the FDA licensed age groups for each brand of IIV.

Summary of Influenza Vaccination Recommendations

- All persons aged 6 months and older who do not have contraindications should be vaccinated annually.
- An age-appropriate formulation of IIV should be used.
- Protection of persons at higher risk for influenza-related complications should continue to be a focus of vaccination efforts as providers and programs transition to routine vaccination of all persons aged 6 months and older.
• When IIV supply is limited, influenza vaccination efforts should focus on delivering vaccination to persons who do not have contraindications and who:
  o are aged 6 months through 59 months;
  o are aged 50 years and older;
  o have chronic pulmonary (including asthma and cystic fibrosis), or cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus);
  o are immunosuppressed (including immunosuppression caused by medications or by human immunodeficiency virus or HIV infection);
  o are or will be pregnant during the influenza season;
  o are aged 6 months through 18 years and receiving long-term aspirin therapy and who therefore might be at risk for experiencing Reye syndrome after influenza virus infection;
  o are residents of nursing homes and other long-term care facilities;
  o are American Indians/Alaska Natives;
  o are extremely obese (i.e., body mass index or BMI is 40 or greater);
  o are health-care personnel, including physicians, nurses, and other workers in inpatient and outpatient-care settings, medical emergency-response workers (e.g., paramedics and emergency medical technicians), employees of nursing home and long-term care facilities who have contact with patients or residents, and students in these professions who will have contact with patients;
  o are household contacts (including children) and caregivers of children aged less than 59 months (i.e., aged less than 5 years) and adults aged 50 years and older, particularly contacts of children aged less than 6 months; and
  o are household contacts (including children) and caregivers of persons with medical conditions that put them at high risk for severe complications from influenza.
### Dosage and Route (See package insert. Dosage is brand-specific.)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose</th>
<th>No. of Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months through 35 months</td>
<td>See package insert</td>
<td>1 or 2³</td>
</tr>
<tr>
<td>6 months through 8 years</td>
<td>See package insert</td>
<td>Only 1 dose of influenza vaccine is required if previously vaccinated with ≥2 total doses of trivalent or quadrivalent influenza vaccine before July 1 of a year IIV is being administered for the current influenza season. If no previous history of ≥2 total doses of trivalent or quadrivalent influenza vaccine before July 1 of a year IIV is being administered for the current influenza season, then 2 doses should be administered this season. The interval between the 2 doses should be at least 4 weeks.</td>
</tr>
<tr>
<td>3 through 8 years</td>
<td>See package insert</td>
<td>1 or 2³</td>
</tr>
<tr>
<td>9 years and older</td>
<td>See package insert</td>
<td>1</td>
</tr>
</tbody>
</table>

Note: ¹The two or more previous doses need not have been received during the same season or consecutive seasons.

### Anatomical Site

- Intramuscular injection, dosage specific for age group. As with other intramuscular injections, use with caution in patients on anticoagulant therapy.
- Adults and older children should be vaccinated in the deltoid muscle.
- Infants and young children should be vaccinated in the anterolateral aspect of the thigh.
- Consult “Epidemiology and Prevention of Vaccine-Preventable Diseases” (The Pink Book), Chapter 6: Vaccine Administration, for information about appropriate needle sizes and lengths for administering vaccines.
Contraindications

- History of severe allergic reaction to any component of the vaccine or after previous dose of any influenza vaccine.
- History of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of IIV.
- ACIP recommendations about the administration of influenza vaccine in persons with a history of egg allergy differ from the contraindications listed in an IIV package insert. However, **DO NOT administer IIV at a Local Health Department to persons with a history of egg allergy.**
  - ACIP recommends that persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine. Refer these persons to their health care provider for evaluation and possible administration of influenza vaccine.
  - ACIP recommends that persons who report having had reactions to egg involving symptoms other than hives, such as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention, may receive any licensed and recommended influenza vaccine that is otherwise appropriate for the recipient’s age and health status. The selected vaccine should be administered in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, and physician offices). Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic conditions. Refer these persons to their health care provider for evaluation and possible administration of influenza vaccine.
- Anaphylactic reaction to latex: The syringe tip cap of some brands of influenza vaccines packaged as single-dose prefilled syringes may contain natural rubber latex, while other brands do not. Check about latex information in the package insert specific to the IIV brands being used in Local Health Departments.
- Providers should consider observing all patients for 15 minutes after vaccination to decrease the risk for injury should they experience syncope, per the ACIP General Recommendations on Immunizations.

Precautions

- Moderate to severe illness with or without fever.
- History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.

Adverse Events

See the product’s package insert.

Storage and Handling

Store between 35°- 46°F (2° - 8°C). **DO NOT FREEZE.** See the product’s package insert.

Other Important Notes:

- A quadrivalent intradermally administered IIV preparation is indicated for persons aged 18 through 64 years. The vaccine is administered intradermally via a single-dose, prefilled microinjection syringe. The preferred site for administration is over the deltoid muscle. The most common adverse reactions include injection-site erythema, induration, swelling, pain, and pruritus. With the exception of pain, these reactions occurred more frequently than with intramuscular vaccine, but generally resolved within 3-7 days. This vaccine is an
alternative to other IIV preparations for those in the indicated age range, with no preferential recommendation.

- Routine annual influenza vaccination is recommended by ACIP for all persons aged 65 years and older who do not have contraindications. No preference is expressed for any age-appropriate IIV formulation (e.g., standard-dose or high-dose, trivalent or quadrivalent, unadjuvanted or adjuvanted), or for any other influenza vaccine licensed for use in persons aged 65 years and older.

- IIV formulations in multidose vials contain the vaccine preservative thimerosal. Preservative-free single dose preparations are available.

References:
Annual updates of the Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices posted online by CDC on the ACIP Website, https://www.cdc.gov/vaccines/hcp/acip-recs/index.html.


Protocol for Administration of Inactivated Poliovirus (IPV) Vaccine

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunization.

Indications and Usage
IPV vaccine is indicated for active immunization of infants (as young as 6 weeks of age), children and adults for the prevention of poliomyelitis caused by poliovirus types 1, 2, and 3.

Recommended Schedule

<table>
<thead>
<tr>
<th>Dose</th>
<th>Recommended Age</th>
<th>Accelerated Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>1¹</td>
<td>2 months</td>
<td>6 weeks or older</td>
</tr>
<tr>
<td>2</td>
<td>4 months</td>
<td>&gt; 4 weeks after 1st dose</td>
</tr>
<tr>
<td>3²</td>
<td>6 through 18 months</td>
<td>&gt; 4 weeks after 2nd dose, but 8 weeks is preferred</td>
</tr>
<tr>
<td>4³</td>
<td>4 through 6 years</td>
<td>The minimum interval from dose 3 to dose 4 is 6 months.</td>
</tr>
</tbody>
</table>
1 Use of the minimum age and minimum intervals for vaccine administration in the first 6 months of life are recommended only if the vaccine recipient is at risk for imminent exposure to circulating poliovirus.

2 If age \( \geq 7 \) years: A total of only 3 doses are needed to complete the primary series.

3 If age < 7 years: A total of 4 doses are needed to complete the primary series, unless the 3rd dose was administered after the 4th birthday, in which case a 4th dose (booster) is not needed.

The final dose in the IPV series should be administered at age \( \geq 4 \) years regardless of the number of previous doses.

**IPV is indicated for:**

**Children:** All infants \( \geq 6 \) weeks of age, and any unvaccinated children through 18 years of age. (For children, adequate proof of immunity to poliovirus is defined as: Documentation of receipt of four or more doses of polio vaccine with a minimum interval of 4 weeks between doses; only 3 doses are needed when the 3rd dose is given on or after the fourth birthday.)

**Adults:** Vaccination is recommended for certain adults (\( \geq 18 \) years of age) who are at greater risk for exposure to poliovirus than the general population. These persons include:

- Travelers to areas or countries where poliomyelitis is or may be epidemic or endemic;
- Members of communities or specific population groups with disease caused by polioviruses;
- Laboratory workers who handle specimen that might contain polioviruses;
- Healthcare workers who have close contact with patients who might be excreting polioviruses.
- Adequate proof of immunity for adults: Documentation of receipt of \( \geq 3 \) doses of polio vaccine with a minimum interval of 4 weeks between doses with documentation of \( \geq 1 \) booster dose.

**Dosage and Route**

Always check the package insert prior to administration.

Administer 0.5 mL subcutaneously (SQ)

**Anatomical Site**

The anterolateral aspect of the thigh or the upper outer triceps area by injecting the needle at a 45° angle in a pinched-up fold of skin and SQ tissue. Use a 5/8- to ¾-inch, 23- to 25-gauge needle.

**Precautions**

Moderate or severe illness with or without fever (temporary precaution)

**Contraindications**

Individuals with:

- Acute, moderate or severe illness with or without fever
- Anaphylactic reaction to previous dose of IPV, streptomycin, polymyxin B, neomycin, or to any other component of the vaccine (see package insert for specific components)

**Adverse Events**

- See the product’s package insert
- See Adverse Events Following Vaccinations page of this section
Storage and Handling
Store in refrigerator at 36°F – 46°F (2°C – 8°C)
DO NOT FREEZE; discard if product has been frozen.

Other Important Notes

- The 1st dose may be administered as early as 6 weeks of age, however use of the minimum age for vaccines in the first 6 months of life are recommended only if the vaccine recipient is at risk for imminent exposure to circulating poliovirus.
- If a 5th dose is needed, the minimum interval from dose 4 to dose 5 should be at least 6 months to provide an optimum booster response.
- Administer IPV simultaneously with all other vaccines indicated, according to the recommended schedule and patient’s vaccine status.
  IPV can be administered to pregnant women who are at risk of exposure to wild-type poliovirus infection.

Protocol for Administration of
Live-Attenuated Influenza Virus (LAIV) Vaccine

All Local Health Department staff who administer influenza immunizations should review the package label and the package insert for influenza vaccines in stock to assure that influenza vaccine for the current influenza season is being administered.

- Administer influenza vaccines as soon as locally available.
- Continue to offer influenza vaccine until the vaccine expiration date.

Indications and Usage

- LAIV vaccine is a live-attenuated, quadrivalent, nasally administered vaccine indicated for the active immunization of healthy non-pregnant persons aged 2 through 49 years against influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.

Persons for whom annual vaccination with LAIV is recommended

- Healthy children (aged 2 through 8 years) who have no contraindications or precautions may be vaccinated with either live attenuated influenza vaccine (LAIV) or inactivated influenza vaccine (IIV). Do not delay influenza vaccination to procure a specific vaccine preparation if an appropriate one is already available.
- No preference is expressed for LAIV or IIV for any healthy person aged 2 years through 49 years for whom either vaccine is appropriate. An age-appropriate formulation of vaccine should be used.
- Healthy children and adolescents (aged 2 through 18 years), except for pregnant adolescents;
- Healthy adults (aged 19 through 49 years), except for pregnant women;
- Healthy non-pregnant healthcare personnel (HCP) aged 49 years or less;
- Healthy household contacts (aged 2 through 49 years) and healthy caregivers of persons in the following high-risk groups:
  - Any children aged less than 2 years;
  - Adults aged 50 years and older;
  - Persons with medical conditions that put them at higher risk for severe complications from influenza.

Note: Inactivated influenza vaccine (IIV) is preferred for vaccinating household members, healthcare personnel (HCP), and others who have close contact with severely immunosuppressed persons (e.g., patients with hematopoietic stem cell transplants) during those periods in which the immunosuppressed person requires care in a protective environment (typically defined as a specialized patient-care area with a positive airflow relative to the corridor, high-efficiency particulate air filtration, and frequent air changes, such a bone marrow transplant unit).
LAIV and Tuberculosis Screening with a Tuberculin Skin Test (TST)

- LAIV can be given on the same day as a TST. If the TST cannot be applied before or on the same day as LAIV is administered, defer the TST until at least 4 weeks after administering LAIV.

**Dosage and Route**

See the product’s package insert.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Vaccination Status</th>
<th>Dosage Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children aged 2 years through 8 years</td>
<td>If no previous history of two or more doses of influenza vaccinations before July 1 of the current year¹</td>
<td>Two doses of LAIV vaccine administered ≥4 weeks apart.²</td>
</tr>
<tr>
<td></td>
<td>Previously vaccinated with two or more doses of influenza vaccine before July 1 of the current year¹</td>
<td>One dose of LAIV vaccine.²</td>
</tr>
<tr>
<td>Children and adults aged 9 through 49 years</td>
<td>Does not apply</td>
<td>One dose of LAIV vaccine.²</td>
</tr>
</tbody>
</table>

Notes: ¹The two previous doses need not have been given during the same season or consecutive seasons
²Administer dosage as 0.1 mL per nostril.

**To administer LAIV vaccine (See the product package insert for complete step-by-step instructions):**

- Place the recipient in an upright position.
- Remove the rubber tip protector from the LAIV sprayer. DO NOT remove the dose-divider clip from the other end of the sprayer.
- Place the tip just inside the first nostril.
- With a single motion, depress the plunger **as rapidly as possible** until the dose-divider clip prevents you from going further.
- Pinch and remove the dose-divider clip from the plunger.
- Place the tip just inside the other nostril and with a single motion depress the plunger **as rapidly as possible** to deliver the remaining vaccine.
- If the vaccine recipient sneezes after administration, the dose should not be repeated.

**Anatomical Site:** Intranasal (Under no circumstances should LAIV be administered by the intramuscular, intradermal or intravenous route.)
Contraindications

- Anaphylactic reaction to a previous dose of influenza vaccine, eggs or any other component of the vaccine (see package insert for specific components). This includes persons who report having had reactions to eggs involving hives, angioedema, respiratory distress, lightheadedness, hypotension, recurrent emesis, or reactions requiring treatment with epinephrine or other emergency medical treatment.

Refer persons with a history of anaphylaxis to a vaccine component, or who report hives or other reactions to eggs listed above, but who are at risk for complications from influenza, to their health care provider for evaluation, desensitization, and possible administration of influenza vaccine.

- Persons aged less than 2 years because of an increased risk for hospitalization and wheezing observed in clinical trials;
- Children aged 2 through 4 years whose parents or caregivers report that a health-care provider has told them during the preceding 12 months that their child had wheezing or asthma or whose medical record indicates a wheezing episode has occurred during the preceding 12 months;
- Persons with asthma;
- Persons aged 50 years and older;
- Adults and children who have chronic pulmonary (including asthma), cardiovascular (except isolated hypertension), renal, hepatic, neurological/neuromuscular, hematological, or metabolic disorders (including diabetes mellitus);
- Adults and children who have immunosuppression (including immunosuppression caused by medications or by HIV);
- Children or adolescents aged 2 through 18 years receiving aspirin or other salicylates (because of the association of Reye syndrome with wild-type influenza virus infection);
- Pregnant women;

Precautions

- Defer administration of LAIV if nasal congestion is present.
- Guillain-Barré Syndrome within 6 weeks following a previous dose of influenza vaccine.
- Moderate or severe illness with or without fever. Postpone administration of LAIV until recovery from the acute phase of moderate or severe illness.
- Because antivirals reduce replication of influenza viruses, LAIV should not be administered until 48 hours after cessation of influenza antiviral therapy. If influenza antiviral medications are administered within 2 weeks after receipt of LAIV, the vaccine dose should be repeated 48 or more hours after the last dose of antiviral medications. Persons receiving antivirals within the period 2 days before to 14 days after vaccination with LAIV should be revaccinated at a later date with any approved vaccine formulation.

Screening for asthma or wheezing illness (or history of wheezing illness) when considering use of LAIV for children aged 2 through 4 years

- Clinicians and vaccination programs should screen for asthma or wheezing illness (or history of wheezing illness) when considering use of LAIV for children aged 2 through 4 years, and should avoid use of this vaccine in children with asthma or a recent wheezing episode within the previous 12 months.
- Health-care providers should consult the medical record, when available, to identify children aged 2 through 4 years with asthma, or recurrent wheezing that might indicate asthma.
- In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving LAIV, parents or caregivers of children aged 2 through 4 years should be asked: "In the past 12 months, has a health-care provider ever told you that your child had wheezing or asthma?"
- Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record during the preceding 12 months should not receive LAIV.

**Adverse Events**

See the product’s package insert.

**Storage and Handling**

LAIV is shipped at 35° – 46°F (2° – 8°C) and can remain at that temperature until the expiration date is reached. **DO NOT FREEZE.**

- Keep LAIV sprayer in outer carton in order to protect from light.
- Vaccine prepared for a previous influenza season should not be administered to provide protection for any subsequent season.

**Other Important Notes**

**Shedding vaccine virus**

- Nasopharyngeal secretions or swabs collected from vaccinees may test positive for influenza virus for up to three weeks post immunization.

**Healthcare personnel and hospital visitors**

- Healthcare personnel (HCP) and hospital visitors who have received LAIV should refrain from contact with severely immunosuppressed patients requiring a protective environment for 7 days after receipt of vaccine. IIV is recommended for vaccinating household members, HCP, and others who have close contact with severely immunosuppressed persons (e.g., patients with hematopoietic stem cell transplants) requiring care in a protective environment.
- Hospital visitors who have received LAIV should avoid contact with severely immunosuppressed persons in protected environments for 7 days after vaccination but should not be restricted from visiting less severely immunosuppressed patients.
- HCP working in environments such as neonatal intensive care, oncology, or labor and delivery units can receive LAIV without any restrictions.
- Healthy nonpregnant persons aged 2 through 49 years, including HCP, who have close contact with persons with lesser degrees of immunosuppression (e.g., persons with chronic immunocompromising conditions such as HIV infection, corticosteroid or chemotherapeutic medication use, or who are cared for in other hospital areas such as neonatal intensive care units) can receive IIV or LAIV.

**Preservatives**

- LAIV vaccine **does not** contain the preservative thimerosal.

**Information for persons with latex allergies**

- The single-use intranasal sprayer for LAIV vaccine **does not** contain natural rubber latex.

**References:**

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2018–19 Influenza Season. MMWR Recomm Rep 2018;67(No. RR-3):1–20. DOI: [http://dx.doi.org/10.15585/mmwr.rr6703a1](http://dx.doi.org/10.15585/mmwr.rr6703a1)

https://www.cdc.gov/mmwr/volumes/67/rr/rr6703a1.htm?s_cid=rr6703a1_w

Update: ACIP Recommendations for the Use of Quadrivalent Live Attenuated Influenza Vaccine (LAIV4) — United States, 2018–19 Influenza Season. MMWR Morb Mortal Wkly Rep 2018;67:643–645. DOI: [http://dx.doi.org/10.15585/mmwr.mm6722a5](http://dx.doi.org/10.15585/mmwr.mm6722a5)

https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a5.htm

Last updated July 1, 2019
Measles, Mumps, and Rubella (MMR) Vaccine
For Adults, 19 Years of Age and Older

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunization.

Recommended Schedule:
All adults born in 1957 or after who do not have a medical contraindication should receive at least one dose of MMR vaccine unless they have documentation of at least one dose of measles, mumps-, and rubella-containing vaccine or evidence of immunity to measles, mumps, and rubella. Evidence of immunity would be documentation of physician diagnosed measles, documentation of physician diagnosed mumps, or laboratory evidence of immunity to measles, mumps, and / or rubella.

A second dose of MMR vaccine is recommended for some adults born in 1957 or after who:
- Are students attending colleges and other post-high school educational institutions
- Plan to travel internationally
- Are close contacts of a suspected or confirmed case of measles or mumps and who have documentation of only one dose of MMR vaccine

A third dose of MMR vaccine is recommended for persons previously vaccinated with two doses of a mumps virus-containing vaccine who are identified by public health authorities as being part of a group or population at increased risk for acquiring mumps because of an outbreak.

All adults born before 1957 are generally considered immune to measles, mumps, and rubella. Adequate vaccination of persons who travel outside the United States would be two doses of MMR vaccine. Individuals, who are close contacts of a suspected or confirmed case of measles or mumps and have no documented doses of MMR vaccine, may receive at least one dose of MMR vaccine.

Health Care Workers should have presumptive evidence of immunity to measles, mumps, and rubella, which includes any of the following:

- Written documentation of vaccination with:
  - 2 doses of MMR vaccine administered at least 28 days apart OR
  - 2 doses of live measles vaccine administered at least 28 days apart AND
  - 2 doses of live mumps vaccine administered at least 28 days apart AND
  - 1 dose of live rubella vaccine
- Laboratory evidence of immunity
- Laboratory confirmation of disease (measles and mumps), or infection or disease (rubella)

Revaccination with MMR vaccine is recommended for certain persons who should be considered unvaccinated and need to receive at least one dose of a measles-containing vaccine. (See the Pink Book, 13th edition, for information.)
**Dosage and Route**
- 0.5 mL subcutaneously

**Anatomical Site**
- Outer aspect of the upper arm, with 23-25 gauge, 5/8” needle.

**Precautions**
- **Pregnancy** Do not vaccinate women who are pregnant. Women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the healthcare facility. MMR or measles, mumps, or rubella vaccination during pregnancy should not ordinarily be a reason to consider interruption of pregnancy.
- Women should avoid getting pregnant for at least 1 month after getting MMR vaccine.¹
- Moderate or severe acute illness.
- If blood, plasma, and/or immune globulin were given in past 11 months, see ACIP statement General Recommendations on Immunization regarding time to wait before vaccinating.
- History or thrombocytopenia or thrombocytopenic purpura

¹October 2001, the ACIP shortened its recommended period to avoid pregnancy after receipt of rubella-containing vaccine from 3 months to 28 days, [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5049a5.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5049a5.htm).

Vaccine Information Statements (VISs) for MMR vaccine, last revised in 2018, include a precaution that “Women should avoid getting pregnant for at least 1 month after getting MMR vaccine”

Note that both the ACIP recommendations and the text of the MMR VIS differ from the package insert precautions to avoid pregnancy for three months after vaccination.

**Contraindications**
As described in the package insert, **DO NOT** give MMR vaccine to:
- Individuals with a hypersensitivity to any component of the vaccine, including gelatin
- Women who are pregnant
- Individuals with a history of anaphylactic or anaphylactoid reactions to neomycin
- Individuals receiving immunosuppressive therapy including high-dose systemic corticosteroids
- Individuals with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems
- Individuals with primary and acquired immunodeficiency states, including AIDS
- See package insert WARNING about administering MMR to individuals with a history of anaphylactic or other immediate hypersensitivity reactions (e.g., hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) after egg ingestion
**Adverse Events**

- See the product’s package insert
- See Adverse Events Following Vaccinations page of this section

**Storage and Handling**

- MMR may be stored in the refrigerator or freezer, (It is recommended to keep MMR in the freezer to prevent confusion with MMRV)
- MMR vaccine can be refrigerated for up to 8 hours after reconstitution and must be protected from light.

**Other Important Notes**

- Breastfeeding is not a contraindication to receipt of MMR vaccine
- Immune Globulin (IG) is not to be given concurrently with MMR

**Tuberculin Testing and Live Vaccines**

Recommendations for use of the tuberculin skin test are independent of those for immunization. Tuberculin testing at any age is not required before administration of live-virus vaccines. A tuberculin skin test (TST) can be applied at the same visit during which these vaccines are administered. Measles vaccine temporarily can suppress tuberculin reactivity for at least 4 to 6 weeks. The effect of live-virus varicella, yellow fever, and live-attenuated influenza vaccines on tuberculin skin test reactivity is not known. In the absence of data, the same TST spacing recommendation should be applied to these vaccines as described for MMR. There is no evidence that inactivated vaccines, polysaccharide vaccines or recombinant or subunit vaccines or toxoids interfere with immune response to TST.

**Tuberculin Skin Testing (TST) and Measles, Mumps, Rubella Vaccine (MMR)**

- Apply TST at same visit as MMR (preferred strategy)
- Apply TST first and administer MMR when TST is read (least favored option because receipt of MMR is delayed) (least preferred strategy)
- Delay TST at least 4 weeks if MMR is given first.

**Resources**

https://cdc.gov/mmwr/volumes/67/wr/mm6701a7.htm


Measles, Mumps, Rubella (MMR) Vaccine

For Children, 12 Months Through 18 Years of Age

Precautions and Contraindications

Screen all patients for precautions and contraindications to immunization.

Recommended Schedule

- Children 12 months through 18 years of age. (See adult protocol for those aged 19 and older)
  - The first dose of MMR vaccine is recommended at 12 to 15 months of age
  - The second dose is recommended at 4 to 6 years of age. The second dose may be administered before age 4 years, provided at least 4 weeks have elapsed since the first dose.
  - The minimum interval between the two doses of MMR vaccine is 4 weeks.
- If MMR and varicella vaccines are not administered at the same visit, they should be separated by at least 4 weeks.
- Infants aged 6 through 11 months who are traveling internationally should receive one dose of MMR vaccine before departure. These children should be revaccinated with 2 doses of MMR vaccine, the first at ages 12 through 15 months and at least 4 weeks after the previous dose, and the second at ages 4 through 6 years.
- During a measles outbreak, MMR vaccine may be given to infants as young as 6 months of age. These infants should be revaccinated with 2 doses of MMR vaccine, the first at ages 12 through 15 months and at least 4 weeks after the previous dose, and the second at ages 4 through 6 years.
- During a mumps outbreak: A third dose of MMR vaccine should be given to persons previously vaccinated with two doses of a mumps virus-containing vaccine and are identified by public health authorities as being part of a group or population at increased risk for acquiring mumps because of an outbreak.

Dosage and Route

- 0.5 mL subcutaneously

Anatomical Site

- Outer aspect of the deltoid of the upper arm or in the higher anterolateral area of the thigh.

Precautions

- Prior to administering the vaccine, obtain a vaccination history to determine any reactions to any vaccine including MMR vaccine.
- Pregnancy should be avoided for at least 1 month after receiving the MMR vaccine.

Contraindications

DO NOT administer MMR vaccine to individuals with:

- A history of anaphylactic reactions to neomycin.
- A history of hypersensitivity to gelatin or any other component of the vaccine.
- Blood dyscrasias, leukemia, lymphomas of any type, malignant neoplasms
- Primary and acquired immunodeficiency states, including AIDS
- Active untreated tuberculosis
- Women who are pregnant
- An active febrile illness with fever greater than 101.3°F.
- Immunosuppressive therapy including high-dose systemic corticosteroids.
• See package insert WARNING about administering MMR to individuals with a history of anaphylactic or other immediate hypersensitivity reactions (e.g., hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) after egg ingestion.

Adverse Events
• See the product’s package insert
• See Adverse Events Following Vaccinations page of this section

Storage and Handling
• MMR vaccine may be stored in the refrigerator or freezer, (It is recommended to keep MMR vaccine in the freezer to prevent confusion with MMRV vaccine).
• MMR vaccine can be refrigerated for up to 8 hours after reconstitution and must be protected from light.

Other Important Notes
• Breastfeeding is not a contraindication to receiving the vaccine.

Tuberculin Testing and Live Vaccines
Recommendations for use of the tuberculin skin test are independent of those for immunization. Tuberculin testing at any age is not required before administration of live-virus vaccines. A tuberculin skin test (TST) can be applied at the same visit during which these vaccines are administered. Measles vaccine temporarily can suppress tuberculin reactivity for at least 4 to 6 weeks. The effect of live-virus varicella, yellow fever, and live-attenuated influenza vaccines on tuberculin skin test reactivity is not known. In the absence of data, the same TST spacing recommendation should be applied to these vaccines as described for MMR. There is no evidence that inactivated vaccines, polysaccharide vaccines or recombinant or subunit vaccines or toxoids interfere with immune response to TST.

Tuberculin Skin Testing (TST) and Measles, Mumps, Rubella Vaccine (MMR)
• Apply TST at same visit as MMR (preferred strategy)
• Apply TST first and administer MMR when TST is read (least favored option because receipt of MMR is delayed) (least preferred strategy)
• Delay TST at least 4 weeks if MMR is given first.

1October 2001, the ACIP shortened its recommended period to avoid pregnancy after receipt of rubella-containing vaccine from 3 months to 28 days, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5049a5.htm. Vaccine Information Statements (VISs) for MMR vaccine, last revised in 2018, include a precaution that “Women should avoid getting pregnant for at least 1 month after getting MMR vaccine.” Note that both the ACIP recommendations and the text of the MMR VIS differ from the package insert precautions to avoid pregnancy for three months after vaccination.
Resources


Advisory Committee on Immunization Practices (ACIP) Resolution No. 10/17-3: Vaccines to Prevent Measles, Mumps, Rubella, and Varicella,


Vaccine Information Statement. MMR (Measles, Mumps, and Rubella) Vaccine: What You Need to Know. Centers for Disease Control and Prevention. Last revised 2/12/2018,

Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, U.S., 2018,
https://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html
Measles, Mumps, Rubella and Varicella
Combination (MMRV) Vaccine
(ProQuad®)

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunization.

Indications and Usage
MMRV vaccine is a combination vaccine indicated for active immunization for the prevention of measles, mumps, rubella, and varicella in children aged 12 months through 12 years.

NOTE: New recommendations were adopted in June 2009 by ACIP regarding use of the combination measles, mumps, rubella, and varicella (MMRV) vaccine and were published in MMWR in May 2010. ACIP now recommends that MMR vaccine AND varicella vaccines be administered separately for the first dose in children aged 12 through 47 months due to the increased risk for febrile seizures with the MMRV combination vaccine. For the second dose of measles, mumps, rubella, and varicella vaccines at any age (i.e., 15 months through 12 years) and for the first dose in children aged 48 months through 12 years, use of the MMRV vaccine is generally preferred over separate injections of its equivalent component vaccines (i.e., MMR vaccine and varicella vaccine).

Recommended Schedule for Measles, Mumps, Rubella, and Varicella Vaccines

- The routinely recommended ages for measles, mumps, rubella, and varicella vaccination continue to be age 12 through 15 months for the first dose and age 4 through 6 years for the second dose.
- **FIRST DOSE** of measles, mumps, rubella, and varicella vaccines
  - For the first dose administered to children aged 12 months through 47 months, MMR vaccine and varicella vaccine should be administered separately in this age group.
  - For the first dose administered to children aged 48 months through 12 years, use of MMRV vaccine is generally preferred over separate injections of its equivalent component vaccines (i.e., MMR vaccine and varicella vaccine).
- **SECOND DOSE** of measles, mumps, rubella, and varicella vaccines
  - For the second dose administered to children aged 15 months through 12 years, use of MMRV vaccine is generally preferred over separate injections of its equivalent component vaccines (i.e., MMR vaccine and varicella vaccine).
  - At least one month should lapse between a dose of measles-containing vaccine, such as MMR vaccine, and a dose of MMRV vaccine. If for any reason a second dose of varicella-containing vaccine is required, at least 3 months should lapse between administrations of the two doses.
- **THIRD DOSE** of MMR vaccine.
  - During a mumps outbreak: A third dose of MMR vaccine should be given to persons previously vaccinated with two doses of a mumps virus-containing vaccine and are identified by public health authorities as being part of a group or population at increased risk for acquiring mumps because of an outbreak.
  - MMRV vaccine, which is the other vaccine licensed in the United States for the prevention of mumps, may also be used when a third dose mumps vaccination is indicated among children aged ≤12 years.
Dosage and Route

- Administer 0.5 mL subcutaneously. Consult “Epidemiology and Prevention of Vaccine-Preventable Diseases” (The Pink Book). Appendix D, for information about appropriate needle sizes and needle lengths for administering vaccines.

- MMRV vaccine is supplied in single-dose vials of lyophilized vaccine to be reconstituted using only the separately packaged sterile water diluent. Withdraw the entire volume of supplied diluent into a syringe. Inject the entire content of the syringe into the vial containing the powder. Gently agitate to dissolve completely. Withdraw the entire amount of the reconstituted vaccine from the vial into the same syringe and inject the entire volume.

Anatomical Site

- Outer aspect of the deltoid region of the upper arm or into the higher anterolateral area of the thigh.

Precautions

- Prior to administering the vaccine, obtain a vaccination history to determine any reactions to any vaccine including measles, mumps, rubella or varicella;
- Pregnancy should be avoided for 3 months following vaccination with MMRV vaccine;
- Recent (i.e. within the preceding 11 months) receipt of antibody-containing blood product
- A history of thrombocytopenia or thrombocytopenic purpura;
- Moderate or severe acute illness with or without fever; and
- A personal or family (i.e., sibling or parent) history of seizure of any etiology.

1October 2001, the ACIP shortened its recommended period to avoid pregnancy after receipt of rubella-containing vaccine from 3 months to 28 days, [http://www.cdc.gov/vaccines/vpd-vac/combo-vaccines/mmr/faq-mmr-hcp.htm#pregnancy](http://www.cdc.gov/vaccines/vpd-vac/combo-vaccines/mmr/faq-mmr-hcp.htm#pregnancy)

Vaccine Information Statements (VISs) for MMR vaccine, last revised in 2018, include a precaution that “Women should avoid getting pregnant for at least 1 month after getting MMR vaccine”

Vaccine Information Statements (VISs) for varicella vaccine, last revised in 2018, include a precaution that “Women should avoid getting pregnant for at least 1 month after getting chickenpox vaccine”

Note that both the ACIP recommendations and the text of the MMR VIS and the varicella VIS differ from the package insert precautions to avoid pregnancy for three months after vaccination.

Contraindications

**DO NOT** administer MMRV vaccine to individuals with:

- A history of anaphylactic reaction to neomycin;
- A history of an allergic reaction to gelatin or any other component of the vaccine, or after previous vaccination with MMRV vaccine, varicella vaccine or MMR vaccine;
- Altered immunity (i.e., blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems);
- Primary and acquired immunodeficiency including HIV infections/AIDS, cellular immune deficiencies, hypogammaglobulinemia, and dysgammaglobulinemia;
- Family history of congenital or hereditary immunodeficiency, unless the immune competence of the potential vaccine recipient has been demonstrated;
• Systemic immunosuppressive therapy, including oral steroids ≥2 mg/kg of body weight or ≥20 mg/day of prednisone or equivalent for persons who weigh >10 kg, when administered for ≥2 weeks);
• Pregnancy;
• Active untreated tuberculosis;
• Febrile illness (>101.3°F or >38.5°C);
• See package insert WARNING about administering MMRV vaccine to individuals with a history of anaphylactic or other immediate hypersensitivity reactions (e.g., hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) after egg ingestion.

**Adverse Events**

• See the product’s package insert
• See Adverse Events Following Vaccinations page of this section

**Storage and Handling**

• Protect the vaccine from light at all times since such exposure may inactivate the vaccine viruses.
• To minimize loss of potency, MMRV vaccine should be administered immediately after reconstitution. If not used immediately, the reconstituted vaccine may be stored at room temperature, protected from light, for up to 30 minutes.
• Reconstituted MMRV vaccine, like varicella vaccine, must be discarded, if not used within 30 minutes.
• Note difference from MMR vaccine, which can be refrigerated for up to 8 hours after reconstitution.
• Please note this important recommendation: Store all live vaccines (i.e., MMR, MMRV, and varicella vaccines) in the freezer at 5°F (-15°C) or below (to prevent damaging varicella and MMRV vaccines) through inadvertent refrigeration.
• MMRV vaccine may be stored at refrigerator temperature (36° to 46°F, 2° to 8°C) for up to 72 hours prior to reconstitution. Discard any MMRV vaccine stored at 36° to 46°F which is not used within 72 hours of removal from 5°F (-15°C) storage.

**Other Important Notes**

**Tuberculin Testing and Live Vaccines**

Recommendations for use of the tuberculin skin test are independent of those for immunization. Tuberculin testing at any age is not required before administration of live-virus vaccines. A tuberculin skin test (TST) can be applied at the same visit during which these vaccines are administered. Measles vaccine temporarily can suppress tuberculin reactivity for at least 4 to 6 weeks. The effect of live-virus varicella, yellow fever, and live-attenuated influenza vaccines on tuberculin skin test reactivity is not known. In the absence of data, the same TST spacing recommendation should be applied to these vaccines as described for MMR. There is no evidence that inactivated vaccines, polysaccharide vaccines or recombinant or subunit vaccines or toxoids interfere with immune response to TST.

**Tuberculin Skin Testing (TST) and Measles, Mumps, Rubella, Varicella Vaccine (MMRV)**

• Apply TST at same visit as MMRV (preferred strategy)
• Apply TST first and administer MMRV when TST is read (least favored option because receipt of MMRV is delayed) (least preferred strategy)
• Delay TST at least 4 weeks if MMRV is given first.
Resources


Protocol for Administration of
Meningococcal (Groups A, C, Y, and W-135) Polysaccharide
Diphtheria Toxoid Conjugate Vaccine (MenACWY-D)
(MENACTRA®)

Indications and Usage
MENACTRA® quadrivalent meningococcal conjugate vaccine is indicated for active immunization of persons aged 9 months through 55 years for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y, and W-135.

Recommended Schedule
Meningococcal conjugate vaccine is recommended by the Advisory Committee on Immunization Practices (ACIP) for these age groups:

- **Routine vaccination of adolescents:** Administer meningococcal conjugate vaccine, either MENACTRA® or MENVEO®, to all adolescents, preferably at age 11 through 12 years with a booster dose at age 16 years.
  - Administer MENACTRA® or MENVEO® to adolescents aged 13 through 18 years if not previously vaccinated.
    - If the first dose is administered at age 13 through 15 years, a booster dose should be administered at age 16 through 18 years with a minimum interval of at least 8 weeks between doses.
    - If the first dose is administered on or after age 16 years a booster dose is not needed unless the person is at increased risk for meningococcal disease.
  - All persons aged 11 through 18 years should preferably receive either MENACTRA® or MENVEO® for routine meningococcal vaccination.
  - All persons aged 19 through 55 years at increased risk for meningococcal disease (see below) should preferably receive either MENACTRA® or MENVEO®.
  - All persons aged 56 years and older at increased risk for meningococcal disease (see below). MENACTRA® or MENVEO® is preferred for adults aged 56 years or older who a) were vaccinated previously with MENACTRA® or MENVEO® and are recommended for revaccination, or b) for whom multiple doses are anticipated (e.g., persons with asplenia, complement deficiencies, HIV infection, and microbiologists).

*Note:* Neither MENACTRA® nor MENVEO® is FDA approved for this age group.

- Adolescents aged 11 through 18 years with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series of MENACTRA® or MENVEO®, with at least 8 through 12 weeks between doses. Evidence suggests that persons with HIV do not respond optimally to a single dose.
- First year college students up through 21 years who are living in residence halls should receive one (1) primary dose of MENACTRA® or MENVEO®, if not previously vaccinated on or after their 16th birthday. Give a booster dose of MENACTRA® or MENVEO® if a previous dose was given when younger than 16 years of age.
• All persons aged 2 months through 23 months of age at increased risk for meningococcal disease (see below) SHOULD ONLY RECEIVE age-appropriate doses of MENVEO® or Menactra® as described below and in the Table below on the “Recommended Vaccination Schedule and Intervals.”
  ○ For children aged 2 through 18 months with anatomic or functional asplenia (including sickle cell disease), administer a 4-dose infant series of MENVEO® at 2, 4, 6, and 12 through 15 months of age, with at least 8 weeks between doses.
  ○ For children aged 2 through 18 months with persistent complement component deficiency, administer a 4-dose infant series of MENVEO® at 2, 4, 6, and 12 through 15 months with at least 8 weeks between doses.
  ○ For children aged 7 through 23 months with persistent complement component deficiency or HIV infection who have not initiated vaccination, two options exist depending on age and vaccine brand:
    ▪ For children who initiate vaccination with MENVEO® at 7 through 23 months of age, a 2-dose series should be administered with the second dose after 12 months of age and at least 3 months after the first dose.
    ▪ For children who initiate vaccination with MENACTRA® at 9 through 23 months of age, a 2-dose series of MENACTRA® should be administered at least 3 months apart.
  ○ In children aged 9 through 23 months, MENACTRA® is given as a 2-dose primary series with 12 weeks between doses.
  ○ For children aged 19 through 23 months who have not completed a series of MENVEO®, administer two primary doses of MENVEO® at least 3 months apart.
  ○ For children aged 19 through 23 months with persistent complement component deficiency who have not received a complete series of MENACTRA®, administer 2 primary doses of MENACTRA® at least 8 weeks apart.
• For children aged 24 months and older with persistent complement component deficiency or anatomic or functional asplenia (including sickle cell disease) or HIV infection, who have not received a complete series of MENVEO® or MENACTRA®, administer 2 primary doses of either MENACTRA® or MENVEO® at least 2 months apart.
• If MENACTRA® is administered to a child with anatomic or functional asplenia (including sickle cell disease) or HIV infection, do not administer MENACTRA® until 2 years of age and at least 4 weeks after the completion of all PCV13 doses. MENVEO® may be given at any time before or after PCV13.
• All persons aged 2 years through 10 years at increased risk for meningococcal disease (see below) should preferably receive either MENACTRA® (approved for ages 9 months through 55 years) or MENVEO® (approved for ages 2 months through 55 years).
• All persons aged 2 years through 55 years with persistent complement component deficiency (e.g., C5 to C9, properdin, factor H, or factor D) and anatomic or functional asplenia (including sickle cell disease), or with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series administered 2 months apart. Both MENACTRA® and MENVEO® are approved for this age group.
• HIV infection is an indication for routine vaccination with MENACTRA® or MENVEO®. Persons with HIV infection who are recommended routinely to receive vaccine (i.e., persons aged ≥9 months at increased risk for meningococcal disease and all persons aged 11 through 18 years) should receive a 2-dose primary series, administered 8–12 weeks apart, because evidence suggests that persons with HIV do not respond optimally to a single dose.
NOTE:

- All persons aged 9 through 23 months of age at increased risk for invasive meningococcal disease (see below) SHOULD ONLY RECEIVE MENACTRA® or MENVEO® for active immunization against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y, and W-135. In children aged 9 through 23 months, MENACTRA® or MENVEO® is given as a 2-dose series three months apart. MENACTRA® and MENVEO® are administered intramuscularly.

### Recommended Vaccination Schedule and Intervals


<table>
<thead>
<tr>
<th>Age Group</th>
<th>Vaccine</th>
<th>Routine Recommendations</th>
<th>Dosing Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mos through 10 years</td>
<td>MenACWY (MENVEO®, Novartis)</td>
<td>High-risk only[[[1]]]</td>
<td><strong>Primary:</strong>&lt;br&gt;• Age 2 through 6 months: 4 doses at 2, 4, 6, and 12 months&lt;br&gt;• Age 7 through 23 months: 2 doses should be given with the second dose given in the second year of life&lt;br&gt;• Age 2 through 10 years: 1 or 2 doses&lt;br&gt;<strong>Booster</strong> (for persons who remain at risk)[[1]]:&lt;br&gt;• 1st booster 3 years after primary series for children who received primary series prior to age &lt;7 years, then every 5 years&lt;br&gt;• Every 5 years for children who received primary series after 7th birthday</td>
</tr>
<tr>
<td></td>
<td>MenACWY (MENACTRA®, Sanofi)</td>
<td>High-risk only[*]</td>
<td><strong>Primary:</strong>&lt;br&gt;• Age 9 through 23 months: 2 dose series with 12 weeks between doses&lt;br&gt;• Age 2 through 10 years: 1 or 2 doses&lt;br&gt;<strong>Booster</strong> (for persons who remain at risk)[[1]]:&lt;br&gt;• 1st booster 3 years after primary series for children who received primary series prior to age &lt;7 years, then every 5 years</td>
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</tbody>
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### Recommended Vaccination Schedule and Intervals


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<tbody>
<tr>
<td>11 through 18 years</td>
<td>MenACWY (MENVEO® or MENACTRA ®)</td>
<td>Children aged 11 through 18 years</td>
<td>• Every 5 years for children who received primary series after 7th birthday</td>
</tr>
</tbody>
</table>

**Adolescents:**

**Primary:**
- Age 11 through 12 years with booster dose at age 16 years

**Booster** (for persons who remain at risk¶):
- A booster dose is not recommended if the first dose is given on or after the child’s 16th birthday

Adolescents with complement component deficiency, or functional or anatomic asplenia; HIV infection
- 2 doses, 8 through 12 weeks apart

Booster for adolescents who remain at increased risk (complement component deficiency, functional or anatomic asplenia, HIV infection, traveling or part of a meningococcal outbreak more than 5 years after the prior dose):
- 1st booster 5 years after primary
- Additional boosters every 5 years

¶ For children with complement component deficiency, functional or anatomic asplenia, HIV infection, part of a community or organizational outbreak, or traveling internationally to a region with hyperendemic or endemic meningococcal disease.

* For children with complement component deficiency, functional or anatomic asplenia, HIV infection, part of a community or organizational outbreak, or traveling internationally to a region with hyperendemic or endemic meningococcal disease. For infants receiving the vaccine prior to travel, the two doses may be administered as early as 8 weeks apart. Infants with functional or anatomic asplenia or HIV infection should wait until 2 years of age to prevent immune interference with PCV13.
§ For children with complement component deficiency, functional or anatomic asplenia, HIV infection, part of a community or organizational outbreak, MENACTRA® or MENVEO® should be used as booster doses for children.

**Note:** Use of brand names is not meant to preclude the use of other meningococcal vaccines where appropriate.

### Vaccination of persons with high-risk conditions and other persons at increased risk of disease:

- **Children with anatomic or functional asplenia (including sickle cell disease) or HIV infection:**
  1. For children younger than 19 months of age, administer a 4-dose infant series of MENVEO® at 2, 4, 6, and 12 through 15 months of age.
  2. For children aged 19 through 23 months who have not completed a series of MENVEO®, administer 2 primary doses of MENVEO® at least 3 months apart.
  3. For children aged 24 months through 18 years who have not received a complete MENVEO® or MENACTRA®, administer two primary doses of either MENACTRA® or MENVEO® at least 2 months apart. If MENACTRA® is administered to a child with asplenia (including sickle cell disease) or HIV infection, do not administer MENACTRA® until 2 years of age and at least 4 weeks after the completion of all PCV13 doses.

- **Children with persistent complement component deficiencies (C3, C5-9, Properdin, Factor D, and Factor H):**
  1. For children younger than 19 months of age, administer a 4-dose infant series of MENVEO® at 2, 4, 6, and 12 through 15 months of age.
  2. For children 7 through 23 months who have not initiated vaccination, two options exist depending on age and vaccine brand:
     a. For children who initiate vaccination with MENVEO® at 7 months through 23 months of age, a 2-dose series should be administered with the second dose after 12 months of age and at least 3 months after the first dose.
     b. For children who initiate vaccination with MENACTRA® at 9 months through 23 months of age, a 2-dose series of MENACTRA® should be administered at least 3 months apart.
     c. For children aged 24 months through 18 years who have not received a complete series of MENVEO®, or MENACTRA®, administer two primary doses of either MENACTRA® or MENVEO® at least 2 months apart.

- **Adults aged 19 years through 55 years with anatomic or functional asplenia (including sickle cell disease) or HIV infection:** Administer a 2-dose primary series of MENACTRA® or MENVEO® with doses spaced 8–12 weeks apart.

- **Adults aged 19 years through 55 years with persistent complement component deficiencies (C3, C5-9, Properdin, Factor D, and Factor H):** Administer a 2-dose primary series of MENACTRA® or MENVEO® with doses spaced 8–12 weeks apart.

- **Adults aged 56 years and older with anatomic or functional asplenia (including sickle cell disease), HIV infection or with persistent complement component deficiencies (C3, C5-9, Properdin, Factor D, and Factor H),** see page 1 of this protocol.

### Catch-up recommendations for persons with high-risk conditions:

- For children who initiate vaccination with MENVEO® at 7 through 9 months of age, a 2-dose series should be administered with the second dose after 12 months of age and at least 3 months after the first dose.
Persons at increased risk for meningococcal disease include:

- College freshmen who live in dormitories
- Persons with HIV infection
- Persons who travel to or reside in countries where meningococcal disease is hyperendemic, such as sub-Saharan Africa, or epidemic, particularly if contact with the local population will be prolonged administer an age-appropriate formulation and series of MENACTRA® or MENVEO® for protection against serogroups A and W meningococcal disease. Prior receipt of MENHIBRIX® is not sufficient for children traveling to the meningitis belt or the Hajj because it does not contain serogroups A or W. Vaccination in the 3 years before the date of travel is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj.
- Persons with anatomic or functional asplenia (including sickle cell disease)
- Persons with persistent complement component deficiencies (e.g., C3, C5-9, properdin, Factor D, and Factor H)
- Microbiologists routinely exposed to isolates of Neisseria meningitidis use MENACTRA® or MENVEO®. A booster dose should be administered every 5 years if exposure is ongoing.
- Military recruits
- Children (aged 6 weeks and older) and adults who are part of a community outbreak of invasive meningococcal disease caused by a vaccine-preventable serogroup, administer or complete an age-and formulation-appropriate series of MENACTRA® or MENVEO®.

Revaccination:

- Persons previously vaccinated with MENACTRA® or MENVEO® who are at prolonged increased risk for meningococcal disease (see below) should be revaccinated, preferably with either MENACTRA® or MENVEO®.
  - Persons who previously were vaccinated with the 2-dose primary series at ages 9 months through 24 months and are at prolonged increased risk should be revaccinated 3 years after their previous meningococcal vaccine.
  - Persons who previously were vaccinated at ages 2 years through 6 years and are at prolonged increased risk should be revaccinated 3 years after their previous meningococcal vaccine
  - Persons who previously were vaccinated at 7 years of age or older and are at prolonged increased risk should be revaccinated 5 years after their previous meningococcal vaccine.
  - Persons who remain in one of the increased risk groups indefinitely should continue to be revaccinated at 5-year intervals thereafter throughout life.

- College freshmen living in dormitories who were not previously vaccinated with MENACTRA® or MENVEO®, five or more years ago are recommended to be revaccinated with either MENACTRA® or MENVEO®.

- International travelers should receive a booster dose of MENACTRA® or MENVEO® if the last dose was administered five or more years previously. Vaccination in the 3 years before the date of travel is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj
NOTE: Revaccination is not mentioned in the MENVEO® Package Insert. Kentucky Immunization Program staff inquired with the CDC National Immunization Program staff as to whether MENVEO® can be used for revaccination. The relevant part of their reply of Jun 09, 2010 was “... our meningococcal group agrees that MENVEO® can be used for any indication within its licensed age range, including revaccination.”

Persons at prolonged increased risk for meningococcal disease who should be revaccinated include:

- Persons with increased susceptibility such as persistent complement component deficiencies (e.g., C3, properdin, Factor D, and late complement component deficiencies),
- Persons with anatomic or functional asplenia
- Persons with HIV infection
- Persons who have prolonged exposure (e.g., microbiologists routinely working with Neisseria meningitidis, or travelers to or residents of countries where meningococcal disease is hyperendemic or epidemic)

Outbreak Control

- MENACTRA® or MENVEO® are recommended for use in the control of meningococcal outbreaks caused by vaccine-preventable serogroups (A, C, Y, and W-135), as an adjunct to chemoprophylaxis.
  - MENVEO® may be used for infants and children aged 2 months through 23 months.
  - MENACTRA® may be used for infants and children aged 9 months through 23 months.
  - MENACTRA® or MENVEO® is preferred for use among children, adolescents, and adults aged 2 years through 55 years for control of meningococcal disease outbreaks.
  - For persons now aged 56 years and older who were vaccinated previously with MENACTRA® or MENVEO® and are recommended for revaccination, MENACTRA® or MENVEO® is preferred.

Dosage and Route (Always check the package insert prior to administration.)

- Administer 0.5 mL intramuscularly (IM). Consult “Epidemiology and Prevention of Vaccine-Preventable Diseases” (The Pink Book), Appendix D, for information about appropriate needle sizes, needle lengths, and sites for administering vaccines.
- Do not administer this product intravenously, subcutaneously, or intradermally.

Anatomical Site

- Intramuscularly (IM) preferably in the deltoid muscle (upper arm).

Precautions

- Moderate or severe illness with or without fever (temporary precaution)
- The safety and effectiveness in pregnant women has not been established therefore MENACTRA® or MENVEO® should only be given to a pregnant woman if clearly needed.


**Contraindications**

- Individuals with anaphylactic reaction to a previous dose of MENACTRA®, diphtheria toxoid, or meningococcal-containing vaccine. (See “Other Important Notes.”).
- Contraindications and Precautions can be found in the package inserts available at [http://www.immunize.org/packageinserts/pi_meningococcal.asp](http://www.immunize.org/packageinserts/pi_meningococcal.asp)

**Warnings:**

- See warnings in the package insert for administration to individuals with a history of bleeding disorders such as hemophilia or thrombocytopenia or to individuals on anticoagulant therapy.

**Adverse Events**

- See the product’s package insert.

**Storage and Handling**

- Store in refrigerator at 36°F – 46°F (2°C – 8°C)
- **DO NOT FREEZE.** Product that has been frozen or previously frozen should not be used.
- Do not use after the expiration date.

**Other Important Notes**

- Pregnancy is not a contraindication to MENACTRA®.
- Breastfeeding is not a contraindication to MENACTRA®.
- Persons with a history of anaphylaxis to a vaccine component, but who are at risk for meningococcal disease, should be referred to an allergist for evaluation and possible administration of MENACTRA® or other age appropriate meningococcal vaccines.
- MENACTRA® is preferred for use among children aged 2 through 10 years for control of meningococcal disease outbreaks.
- The vial stopper is not made with natural rubber latex.
References:

MMWR “Recommendations for Use of Meningococcal Conjugate Vaccines in HIV Infected Persons”-Advisory Committee on Immunization Practices (ACIP (November 4, 2016)
http://www.cdc.gov/mmwr/volumes/65/wr/mm6543a3.htm

VFC Resolutions – 10/16 Vaccines to Prevent Meningococcal Disease

MENACTRA® Package Insert (dated September 2016):
http://www.immunize.org/fda/#mena

Immunization Action Coalition (IAC), “Meningococcal Vaccine Recommendations by Age and Risk Factor for Serogroups A, C, W, or Y Protection (12/16)

MMWR “Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP) (March 22, 2013)
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm

Footnotes to the “Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2018”:

Footnotes to the “Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States, 2018”:

VFC Resolutions – 10/13 Meningococcal:
http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html
Protocol for Administration of
Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide
Diphtheria CRM197 Conjugate Vaccine (MenACWY-CRM)
(MENVEO®)

Indications and Usage
MENVEO® quadrivalent meningococcal conjugate vaccine is indicated for active immunization of persons aged 2 months through 55 years for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y, and W-135.

Recommended Schedule
Meningococcal conjugate vaccine is recommended by the Advisory Committee on Immunization Practices (ACIP) for these age groups:

- **Routine Vaccination of Adolescents:** Administer meningococcal conjugate vaccine, either MENACTRA® or MENVEO®, to all adolescents, preferably at age 11 through 12 years with a booster dose at age 16 years.
  - Administer MENACTRA® or MENVEO® to adolescents aged 13 through 18 years if not previously vaccinated.
    - If the first dose is administered at age 13 through 15 years, a booster dose should be administered at age 16 through 18 years with a minimum interval of at least 8 weeks between doses.
    - If the first dose is administered on or after age 16 years a booster dose is not needed unless the person is at increased risk for meningococcal disease.
  - All adolescents aged 11 through 18 years should preferably receive either MENACTRA® or MENVEO® for routine meningococcal vaccination.

- All persons aged 19 through 55 years at increased risk for meningococcal disease (see below) should preferably receive either MENACTRA® or MENVEO®.

- All persons aged 56 years and older at increased risk for meningococcal disease. MENACTRA® or MENVEO® is preferred for adults aged 56 years or older who a) were vaccinated previously with MENACTRA® or MENVEO® and are recommended for revaccination, or b) for whom multiple doses are anticipated (e.g., persons with asplenia, complement deficiencies, HIV infection, and microbiologists).

  **Note:** Neither MENACTRA® nor MENVEO® is FDA approved for this age group.

- Adolescents aged 11 through 18 years with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series of MENACTRA® or MENVEO®, with at least 8 weeks between doses. Evidence suggests that persons with HIV do not respond optimally to a single dose.

- First year college students up through 21 years who are living in residence halls should receive one (1) primary dose of MENACTRA® or MENVEO®, if not previously vaccinated on or after their 16th birthday. Give a booster dose of MENACTRA® or MENVEO® if a previous dose was given when younger than 16 years of age.

- All persons aged 2 months through 23 months of age at increased risk for meningococcal disease (see below) **SHOULD ONLY RECEIVE** age-appropriate doses of MENVEO® or MENACTRA® as described below and in the Table below on the “Recommended Vaccination Schedule and Intervals.”
- For children aged 2 through 18 months with anatomic or functional asplenia (including sickle cell disease), administer a 4-dose infant series of **MENVEO®** at 2, 4, 6, and 12 through 15 months of age, with at least 8 weeks between doses.

- For children aged 2 through 18 months with persistent complement component deficiency, administer a 4-dose infant series of **MENVEO®** at 2, 4, 6, and 12 through 15 months with at least 8 weeks between doses.

- For children aged 7 through 23 months with persistent complement component deficiency who have not initiated vaccination, two options exist depending on age and vaccine brand:
  - For children who initiate vaccination with **MENVEO®** at 7 through 23 months of age, a 2-dose series should be administered with the second dose after 12 months of age and at least 3 months after the first dose.
  - For children who initiate vaccination with **MENACTRA®** at 9 through 23 months of age, a 2-dose series of **MENACTRA®** should be administered at least 3 months apart.

- In children aged 9 through 23 months, **MENACTRA®** is given as a 2-dose primary series with 12 weeks between doses.

- For children aged 19 through 23 months who have not completed a series of **MENVEO®**, administer two primary doses of **MENVEO®** at least 3 months apart.

- For children aged 19 through 23 months with persistent complement component deficiency who have not received a complete series of **MENACTRA®**, administer 2 primary doses of **MENACTRA®** at least 8 weeks apart.

- For children aged 24 months and older with persistent complement component deficiency or anatomic or functional asplenia (including sickle cell disease), or HIV infection who have not received a complete series of **MENVEO®** or **MENACTRA®**, administer 2 primary doses of either **MENACTRA®** or **MENVEO®** at least 2 months apart.

- If **MENACTRA®** is administered to a child with anatomic or functional asplenia (including sickle cell disease) or HIV infection, do not administer **MENACTRA®** until 2 years of age and at least 4 weeks after the completion of all PCV13 doses. **MENVEO®** may be given at any time before or after PCV13.

- All persons aged 2 years through 10 years at increased risk for meningococcal disease (see below) should preferably receive either **MENACTRA®** (approved for ages 9 months through 55 years) or **MENVEO®** (approved for ages 2 months through 55 years). All persons aged 2 through 55 years with persistent complement component deficiency (C5 to C9, properdin, factor H, or factor D) and anatomic or functional asplenia (including sickle cell disease), or human immunodeficiency virus (HIV) infection should receive a 2-dose primary series administered two months apart. Both **MENACTRA®** and **MENVEO®** are approved for this age group.

- HIV infection is an indication for routine vaccination with **MENACTRA®** or **MENVEO®**. Persons with HIV infection who are recommended routinely to receive vaccine (i.e., persons aged ≥9 months at increased risk for meningococcal disease and all persons aged 11 through 18 years) should receive a 2-dose primary series, administered 8-12 weeks apart, because evidence suggests that persons with HIV do not respond optimally to a single dose.

**NOTE:**

- All persons aged 9 through 23 months of age at increased risk for invasive meningococcal disease (see below) **SHOULD ONLY RECEIVE** **MENACTRA®** or **MENVEO®** for active immunization against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and
W-135. In children aged 9 through 23 months, MENACTRA® or MENVEO® is given as a 2-dose series three months apart. MENACTRA® and MENVEO® are administered intramuscularly.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Vaccine</th>
<th>Routine Recommendations</th>
<th>Dosing Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mos through 10 years</td>
<td>MenACWY (MENVEO®, Novartis)</td>
<td>High-risk only</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Age 2 through 6 months: 4 doses at 2, 4, 6, and 12 months</td>
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<td>• Age 7 through 23 months: 2 doses should be given with the second dose given in the second year of life</td>
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<td>• Age 2 through 10 years: 1 or 2 doses</td>
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<td><strong>Booster</strong> (for persons who remain at risk³):</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• 1st booster 3 years after primary series for children who received primary series prior to age &lt;7 years, then every 5 years</td>
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<td>• Every 5 years for children who received primary series after 7th birthday</td>
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<td></td>
<td></td>
<td></td>
<td><strong>Primary:</strong></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Age 9 through 23 months: 2 dose series with 12 weeks between doses</td>
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<tr>
<td></td>
<td></td>
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<td>• Age 2 through 10 years: 1 or 2 doses</td>
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<td></td>
<td>• Every 5 years for children who received primary series after 7th birthday</td>
</tr>
</tbody>
</table>

### **Recommended Vaccination Schedule and Intervals**


<table>
<thead>
<tr>
<th>Age Group</th>
<th>Vaccine</th>
<th>Routine Recommendations</th>
<th>Dosing Schedule</th>
</tr>
</thead>
</table>
| 11 through 18 years | MenACWY (MENVEO® or MENACTRA®) | Children aged 11 through 18 years | **Adolescents:**  
**Primary:**  
- Age 11 through 12 years  
  with booster dose at age 16 years  
**Booster** (for persons who remain at risk³):  
- A booster dose is not recommended  
  if the first dose is given on or after  
  the child’s 16th birthday  
Adolescents with complement component deficiency, or functional or anatomic asplenia; HIV infection:  
- 2 doses, 8 through 12 weeks apart  
Booster for adolescents who remain at increased risk (complement component deficiency, functional or anatomic asplenia, HIV infection, traveling or part of a meningococcal outbreak more than 5 years after the prior dose):  
- 1st booster 5 years after primary  
- Additional boosters every 5 years |

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³ For children with complement component deficiency, functional or anatomic asplenia, HIV infection, part of a community or organizational outbreak, or traveling internationally to a region with hyperendemic or endemic meningococcal disease.

* For children with complement component deficiency, functional or anatomic asplenia, HIV infection, part of a community or organizational outbreak, or traveling internationally to a region with hyperendemic or endemic meningococcal disease. For infants receiving the vaccine prior to travel, the two doses may be administered as early as 8 weeks apart. Infants with functional or anatomic asplenia or HIV infection should wait until 2 years of age to prevent immune interference with PCV13.

§ For children with complement component deficiency, functional or anatomic asplenia, part of a community or organizational outbreak, MENACTRA® or MENVEO® should be used as booster doses for children.

**Note:** Use of brand names is not meant to preclude the use of other meningococcal vaccines where appropriate.
Vaccination of persons with high-risk conditions and other persons at increased risk of disease:

- Children with anatomic or functional asplenia (including sickle cell disease) or HIV infection:
  1. For children younger than 19 months of age, administer a 4-dose infant series of MENVEO® at 2, 4, 6, and 12 through 15 months of age.
  2. For children aged 19 through 23 months who have not completed a series of MENVEO®, administer two primary doses of MENVEO® at least three months apart.
  3. For children aged 24 months and older who have not received a complete series of MENVEO® or MENACTRA®, administer two primary doses of either MENACTRA® or MENVEO® at least 2 months apart. If MENACTRA® is administered to a child with asplenia (including sickle cell disease), do not administer MENACTRA® until 2 years of age and at least 4 weeks after the completion of all PCV13 doses.

- Children with persistent complement component deficiencies: (C3, C5-9, Properdin, Factor D, and Factor H)
  1. For children younger than 19 months of age, administer a 4-dose infant series of MENVEO® at 2, 4, 6, and 12 through 15 months of age.
  2. For children 7 through 23 months who have not initiated vaccination, two options exist depending on age and vaccine brand:
     a. For children who initiate vaccination with MENVEO® at 7 months through 23 months of age, a 2-dose series should be administered with the second dose after 12 months of age and at least 3 months after the first dose.
     b. For children who initiate vaccination with MENACTRA® at 9 months through 23 months of age, a 2-dose series of MENACTRA® should be administered at least 3 months apart.
     c. For children aged 24 months and older who have not received a complete series of MENVEO® or MENACTRA®, administer two primary doses of either MENACTRA® or MENVEO® at least 2 months apart.

- Adults aged 19 years through 55 years with anatomic or functional asplenia (including sickle cell disease) or HIV infection: Administer a 2-dose primary series of MENACTRA® or MENVEO® with doses spaced 8–12 weeks apart.

- Adults aged 19 years through 55 years with persistent complement component deficiencies (C3, C5-9, Properdin, Factor D, and Factor H): Administer a 2-dose primary series of MENACTRA® or MENVEO® with doses spaced 8–12 weeks apart.

- Adults aged 56 years and older with anatomic or functional asplenia (including sickle cell disease), HIV infection, or with persistent complement component deficiencies (C3, C5-9, Properdin, Factor D, and Factor H), see page 1 of this protocol.

Catch-up recommendations for persons with high-risk conditions:

- For children who initiate vaccination with MENVEO® at 7 through 9 months of age, a 2-dose series should be administered with the second dose after 12 months of age and at least 3 months after the first dose.
Persons at increased risk for meningococcal disease include:
- College freshmen who live in dormitories
- Persons with HIV infection
- Persons who travel to or reside in countries where meningococcal disease is hyperendemic, such as sub-Saharan Africa, or epidemic, particularly if contact with the local population will be prolonged. Administer an age-appropriate formulation and series of MENACTRA® or MENVEO® for protection against serogroups A and W meningococcal disease. Prior receipt of MENHIBRIX® is not sufficient for children traveling to the meningitis belt or the Hajj because it does not contain serogroups A or W. Vaccination in the 3 years before the date of travel is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj.
- Persons with anatomic or functional asplenia (including sickle cell disease)
- Persons with persistent complement component deficiencies (e.g., C3, C5-9, properdin, Factor D, and Factor H)
- Microbiologists routinely exposed to isolates of Neisseria meningitidis use MENACTRA® or MENVEO®. A booster dose should be administered every 5 years if exposure is ongoing.
- Military recruits
- Children (aged 6 weeks and older) and adults who are part of a community outbreak of invasive meningococcal disease caused by a vaccine-preventable serogroup, administer or complete an age-and formulation-appropriate series of MENACTRA® or MENVEO®.

Revaccination:
- Persons previously vaccinated with MENACTRA® or MENVEO®, who are at prolonged increased risk for meningococcal disease (see below) should be revaccinated, preferably with either MENACTRA® or MENVEO®.
  o Persons who previously were vaccinated with the 2-dose primary series at ages 9 months through 24 months and are at prolonged increased risk should be revaccinated 3 years after their previous meningococcal vaccine.
  o Persons who previously were vaccinated at ages 2 through 6 years and are at prolonged increased risk should be revaccinated 3 years after their previous meningococcal vaccine.
  o Persons who previously were vaccinated at 7 years of age or older and are at prolonged increased risk should be revaccinated 5 years after their previous meningococcal vaccine.
  o Persons who remain in one of the increased risk groups indefinitely should continue to be revaccinated at 5-year intervals.
- College freshmen living in dormitories who were not previously vaccinated with MENACTRA® or MENVEO®, five or more years ago are recommended to be revaccinated with either MENACTRA® or MENVEO®.
  
  International travelers should receive a booster dose of MENACTRA® or MENVEO® if the last dose was administered five or more years previously. Vaccination in the three years before the date of travel is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj.

NOTE: Revaccination is not mentioned in the MENVEO® Package Insert. Kentucky Immunization Program staff inquired with the CDC National Immunization Program staff as to whether MENVEO® can be used for revaccination. The relevant part of their reply of Jun 09, 2010 was “. . . our meningococcal group agrees that MENVEO® can be used for any indication within its licensed age range, including revaccination.”
Persons at prolonged increased risk for meningococcal disease who should be revaccinated include:

- Persons with increased susceptibility such as persistent complement component deficiencies (e.g., C3, properdin, Factor D, and late complement component deficiencies)
- Persons with anatomic or functional asplenia
- Persons with HIV infection
- Persons who have prolonged exposure (e.g., microbiologists routinely working with *Neisseria meningitidis*, or travelers to or residents of countries where meningococcal disease is hyperendemic or epidemic)

**Outbreak Control**

- MENACTRA® or MENVEO®, are recommended for use in the control of meningococcal outbreaks caused by vaccine-preventable serogroups (A, C, Y, and W-135), as an adjunct to chemoprophylaxis.
  - **MENVEO®** may be used for infants and children aged 2 months through 23 months.
  - **MENACTRA®** may be used for infants and children aged 9 months through 23 months.
  - **MENACTRA®** or **MENVEO®** is preferred for use among children adolescents, and adults aged 2 years through 55 years for control of meningococcal disease outbreaks.
  - For persons now aged 56 years and older who were vaccinated previously with MENACTRA® or MENVEO® and are recommended for revaccination, MENACTRA® or MENVEO® is preferred.

**Preparation for Administration of MENVEO®** (See the Package Insert)

- **MENVEO®** is supplied in two vials that must be combined prior to administration. Vaccine must be reconstituted by using a graduated syringe to withdraw the entire contents of the vial of MenCYW-135 liquid conjugate component and injecting it into the MenA lyophilized conjugate component vial. Gently invert or swirl the reconstituted vial until vaccine is dissolved, and then withdraw 0.5 mL of reconstituted product.
- Following reconstitution, the vaccine is a clear, colorless solution, free from visible foreign particles.
- Please note that it is normal for a small amount of liquid to remain in the vial following withdrawal of the dose.
- Do not mix MENVEO® or any of its components with any other vaccine or diluent in the same syringe or vial.

**Dosage and Route** (Always check the package insert prior to administration.)

- Administer 0.5 mL intramuscularly (IM). Consult “Epidemiology and Prevention of Vaccine-Preventable Diseases” (The Pink Book), Appendix D, for information about appropriate needle sizes, needle lengths, and sites for administering vaccines.
- Do not administer this product intravenously, subcutaneously, or intradermally.

**Anatomical Site**

- Intramuscularly (IM), preferably into the deltoid muscle (upper arm).
Precautions

- The safety and effectiveness in pregnant women has not been established therefore MENACTRA® or MENVEO® should only be given to a pregnant woman if clearly needed.
- It is not known whether this drug is excreted in human milk. Use caution in nursing mothers.
- The safety and effectiveness in adults 65 years of age and older has not been established.

Contraindications

- Individuals with anaphylactic reaction to previous dose of MENVEO®, diphtheria toxoid, or meningococcal-containing vaccine.
- Contraindications and Precautions can be found in the package inserts available at: http://www.immunize.org/fda/#mena.

Warnings:

- MENVEO® should not be administered to persons with any bleeding disorder, or persons receiving anticoagulant therapy, unless the potential benefit outweighs the risk of administration.
- Syncope sometimes associated with temporary tonic-clonic movements and other seizure-like activity. Observation for 15 minutes after administration is recommended.
- Safety and effectiveness has not been established in pregnant women.
- Immunocompromised individuals, including those receiving immunosuppressive therapy, may not receive the expected immune response.

Adverse Events

- See the product’s package insert.

Storage and Handling

- Store in refrigerator at 36°F – 46°F (2°C – 8°C).
- Vaccine must be maintained at 36°F to 46°F (2°C – 8°C) during transport.
- DO NOT FREEZE. Product that has been frozen or previously frozen should not be used.
- Protect from light.
- Do not use after the expiration date. The reconstituted vaccine should be used immediately but may be held at or below 77°F (25°C) for up to 8 hours.

Other Important Notes

- The duration of protection following immunization is not known.
- MENVEO® does not contain thimerosal or other preservatives and does not contain an adjuvant.
- The stopper to the MENVEO® vial is synthetic rubber and does not contain latex.
References:

MMWR “Recommendation for Use of Meningococcal Conjugate Vaccines in HIV-Infected Persons”, Advisory Committee on Immunization Practices (ACIP) (November 4, 2016)
http://www.cdc.gov/mmwr/volumes/65/wr/mm6543a3.htm

VFC Resolution – 10/16-3. Vaccines to Prevent Meningococcal Disease

Immunization Action Coalition (IAC), Meningococcal Vaccine Recommendations by Age and Risk Factor for Serogroups A, C, W, or Y Protection (12/16)

MMWR “Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP) (March 22, 2013)
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm

Footnotes to the “Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2018”: https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

Footnotes to the “Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States, 2018”: http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

VFC Resolution – 10/2016 Meningococcal
http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.htm

MENVEO® Package Insert (revised 1/2017):
https://gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Menveo/pdf/MENVEO.PDF
Protocol for Meningococcal Group B Vaccine (MenB)  
BEXSERO®

Precautions and Contraindications

Screen all patients for precautions and contraindications to immunizations.

Vaccine Information Statements

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at http://www.immunize.org/vis.

FDA Approved Indications and Usage (See Package Insert, current version dated 09/2016)

- BEXSERO® is a vaccine indicated for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroup B.
- BEXSERO® is approved for use in persons aged 10 through 25 years.

ACIP Recommended Use of MenB Vaccines (Note that some of these recommendations differ from the package inserts)

- High-Risk (See “Eligible Groups” on page 3):
  - BEXSERO® is recommended routinely for use in persons aged 10 through 25 years at increased risk for meningococcal disease attributable to serogroup B.
  - BEXSERO® is recommended routinely for use in persons aged 26 years or older at increased risk for meningococcal disease attributable to serogroup B.

- Other than High-Risk (See “Eligible Groups” on page 3):
  - BEXSERO® may be administered to adolescents aged 16 through 18 years to provide short-term protection against most strains of serogroup B meningococcal disease.
  - BEXSERO® may be administered to young adults aged 19 through 23 years to provide short-term protection against most strains of serogroup B meningococcal disease.

- No preference is stated for the use of either of the two currently licensed MenB vaccines, BEXSERO® (MenB-4C) or TRUMENBA® (MenB-FHbp).

- Because the two MenB vaccines are antigenically different, the same vaccine product must be used for all doses.

- BEXSERO® is a 2-dose series and TRUMENBA® is either a 2-dose or a 3-dose series. The 2-dose TRUMENBA series can be used for routine vaccination of healthy persons (i.e., other than high-risk) aged 16 through 23 years.
### ACIP Recommended Schedule

<table>
<thead>
<tr>
<th>Age Group</th>
<th>MenB Vaccine</th>
<th>Routine Recommendations</th>
<th>Dosing Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 through 18 Years</td>
<td><strong>BEXSERO</strong>, Novartis</td>
<td>High-Risk only</td>
<td>Give two doses, at least one month apart (0 and 1-6 month schedule)</td>
</tr>
<tr>
<td>19 Years or Older</td>
<td><strong>BEXSERO</strong>, Novartis</td>
<td>High-Risk only</td>
<td>Give two doses, at least one month apart (0 and 1-6 month schedule)</td>
</tr>
<tr>
<td>10 through 18 Years</td>
<td><strong>TRUMENBA</strong>, Pfizer</td>
<td>High-Risk only</td>
<td>Give three doses (0, 2, and 6 month schedule)</td>
</tr>
<tr>
<td>19 Years or Older</td>
<td><strong>TRUMENBA</strong>, Pfizer</td>
<td>High-Risk only</td>
<td>Give three doses (0, 2, and 6 month schedule)</td>
</tr>
</tbody>
</table>

Note: "Both MenB vaccines are approved for use in persons aged 10 through 25 years; however, because there are no theoretical differences in safety for persons aged >25 years compared with those aged 10 through 25 years, ACIP supported routine use of MenB vaccines in persons aged ≥ 10 years who are at increased risk for serogroup B meningococcal disease."

Note: Use of MenB vaccines in persons aged 26 years or older would be an off-label use.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>MenB Vaccine</th>
<th>Permissive Recommendations</th>
<th>Dosing Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 through 18 Years</td>
<td><strong>BEXSERO</strong>, Novartis</td>
<td>Other than High-Risk</td>
<td>Give two doses, at least one month apart (0 and 1-6 month schedule)</td>
</tr>
<tr>
<td>19 through 23 Years</td>
<td><strong>BEXSERO</strong>, Novartis</td>
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<td>19 through 23 Years</td>
<td><strong>TRUMENBA</strong>, Pfizer</td>
<td>Other than High-Risk</td>
<td>Give two doses (0, and 6 month schedule)</td>
</tr>
</tbody>
</table>

Note: ACIP recommended in October 2015 that a MenB vaccine series may be administered to adolescents and young adults aged 16 through 23 years to provide short-term protection against most strains of serogroup B
meningococcal disease. The preferred age for MenB vaccination is 16 through 18 years, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm?s_cid=mm6441a3_w#tab1

Eligible Groups

- **High-Risk**: Children and adults aged 10 years and older, at increased risk for meningococcal disease attributable to serogroup B, including:
  - Persons with persistent complement component deficiencies (including inherited or chronic deficiencies in C3, C5-C9, properdin, factor H, or factor D or taking eculizumab [Soliris®]).
  - Persons with anatomic or functional asplenia, including sickle cell disease
  - Microbiologists who routinely work with Neisseria meningitidis isolates in a laboratory.
  - Persons identified to be at increased risk because of a meningococcal disease outbreak attributable to serogroup B.
- **Other than High-Risk**: Adolescents and young adults aged 16 through 23 years without high-risk conditions may be vaccinated, with a preferred age of vaccination at 16 through 18 years.

**Dosage and Route** (Always check the package insert prior to administration.)

- Administer two doses (0.5 mL each) of BEXSERO® at least 1 month apart on a 0 and 1-6 month schedule.
- For intramuscular injection in the deltoid muscle of the upper arm only.
- A dose of MenB vaccine and a dose of MenACWY vaccine may be administered at the same visit, but at a different anatomic site, or at any time before or after the other.

**Contraindications**

- Hypersensitivity, including severe allergic reaction, to any component of the vaccine or after a previous dose of BEXSERO®.

**Warnings and Precautions:**

- The tip caps of the pre-filled syringes contain natural rubber latex, which may cause allergic reactions in latex sensitive individuals.
- Syncope (fainting) can occur in association with administration of BEXSERO®.
- BEXSERO® may not protect all vaccine recipients.
- BEXSERO® may not provide protection against all meningococcal serogroup B strains.
- Individuals with altered immunocompetence may have reduced immune response to BEXSERO®.

**Adverse Events:**

- See product’s package insert.
Use in Specific Populations

- **BEXERO®** should be used during pregnancy only if clearly needed. A Pregnancy registry is available for women who receive **BEXERO®** during pregnancy. Contact Novartis Vaccines and Diagnostics at 1-877-683-4732.
- Caution should be exercised when **BEXERO®** is administered to a nursing woman.
- Safety and effectiveness of **BEXERO®** have not been established in children younger than 10 years of age.
- Safety and effectiveness of **BEXERO®** have not been established in adults older than 65 years of age.
- **BEXERO®** is not currently recommended for persons who travel to or reside in countries where meningococcal disease is hyperendemic or epidemic because the risk for meningococcal disease in these countries generally is not caused by serogroup B.

**Storage and Handling:**

- Do not freeze. Discard if the vaccine has been frozen.
- Store refrigerated, at 36°F to 46°F (2°C to 8°C).
- Protect from light
- Do not use after the expiration date.

**Patient Counseling Information:**

Prior to administration of this vaccine, the healthcare professional should inform the individual, parent, guardian, or other responsible adult about:

- The importance of completing the 2-dose immunization series with the same MenB vaccine brand.
- Report any suspected adverse reactions to a healthcare professional.
- Individuals with altered immunocompetence may have reduced immune responses to **BEXERO®**.
- Register women who receive **BEXERO®** while pregnant in the pregnancy registry by calling 1-877-683-4732.

**References:**

Advisory Committee on Immunization Practices, Vaccines for Children Program, Vaccine to Prevent Meningococcal Disease. Resolution No. 10/16-3:


[http://www.immunize.org](http://www.immunize.org)


Protocol for Meningococcal Group B Vaccine (MenB)

TRUMENBA®

Precautions and Contraindications

Screen all patients for precautions and contraindications to immunizations

Vaccine Information Statements

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at http://www.immunize.org/vis.

FDA Approved Indications and Usage (See Package Insert, current version dated 04/2016)

- **TRUMENBA®** is indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B.
- **TRUMENBA®** is approved for use in persons aged 10 through 25 years.

ACIP Recommended Use of MenB Vaccines (Note that some of these recommendations differ from the package inserts)

- **High-Risk (See “Eligible Groups” on page 3)**
  - **TRUMENBA®** is recommended routinely for use in persons aged 10 through 25 years at increased risk for meningococcal disease attributable to serogroup B.
  - **TRUMENBA®** is recommended routinely for use in persons aged 26 years or older at increased risk for meningococcal disease attributable to serogroup B.

- **Other than High-Risk (See “Eligible Groups” on page 3)**
  - **TRUMENBA®** may be administered to adolescents aged 16 through 18 years to provide short-term protection against most strains of serogroup B meningococcal disease.
  - **TRUMENBA®** may be administered to young adults aged 19 through 23 years to provide short-term protection against most strains of serogroup B meningococcal disease.

- No preference is stated for the use of either of the two currently licensed MenB vaccines, **TRUMENBA®** (MenB-FHbp) or BEXSERO® (MenB-4C).
• Because the two MenB vaccines are antigenically different, the same vaccine product must be used for all doses.

• TRUMENBA® may be a two-dose or three-dose series and BEXSERO® is a two-dose series. The 2-dose TRUMENBA® series can be used for routine vaccination of healthy persons (i.e., other than high-risk) aged 16 through 23 years.

ACIP Recommended Schedule

<table>
<thead>
<tr>
<th>Age Group</th>
<th>MenB Vaccine</th>
<th>Routine Recommendations</th>
<th>Dosing Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 through 18 Years</td>
<td>BEXSERO®, Novartis</td>
<td>High-Risk only</td>
<td>Give two doses, at least one month apart (0 and 1-6 month schedule)</td>
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<td>BEXSERO®, Novartis</td>
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<td>10 through 18 Years</td>
<td>TRUMENBA®, Pfizer</td>
<td>High-Risk only</td>
<td>Give three doses (0, 1-2, and 6 month schedule)</td>
</tr>
<tr>
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<td>TRUMENBA®, Pfizer</td>
<td>High-Risk only</td>
<td>Give three doses (0, 1-2, and 6 month schedule)</td>
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Note: "Both MenB vaccines are approved for use in persons aged 10 through 25 years; however, because there are no theoretical differences in safety for persons aged >25 years compared with those aged 10 through 25 years, ACIP supported routine use of MenB vaccines in persons aged ≥ 10 years who are at increased risk for serogroup B meningococcal disease."

Note: Use of MenB vaccines in persons aged 26 years or older would be an off-label use.

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Note: ACIP recommended in October 2015 that a MenB vaccine series may be administered to adolescents and young adults aged 16 through 23 years to provide short-term protection against most strains of serogroup B meningococcal disease. The preferred age for MenB vaccination is 16 through 18 years, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm?s_cid=mm6441a3_w#tab1

**Eligible Groups**

- **High-Risk**: Children and adults aged 10 years or older, at increased risk for meningococcal disease attributable to serogroup B, including:
  - Persons with persistent complement component deficiencies (including inherited or chronic deficiencies in C3, C5-C9, properdin, factor H, or factor D or taking eculizumab [Soliris™])
  - Persons with anatomic or functional asplenia, including sickle cell disease
  - Microbiologists who routinely work with *Neisseria meningitidis* isolates in a laboratory
  - Persons identified to be at increased risk because of a meningococcal disease outbreak attributable to serogroup B

- **Other than High-Risk**: Adolescents and young adults aged 16 through 23 years without high-risk conditions may be vaccinated, with a preferred age of vaccination at 16 through 18 years.

**Dosage and Route** (Always check the package insert prior to administration)

- Administer either two doses (0.5 mL each) of TRUMENBA™ at a 0 and 6-month schedule or three doses (0.5 mL each) of TRUMENBA™ at a 0-, 1-2-, and 6-month schedule.
- For intramuscular injection in the deltoid muscle of the upper arm only.
- A dose of MenB vaccine and a dose of MenACWY vaccine may be administered at the same visit, but at a different anatomic site, or at any time before or after the other.

**Contraindications**

- Severe allergic reaction after a previous dose of TRUMENBA™.

**Warnings and Precautions:**

- Epinephrine and other appropriate agents used to manage immediate allergic reactions must be immediately available should an acute anaphylactic reaction occur following administration of TRUMENBA™
- Individuals with altered immunocompetence may have reduced immune response to TRUMENBA™
- LATEX SENSITIVE INDIVIDUALS - The tip cap and rubber plunger of the prefilled syringe ARE NOT MADE with natural rubber latex.

**Adverse Events:**

- See product’s package insert
Use in Specific Populations

- **TRUMENBA**™ should be used during pregnancy only if clearly needed.
- Caution should be exercised when **TRUMENBA**™ is administered to a nursing woman.
- Safety and effectiveness of **TRUMENBA**™ have not been established in children younger than 10 years of age.
- Safety and effectiveness of **TRUMENBA**™ in adults older than 65 years of age have not been established.
- **TRUMENBA**™ is not currently recommended for persons who travel to or reside in countries where meningococcal disease is hyperendemic or epidemic because the risk for meningococcal disease in these countries generally is not caused by serogroup B.

Storage and Handling:

- Do not freeze. Discard if the vaccine has been frozen.
- Store refrigerated, at 36°F to 46°F (2°C to 8°C).
- Store syringes in the refrigerator horizontally (lying flat on the shelf) to minimize the re-dispersion time.
- Do not use after the expiration date.
- Do not use if particulate matter or discoloration is found in the syringe.
- Do not mix **TRUMENBA**™ with any other vaccine in the same syringe.

Patient Counseling Information:

Prior to administration of this vaccine, the healthcare professional should inform the individual, parent, guardian, or other responsible adult of the following:

- The importance of completing the 3-dose immunization series with the same MenB vaccine brand.
- Report any suspected adverse reactions to a healthcare professional.
- Individuals with altered immunocompetence may have reduced immune responses to **TRUMENBA**™.
References:

Advisory Committee on Immunization Practices, Vaccines for Children Program, Vaccines to Prevent Meningococcal Disease. Resolution No. 10/16-2:

Immunization Action Coalition (IAC): Needle Tips; ACIP Votes to Update Recommendations for HPV, Tdap, MenB and HepB Vaccines; Vol. 26-Number 4; December 2016.
http://www.immunize.org


Vaccine Information Sheet: http://www.immunize.org/vis/ meningococcal_b.pdf

TRUMENBA® Package Insert (Revised 4/2016):
Protocol for Administration of the
13-Valent Pneumococcal Conjugate Vaccine (PCV13)

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunization.

Indications and Usage

The 13-valent pneumococcal conjugate vaccine (PCV13) is indicated for active immunization for the prevention of invasive pneumococcal disease [IPD] caused by the 13 serotypes covered by the vaccine and is indicated for prevention of otitis media caused by serotypes in the original 7-valent pneumococcal conjugate vaccine (PCV7). PCV13 replaces PCV7 and provides protection against 13 pneumococcal serotypes (i.e., 6 more serotypes than PCV7).

PCV13 is recommended to be administered before PPSV23 [the 23-valent pneumococcal vaccine] among persons for whom both vaccines are recommended, [URLs]

Recommended Schedule

The 13-valent pneumococcal conjugate vaccine (PCV13) is recommended by the Advisory Committee on Immunization Practices (ACIP) for:

- Routine vaccination of all children aged 2 through 59 months with PCV13
  - Administer a 4-dose series of PCV13 vaccine at ages 2, 4 and 6 months and at age 12 through 15 months (Table 1).
  - Administer fewer doses to unvaccinated children, aged 7 months or older (Table 2).
  - Complete the vaccine series for children who have received one or more doses of 7-valent PCV (PCV7) vaccine. For children aged 12 through 59 months who have received an age-appropriate series PCV7, administer a single supplemental dose of PCV13 (Table 2).
- Routine use of PCV13 is not recommended for healthy children aged 5 years and older
- Routine vaccination of all persons aged 65 years and older who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown
  - Administer a dose of PCV13 first, followed in series by a dose of PPSV23. See Box 1 and Table 3 below. The two vaccines should not be co-administered.
    - The dose of PPSV23 should be given at least 1 year after a dose of PCV13 for immunocompetent adults aged 65 years and older. If a dose of PPSV23 is inadvertently given earlier than the recommended interval, the dose need not be repeated.
• The interval between doses of PCV13 and PPSV23 should be 8 weeks or greater for adults aged 65 years and older with immunocompromising conditions, functional or anatomic asplenia, cerebrospinal fluid leaks, or cochlear implants.

• Routine use of PCV13 among adults aged 65 years and older who had previous vaccination with PPSV23 at age 65 years and older.
  o Adults aged 65 years and older who have previously received one or more doses of PPSV23 also should receive a dose of PCV13 if they have not yet received it.
  o A dose of PCV13 should be given at least 1 year after receipt of the most recent dose of PPSV23.

• Routine use of PCV13 among adults aged 65 years and older who had previous vaccination with PPSV23 before age 65 years who are now aged 65 years and older.
  o Adults aged 65 years and older who have previously received one or more doses of PPSV23 also should receive a dose of PCV13 if they have not yet received it. A dose of PCV13 should be given at least 1 year after receipt of the most recent dose of PPSV23.
  o For those for whom an additional dose of PPSV23 is indicated, this subsequent dose of PPSV23 should be given at least 1 year after PCV13 and at least 5 years after the most recent dose of PPSV23.

• Vaccination of children aged 60 through 71 months with underlying medical conditions that increase their risk of pneumococcal disease or complications** (See Table 4 below)

• Routine vaccination of children aged 6 through 18 years who are at increased risk for invasive pneumococcal disease because of anatomic or functional asplenia, including sickle cell disease (SCD), HIV-infection or other immunocompromising condition, cochlear implant, or cerebrospinal fluid leak who have not previously received PCV7.
  o This recommendation [by ACIP] reflects a policy change from permissive and off-label recommendation of PCV13 for children aged 6 to 18 years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks or cochlear implants to a category A recommendation [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6225a3.htm].
  o **PPSV23-naïve children.** ACIP recommends that children aged 6–18 years who have not received PCV13 and are at increased risk for IPD because of anatomic or functional asplenia (including SCD), HIV infection, cochlear implant, CSF leak, or other immunocompromising conditions receive a single PCV13 dose first, followed ≥8 weeks later by a dose of PPSV23.
    ▪ A second PPSV23 dose is recommended 5 years after the first PPSV23 dose for children with anatomic or functional asplenia (including SCD), HIV infection, or other immunocompromising conditions
  o **Previous vaccination with PPSV23.** Children aged 6–18 years who have not received PCV13; are at increased risk for IPD because of anatomic or functional asplenia, including SCD, HIV infection, CSF leaks, cochlear implants, or other immunocompromising conditions; and who previously received ≥1 doses of PPSV23 should be given a single PCV13 dose ≥8 weeks after the last PPSV23 dose, even if they have received PCV7.

• If a second PPSV23 dose is indicated, it should be given ≥5 years after the first PPSV23 dose. These children should not receive more than two doses of PPSV23 before age 65 years.

• Vaccination of adults aged 19 years and older with immunocompromising conditions (including chronic renal failure and nephrotic syndrome), functional or anatomic asplenia, cerebrospinal fluid (CSF) leaks, or cochlear implants.** PCV13 should be administered to eligible adults in addition to PPSV23.
  o **Recommendation for the use of PCV13 among pneumococcal vaccine naïve individuals:**
    ▪ Adults aged 19 years and older with immunocompromising conditions (including chronic renal failure and nephrotic syndrome), functional or anatomic asplenia, CSF leaks, or cochlear implants, and who have not previously received PCV13 or PPSV23, should receive a single dose of PCV13 first followed by a dose of PPSV23 at least 8 weeks later (See Table 5).
Subsequent doses of PPSV23 should follow current PPSV23 recommendations for these adults at high risk. Specifically, a second PPSV23 dose is recommended 5 years after the first PPSV23 dose for persons aged 19 through 64 years with functional or anatomic asplenia and for persons with immunocompromising conditions. Persons with CSF leaks or cochlear implants should receive no additional doses of PPSV23 until age 65 years.

Additionally, those who received 1 or 2 doses of PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years or later if at least 5 years have elapsed since their previous PPSV23 dose.

- Recommendations for the use of PCV13 among adults who have previously been vaccinated with PPSV23:
  - Adults aged 19 years and older with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, who previously have received one or more doses of PPSV23 should be given a dose of PCV13 one or more years after the last PPSV23 dose was received. For those who require additional doses of PPSV23 (see Table 5), the first such dose should be given no sooner than 8 weeks after PCV13 and at least 5 years after the most recent dose of PPSV23.

[**Note that these ACIP recommendations differ from those in the PCV13 Package Insert**]

<table>
<thead>
<tr>
<th>TABLE 1. PCV13 Vaccine Schedule for Children Aged 2 through 59 months, unless a contraindication</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommended Age</strong></td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>2 months</td>
</tr>
<tr>
<td>4 months</td>
</tr>
<tr>
<td>6 months</td>
</tr>
<tr>
<td>12 through 15 months</td>
</tr>
</tbody>
</table>

¹The recommended interval between doses is eight weeks, but may be as short as four weeks.
<table>
<thead>
<tr>
<th>Age</th>
<th>Vaccination history: Total number of PCV7 and/or PCV13 doses received previously</th>
<th>Recommended PCV13 Regimen¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 months through 6 months</td>
<td>0 doses</td>
<td>3 doses, 8 weeks apart; fourth (booster) dose at age 12 through 15 mos</td>
</tr>
<tr>
<td></td>
<td>1 dose</td>
<td>2 doses, 8 weeks apart; fourth dose at age 12 through 15 mos</td>
</tr>
<tr>
<td></td>
<td>2 doses</td>
<td>1 dose, 8 weeks after the most recent dose; fourth dose at age 12 through 15 mos</td>
</tr>
<tr>
<td>7 months through 11 months</td>
<td>0 doses</td>
<td>2 doses, 8 weeks apart; third dose at 12 through 15 mos</td>
</tr>
<tr>
<td></td>
<td>1 or 2 doses before age 7 mos</td>
<td>1 dose at age 7 through 11 mos, with a second dose at 12 through 15 mos (≥ 8 weeks later)</td>
</tr>
<tr>
<td>12 months through 23 months</td>
<td>0 doses</td>
<td>2 doses, ≥ 8 weeks apart with no booster dose of PCV13</td>
</tr>
<tr>
<td></td>
<td>1 dose before age 12 mos</td>
<td>2 doses, ≥ 8 weeks apart</td>
</tr>
<tr>
<td></td>
<td>1 dose at ≥12 mos</td>
<td>1 dose, ≥ 8 weeks after the most recent dose ²</td>
</tr>
<tr>
<td></td>
<td>2 or 3 doses before age 12 mos</td>
<td>1 dose, ≥ 8 weeks after the most recent dose ²</td>
</tr>
<tr>
<td></td>
<td>4 doses of PCV7 or other age-appropriate, complete PCV7 schedule</td>
<td>1 supplemental dose, ≥ 8 weeks after the most recent dose *</td>
</tr>
<tr>
<td>Healthy children 24 months through 59 months</td>
<td>Any incomplete schedule</td>
<td>1 dose, ≥ 8 weeks after the most recent dose ²</td>
</tr>
<tr>
<td></td>
<td>4 doses of PCV7 or other age-appropriate, complete PCV7 schedule</td>
<td>1 supplemental dose, ≥ 8 weeks after the most recent dose of PCV7 vaccine*</td>
</tr>
</tbody>
</table>

¹ Recommended PCV13 Regimen

**TABLE 2. Recommended schedules for administering doses of PCV13 among children who have not previously received PCV7 or PCV13 and those incompletely vaccinated with PCV7 or PCV13 for age and supplemental PCV13 immunization**


<table>
<thead>
<tr>
<th>Age</th>
<th>Vaccination history: total number of PCV7 and/or PCV13 doses received previously</th>
<th>Recommended PCV13 Regimen¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children 24 months through 71 months with underlying medical conditions as defined in Table 1 ²</td>
<td>Any incomplete schedule of &lt;2 doses</td>
<td>2 doses, one ≥ 8 weeks after the most recent dose and another dose ≥ 8 weeks later</td>
</tr>
<tr>
<td></td>
<td>Any incomplete schedule of 3 doses</td>
<td>1 dose, ≥ 8 weeks after the most recent dose</td>
</tr>
<tr>
<td></td>
<td>4 doses of PCV7 or other age-appropriate complete PCV7 schedule</td>
<td>1 supplemental dose, ≥ 8 weeks after the most recent dose*</td>
</tr>
<tr>
<td>Children 6 years through 18 years who are at increased risk for invasive pneumococcal disease as defined in footnote 4</td>
<td>Not previously vaccinated with PCV13</td>
<td>1 dose</td>
</tr>
</tbody>
</table>

**Footnotes:**

¹ Minimum interval between doses is 8 weeks except for children vaccinated at age <12 months, for whom the minimum interval between doses is 4 weeks. Minimum age for administration of the first dose is 6 weeks.

² No additional PCV13 doses are indicated for children 12 through 23 months of age who have received 2 or 3 doses of PCV7 before age 12 months and at least 1 dose of PCV13 at age 12 months or older.

³ For children with underlying medical conditions (See Table 4), PCV13 is indicated through 71 months of age.

⁴ Includes children with anatomic or functional asplenia, including sickle cell disease, HIV infection or other immunocompromising condition, cochlear implant or cerebrospinal fluid leak.

* A single supplemental dose of PCV13 is given at least 8 weeks after the last dose of PCV7 is recommended for all children 14 through 59 months of age who have received 4 doses of PCV7 or other age-appropriate, complete PCV7 schedule (fully vaccinated with PCV7). For children who have underlying medical conditions, a supplemental dose is recommended through 71 months of age.
BOX 1. Recommended intervals for sequential use of PCV13 and PPSV23 for immunocompetent adults aged ≥65 years — Advisory Committee on Immunization Practices, United States

Abbreviations: PCV13 = 13-valent pneumococcal conjugate vaccine; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.
<table>
<thead>
<tr>
<th>Risk group/Underlying medical condition</th>
<th>Intervals for PCV13–PPSV23 sequence, by age group</th>
<th>Intervals for PPSV23–PCV13 sequence, by age group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>24–71 months</td>
<td>6–18 years</td>
</tr>
<tr>
<td>No underlying chronic conditions</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Immunocompetent persons</td>
<td>≥8 weeks</td>
<td>NA</td>
</tr>
<tr>
<td>Chronic heart disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td></td>
<td></td>
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<tr>
<td>Alcoholism*</td>
<td></td>
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<tr>
<td>Chronic liver disease, cirrhosis*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cigarette smoking*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunocompetent persons</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
</tr>
<tr>
<td>Cerebrospinal fluid leak</td>
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<tr>
<td>Cochlear implant</td>
<td></td>
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<tr>
<td>Persons with functional or anatomic asplenia</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
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<tr>
<td>Sickle cell disease/other hemoglobinopathy</td>
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<tr>
<td>Congenital or acquired asplenia</td>
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### TABLE 3. Summary of recommended intervals, by risk and age groups, for persons with indications to receive PCV13 and PPSV23 sequence — Advisory Committee on Immunization Practices, United States, September 2015

<table>
<thead>
<tr>
<th>Risk group/Underlying medical condition</th>
<th>Intervals for PCV13–PPSV23 sequence, by age group</th>
<th>Intervals for PPSV23–PCV13 sequence, by age group</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>24–71 months 6–18 years 19–64 years ≥65 years</td>
<td>24–71 months 6–18 years 19–64 years ≥65 years</td>
</tr>
<tr>
<td>Immunocompromised persons</td>
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<td>Congenital or acquired immunodeficiency</td>
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<td>Human immunodeficiency virus infection</td>
<td>≥8 weeks</td>
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</tr>
<tr>
<td>Chronic renal failure</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
</tr>
<tr>
<td>Nephrotic syndrome</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
</tr>
<tr>
<td>Leukemia</td>
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<td>≥1 year</td>
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<td>Lymphoma</td>
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<td>Hodgkin disease</td>
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<tr>
<td>Generalized malignancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iatrogenic immunosuppression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solid organ transplant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple myeloma*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviation:** NA = not applicable, sequential use of PCV13 and PPSV23 is not recommended for these age and risk groups.

* Underlying medical conditions that are not included in the recommendations for children aged <6 years.
### TABLE 4. Underlying medical conditions that are indications for pneumococcal vaccination among children, by risk group --- ACIP, United States

[http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm)  

<table>
<thead>
<tr>
<th>Risk group</th>
<th>Condition</th>
</tr>
</thead>
</table>
| Immunocompetent persons           | Chronic heart disease*  
                                    | Chronic lung disease†  
                                    | Diabetes mellitus  
                                    | Cerebrospinal fluid leaks  
                                    | Cochlear implant          |
| Functional or anatomic asplenia   | Sickle cell disease and other hemoglobinopathies  
                                    | Congenital or acquired asplenia, or splenic dysfunction |
| Immunocompromised persons         | HIV infection  
                                    | Chronic renal failure and nephrotic syndrome  
                                    | Diseases associated with immunosuppressive chemotherapy or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; or solid organ transplantation  
                                    | Congenital immunodeficiency§ |

* Particularly cyanotic congenital heart disease and cardiac failure.  
† Including asthma if treated with high-dose oral corticosteroid therapy.  
§ Includes B- (humoral) or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, and C4 deficiency; and phagocytic disorders (excluding chronic granulomatous disease).
Table 5. Medical conditions or other indications for administration of 13-valent pneumococcal conjugate vaccine (PCV13), as well as indications for 23-valent pneumococcal polysaccharide vaccine (PPSV23) administration and revaccination for children aged 6-18 years, and adults aged 19 through 64 years.*  [http://www.cdc.gov/mmwr/pdf/wk/mm6225.pdf](http://www.cdc.gov/mmwr/pdf/wk/mm6225.pdf)

<table>
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<tr>
<th>Risk Group</th>
<th>Underlying Medical Condition</th>
<th>PCV13 Recommended</th>
<th>PPSV23 Recommended</th>
<th>Revaccination 5 years after first dose</th>
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<tr>
<td>Immunocompetent persons</td>
<td>Chronic heart disease †</td>
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<tr>
<td></td>
<td>Chronic lung disease §</td>
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<tr>
<td></td>
<td>Diabetes mellitus</td>
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<td>CSF leaks</td>
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<td></td>
<td>Cochlear implants</td>
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<td>Alcoholism</td>
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<td>Chronic liver disease, cirrhosis</td>
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<td>Cigarette smoking</td>
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<tr>
<td>Persons with functional or anatomic asplenia</td>
<td>Sickle cell disease/other hemoglobinopathies</td>
<td>X</td>
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<td>Congenital or acquired asplenia</td>
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<tr>
<td>Immunocompromised persons</td>
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<td>HIV infection</td>
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<td>Chronic renal failure</td>
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<td>X</td>
<td>X</td>
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<td>Nephrotic syndrome</td>
<td>X</td>
<td>X</td>
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<td>Leukemia</td>
<td>X</td>
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<td>Lymphoma</td>
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<td>Hodgkin disease</td>
<td>X</td>
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<td></td>
<td>Generalized malignancy</td>
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<td>X</td>
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<tr>
<td></td>
<td>Iatrogenic immunosuppression **</td>
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<td>Solid organ transplant</td>
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<tr>
<td></td>
<td>Multiple myeloma</td>
<td>X</td>
<td>X</td>
<td>X</td>
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</table>
Table 5. Medical conditions or other indications for administration of 13-valent pneumococcal conjugate vaccine (PCV13), as well as indications for 23-valent pneumococcal polysaccharide vaccine (PPSV23) administration and revaccination for children aged 6-18 years, and adults aged 19 through 64 years.* [http://www.cdc.gov/mmwr/pdf/wk/mm6225.pdf]

* Both PCV13 and PPSV23 should be administered routinely in series to all adults aged 65 years and older, regardless of previous history of vaccination with pneumococcal vaccine before age 65 years (See pages 1 and 2).
† Including congestive heart failure and cardiomyopathies, excluding hypertension.
§ Including chronic obstructive pulmonary disease, emphysema, and asthma.
¶ Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).
** Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy.

Dosage and Route
Give PCV13 vaccine 0.5 mL intramuscularly (IM) according to the recommended schedule. Always check the package insert prior to administration of any vaccine.

Anatomical Site
Administer IM vaccines at a 90° angle with a 22- to 25-gauge needle.

- For infants < 12 months of age, administer into the anterolateral aspect of the thigh with a 7/8- to 1-inch needle. (For newborn and or low birth weight infants only, a 5/8” needle may be considered.)
- For children > 12 months of age, administer into the anterolateral aspect of the thigh or deltoid muscle, using a 7/8- to 1¼-inch needle.
- For adults, aged 19 years and older, administer in the deltoid muscle. Consult “Epidemiology and Prevention of Vaccine Preventable Diseases” (The Pink Book), Appendix D, for information about appropriate needle sizes and lengths for administering vaccines. As with other intramuscular injections, use with caution in patients on anticoagulant therapy.
Use with Other Vaccines:

Immunize.org Ask the Experts column,  
http://www.immunize.org/askexperts/experts_pneumococcal_vaccines.asp#pcv13_adults

The pneumococcal conjugate vaccine (PCV13) package insert says that in adults, antibody responses to PREVNAR 13 (Pfizer) were diminished when given with inactivated influenza vaccine.

Does this mean we should not give PCV13 and influenza vaccine at the same visit?

No. The available data have been interpreted that any changes in antibody response to either vaccines' components were clinically insignificant.

If PCV13 and influenza vaccine are both indicated and recommended, they should be administered at the same visit.

See the PCV13 ACIP recommendations,  

ACIP Recommendations,  
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm

Coadministration with Other Vaccines

Concomitant administration of PCV13 and trivalent inactivated influenza vaccine (TIV) has been demonstrated to be immunogenic and safe. PCV13 can be coadministered with TIV in an adult immunization program. However, a randomized double-blind trial found slightly lower pneumococcal serotype-specific geometric mean concentrations and lower proportion achieving at least a fourfold rise in hemagglutination inhibition assay titer for one of three influenza subtypes (influenza A[H3N2]) with PCV13 plus TIV compared with PCV13 alone or TIV alone among adults aged ≥65 years (16). Currently, no data are available on coadministration with other vaccines (e.g., tetanus, diphtheria, and acellular pertussis vaccine or zoster vaccine) among adults.

See the PCV13 package insert,  

DRUG INTERACTIONS ---------------------------

In adults, antibody responses to PREVNAR 13 were diminished when given with inactivated trivalent influenza vaccine (TIV).

There is no true waiting period between inactivated influenza vaccine and PCV13 vaccine, as both are inactivated vaccines. However, if not given at the same visit, separating the doses by at least five to seven days would enable any perceived and immediate adverse events to be possibly identified as caused by only one of the vaccines given.
**Precautions (See package insert for a complete listing of precautions):**

- Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including PCV13, to infants born prematurely should be based on consideration of the individual infant’s medical status, and the potential benefits and possible risks of vaccination.
- For intramuscular use only. DO NOT inject intravenously, intradermally, or subcutaneously.
- The preferred sites for injection are the anterolateral aspect of the thigh in infants or the deltoid muscle of the upper arm in toddlers, young children, adolescents, and adults. PCV13 vaccine should not be injected in the gluteal area or areas where there may be a major nerve trunk and/or blood vessel.
- Since this product is a suspension containing an adjuvant, shake vigorously immediately prior to use to obtain a homogenous, white suspension in the vaccine container.

**Contraindications**

- Severe allergic reaction (e.g., anaphylaxis) to any component of PCV13, PCV7, or any diphtheria toxoid-containing vaccine.

**Adverse Events**

- See the product’s package insert
- See Adverse Events Following Vaccinations page of this section

**Storage and Handling**

- Store in refrigerator at 36°F to 46°F (2°C to 8°C)
- DO NOT FREEZE. Discard if PCV13 has been frozen.

**Other Important Notes**

- The tip cap and rubber plunger of the prefilled syringe are not made with natural latex rubber.
- PCV13 does not contain thimerosal.
- PCV13 will not protect against disease caused by *Streptococcus pneumoniae* serotypes that are not in the vaccine.

**References:**

MMWR September 4, 2015 / 64(34):944-947: Intervals Between PCV13 and PPSV23 Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP),
[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6434a4.htm?c_id=mm6434a4_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6434a4.htm?c_id=mm6434a4_w)


Recommended Immunization Schedule for Persons Aged 0 Through 18 Years, United States, 2015: [http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html](http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html)

Pneumococcal Vaccine, Polyvalent

[23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23)]

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunization.

Indications and Usage:
The 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23) is indicated for vaccination against pneumococcal disease caused by those pneumococcal types included in the vaccine.

Recommended Schedule

Note: All recommended PCV13 [the 13-valent pneumococcal vaccine] doses should be administered prior to PPSV23 [the 23-valent pneumococcal vaccine] vaccination, if possible, among persons for whom both vaccines are recommended. If a dose of PPSV23 is inadvertently given earlier than the recommended interval, the dose need not be repeated. http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

Vaccination with PPSV23 vaccine is recommended for selected individuals as follows:

- **Immunocompetent persons:**
  - ACIP recommends routine vaccination for persons aged 65 years and older. As described in the package insert, both PCV13 and PPSV23 vaccine are FDA approved for vaccination of persons aged 50 years and older.
  - Routine vaccination of all persons aged 65 years and older who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown
    - Administer a dose of PCV13 first, followed in series by a dose of PPSV23
      See Box 1 and Table 1 below. The two vaccines should not be co-administered.
    - The dose of PPSV23 should be given at least 1 year after a dose of PCV13. If PPSV23 cannot be given during this time window, the dose of PPSV23 should be given during the next visit. If a dose of PPSV23 is inadvertently given earlier than the recommended interval, the dose need not be repeated.
  - Routine use of PCV13 among adults aged 65 years and older who had previous vaccination with PPSV23 at age 65 years and older.
    - Adults aged 65 years and older who have previously received one or more doses of PPSV23 also should receive a dose of PCV13 if they have not yet received it.
    - A dose of PCV13 should be given at least 1 year after receipt of the most recent dose of PPSV23.
  - Routine use of PCV13 among adults aged 65 years and older who had previous vaccination with PPSV23 before age 65 years who are now aged 65 years and older.
    - Adults aged 65 years and older who have previously received one or more doses of PPSV23 also should receive a dose of PCV13 if they have not yet received it. A dose of PCV13 should be given at least 1 year after receipt of the most recent dose of PPSV23.
    - For those for whom an additional dose of PPSV23 is indicated, this subsequent PPSV23 dose should be given at least 1 year after PCV13 and at least 5 years after the most recent dose of PPSV23.
  - Persons aged 2 years age and older with chronic pulmonary disease (including chronic obstructive pulmonary disease and emphysema) (Table 1 and Table 2)
• Persons aged 2 years age and older with chronic cardiovascular diseases (including cyanotic congenital heart disease, congestive heart failure, and cardiomyopathies),
• Persons aged 2 years age and older with diabetes mellitus
• Persons aged 2 years and older with alcoholism and chronic liver diseases (including cirrhosis)
• Persons aged 2 years age and older with chronic renal failure or nephrotic syndrome
• Persons aged 2 years and older with functional or anatomic asplenia (including sickle cell disease and splenectomy [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]) and other hemoglobinopathies
• Persons aged 2 years and older with cochlear implants or cerebrospinal fluid leaks
• Persons aged 2 years and older living in special environments or social settings, e.g. residents of nursing homes or other long-term care facilities (including Alaskan Natives and certain American Indian populations)
• Persons aged 19 through 64 years who smoke cigarettes should receive a single dose of PPSV23 and smoking cessation counseling (Table 3)
• Persons aged 19 through 64 years who have asthma should receive a single dose of PPSV23

• Immunocompromised persons (Vaccination of persons with high-risk conditions with PCV13 and PPSV23, Table 1 through Table 3):
  • For children aged 2 through 5 years, including those with HIV infection, malignant neoplasms, leukemia, lymphoma, Hodgkin’s disease, multiple myeloma, generalized malignancy, chronic renal failure or nephrotic syndrome; those receiving immunosuppressive chemotherapy (including corticosteroids) or radiation therapy; and those who have received a solid organ or bone marrow transplant or have congenital immunodeficiency:
    ▪ Administer 1 dose of PCV13 if 3 doses of PCV (PCV7 and/or PCV13) were received previously.
    ▪ Administer 2 doses of PCV13 at least 8 weeks apart if fewer than 3 doses of PCV (PCV7 and/or PCV13)
    ▪ Administer one supplemental dose of PCV13 if four doses of PCV7 or other age-appropriate complete PCV7 series was received previously.
    ▪ The minimum interval between doses of PCV (PCV7 or PCV13) is 8 weeks.
    ▪ For children with no history of PPSV23 vaccination, administer PPSV23 at least 8 weeks after the most recent dose of PCV13.
  • Children aged 6 through 18 years, who are PPSV23-naïve children and have not received PCV13 and are at an increased risk for invasive pneumococcal disease (IPD) because of anatomic or functional asplenia (including sickle cell disease [SCD]), HIV infection, cochlear implant, CSF leak, or other immunocompromising condition should receive a single PCV13 dose first, followed 8 or more weeks later by a dose of PPSV23. A second PPSV23 dose is recommended 5 years after the first PPSV23 dose for children with anatomic or functional asplenia (including SCD), HIV infection, or other immunocompromising conditions.
  • Children aged 6 through 18 years who have not received PCV13; are at increased risk for IPD because of anatomic or functional asplenia (including SCD), HIV infection, CSF leaks, cochlear implants, or other immunocompromising conditions; and who previously received 1 or more doses of PPSV23 should be given a single PCV13 dose 8 or more weeks after the last PPSV23 dose, even if they have received PCV7. If a second PPSV23 dose is indicated, it should be given 5 or more years after the first PPSV23 dose. These children should not receive more than two doses of PPSV23 before age 65 years.
Adults aged 19 years or older with immunocompromising conditions (including chronic renal failure and nephrotic syndrome), functional or anatomic asplenia, cerebrospinal fluid leaks, or cochlear implants who have not previously received PCV13 or PPSV23 should receive a single dose of PCV13 followed by a dose of PPSV23 at least 8 weeks later.

ACIP recommends routine vaccination for persons aged 65 years and older. As described in the package insert, both PCV13 and PPSV23 vaccine are FDA approved for vaccination of persons aged 50 years and older.

- Routine vaccination of all persons aged 65 years and older who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown
  - Administer a dose of PCV13 first, followed in series by a dose of PPSV23. See Box 1 and Table 1 below. The two vaccines should not be co-administered.
  - The interval between doses of PCV13 and PPSV23 should be 8 weeks or greater for adults aged 65 years and older with immunocompromising conditions, functional or anatomic asplenia, cerebrospinal fluid leaks, or cochlear implants.

- Routine use of PCV13 among adults aged 65 years and older who had previous vaccination with PPSV23 at age 65 years and older.
  - Adults aged 65 years and older who have previously received one or more doses of PPSV23 also should receive a dose of PCV13 if they have not yet received it.
  - A dose of PCV13 should be given at least 1 year after receipt of the most recent dose of PPSV23.

- Routine use of PCV13 among adults aged 65 years and older who had previous vaccination with PPSV23 before age 65 years who are now aged 65 years and older.
  - Adults aged 65 years and older who have previously received one or more doses of PPSV23 also should receive a dose of PCV13 if they have not yet received it. A dose of PCV13 should be given at least 1 year after receipt of the most recent dose of PPSV23.
  - For those for whom an additional dose of PPSV23 is indicated, this subsequent PPSV23 dose should be given at least 1 year after PCV13 and at least 5 years after the most recent dose of PPSV23.

Vaccination with PPSV23 vaccine is NOT recommended for selected individuals as follows:

- **American Indian/Alaska Native children aged 24 through 59 months:**
  - Routine use of PPSV23 is not recommended for Alaska Native or American Indian children aged 24 through 59 months. However, in special situations, public health authorities may recommend the use of PPSV23 after PCV7 for Alaska Native or American Indian children aged 24 through 59 months who are living in areas in which risk of invasive pneumococcal disease is increased.

- **American Indian/Alaska Native adults:**
  - Routine use of PPSV23 is not recommended for Alaska Native or American Indian persons younger than 65 years old unless they have underlying medical conditions that are PPSV23 indications. However, in special situations, public health authorities may recommend PPSV23 for Alaska Natives and American Indians aged 50 through 64 years who are living in areas in which the risk of invasive pneumococcal disease is increased.
Timing of Vaccination:

- PPSV23 should be given at least two weeks before elective splenectomy, if possible
- Persons with asymptomatic or symptomatic HIV infection should be vaccinated as soon as possible after their diagnosis is confirmed
- For planning cancer chemotherapy or other immunosuppressive therapy (e.g., for patients with Hodgkin’s disease or those who undergo organ or bone marrow transplantation), pneumococcal vaccine should be administered at least two weeks prior to the initiation of immunosuppressive therapy
- Vaccination during chemotherapy or radiation therapy should be avoided
- Pneumococcal vaccine may be given as early as several months following completion of chemotherapy or radiation therapy for neoplastic disease
- In Hodgkin’s disease immune response to vaccination may be impaired for two years or longer after intensive chemotherapy (with or without radiation)

Use with Other Vaccines:

The ACIP states that pneumococcal vaccine may be administered at the same time as influenza vaccine (by separate injection in the other arm) without an increase in side effects or decreased antibody response to either vaccine, http://www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm.

ACIP recommends that zoster vaccine and PPSV23 can be given at the same time or any time before or after each other, http://www.immunize.org/askexperts/experts_zos.asp. This ACIP recommendation is different from the contents of the ZOSTAVAX package insert that states, “Consider administration of the two vaccines separated by at least 4 weeks,” http://www.merck.com/product/usa/pi_circulars/z/zostavax_piz.pdf.
BOX 1. Recommended intervals for sequential use of PCV13 and PPSV23 for immunocompetent adults aged ≥65 years — Advisory Committee on Immunization Practices, United States

Abbreviations: PCV13 = 13-valent pneumococcal conjugate vaccine; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.
TABLE 1. Summary of recommended intervals, by risk and age groups, for persons with indications to receive PCV13 and PPSV23 sequence — Advisory Committee on Immunization Practices, United States, September 2015

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<th>Risk group/Underlying medical condition</th>
<th>Intervals for PCV13–PPSV23 sequence, by age group</th>
<th>Intervals for PPSV23–PCV13 sequence, by age group</th>
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<tr>
<td></td>
<td>24–71 months</td>
<td>6–18 years</td>
</tr>
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<td>No underlying chronic conditions</td>
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<td>NA</td>
</tr>
<tr>
<td>Immunocompetent persons</td>
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<tr>
<td>Chronic heart disease</td>
<td>≥8 weeks</td>
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</tr>
<tr>
<td>Chronic lung disease</td>
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<td>Diabetes mellitus</td>
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<tr>
<td>Cerebrospinal fluid leak</td>
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<td>Congenital or acquired asplenia</td>
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</tbody>
</table>
TABLE 1. Summary of recommended intervals, by risk and age groups, for persons with indications to receive PCV13 and PPSV23 sequence — Advisory Committee on Immunization Practices, United States, September 2015

<table>
<thead>
<tr>
<th>Risk group/Underlying medical condition</th>
<th>Intervals for PCV13–PPSV23 sequence, by age group</th>
<th>Intervals for PPSV23–PCV13 sequence, by age group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>24–71 months</td>
<td>6–18 years</td>
</tr>
<tr>
<td>Immunocompromised persons</td>
<td>≥8 weeks</td>
<td>≥8 weeks</td>
</tr>
<tr>
<td>Congenital or acquired immunodeficiency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human immunodeficiency virus infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic renal failure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nephrotic syndrome</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leukemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lymphoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hodgkin disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generalized malignancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iatrogenic immunosuppression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solid organ transplant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple myeloma*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviation:** NA = not applicable, sequential use of PCV13 and PPSV23 is not recommended for these age and risk groups.

* Underlying medical conditions that are not included in the recommendations for children aged <6 years.
<table>
<thead>
<tr>
<th>Risk group</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunocompetent persons</td>
<td>Chronic heart disease*</td>
</tr>
<tr>
<td></td>
<td>Chronic lung disease†</td>
</tr>
<tr>
<td></td>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td></td>
<td>Cerebrospinal fluid leaks</td>
</tr>
<tr>
<td></td>
<td>Cochlear implant</td>
</tr>
<tr>
<td>Functional or anatomic asplenia</td>
<td>Sickle cell disease and other hemoglobinopathies</td>
</tr>
<tr>
<td></td>
<td>Congenital or acquired asplenia, or splenic dysfunction</td>
</tr>
<tr>
<td>Immunocompromised persons</td>
<td>HIV infection</td>
</tr>
<tr>
<td></td>
<td>Chronic renal failure and nephrotic syndrome</td>
</tr>
<tr>
<td></td>
<td>Diseases associated with immunosuppressive chemotherapy or radiation therapy, including malignant</td>
</tr>
<tr>
<td></td>
<td>neoplasms, leukemias, lymphomas, and Hodgkin disease; or solid organ transplantation</td>
</tr>
<tr>
<td></td>
<td>Congenital immunodeficiency†</td>
</tr>
</tbody>
</table>

* Particularly cyanotic congenital heart disease and cardiac failure.
† Including asthma if treated with high-dose oral corticosteroid therapy.
‡ Includes B- (humoral) or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, and C4 deficiency; and phagocytic disorders (excluding chronic granulomatous disease).
Table 3. Medical conditions or other indications for administration of 13-valent pneumococcal conjugate vaccine (PCV13), as well as indications for 23-valent pneumococcal polysaccharide vaccine (PPSV23) administration and revaccination for children aged 6-18 years, and adults aged 19 through 64 years.* [http://www.cdc.gov/mmwr/pdf/wk/mm6225.pdf](http://www.cdc.gov/mmwr/pdf/wk/mm6225.pdf)

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Underlying Medical Condition</th>
<th>PCV13 Recommended</th>
<th>PPSV23 Recommended</th>
<th>Revaccination 5 years after first dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunocompetent persons</td>
<td>Chronic heart disease †</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chronic lung disease §</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes mellitus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>CSF leaks</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cochlear implants</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alcoholism</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chronic liver disease, cirrhosis</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cigarette smoking</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>anatomic asplenia</td>
<td>Sickle cell disease (other hemoglobinopathies)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Persons with functional or</td>
<td>asplenia</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Immunocompromised persons</td>
<td>Congenital or acquired immunodeficiencies ¶</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>HIV infection</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Chronic renal failure</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Nephrotic syndrome</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>persons</td>
<td>Leukemia</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Lymphoma</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Hodgkin disease</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Generalized malignancy</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
Table 3. Medical conditions or other indications for administration of 13-valent pneumococcal conjugate vaccine (PCV13), as well as indications for 23-valent pneumococcal polysaccharide vaccine (PPSV23) administration and revaccination for children aged 6-18 years, and adults aged 19 through 64 years.* [http://www.cdc.gov/mmwr/pdf/wk/mm6225.pdf]

* Both PCV13 and PPSV23 should be administered routinely in series to all adults aged 65 years and older, regardless of previous history of vaccination with pneumococcal vaccine before age 65 years (See pages 1 and 2).
† Including congestive heart failure and cardiomyopathies, excluding hypertension.
§ Including chronic obstructive pulmonary disease, emphysema, and asthma.
¶ Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).
** Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy.

Revaccination:

- Revaccination of immunocompetent persons previously vaccinated with PPSV23 vaccine is not routinely recommended.
- However, revaccination once is recommended for persons aged 2 years and older who are at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels, provided that at least five years have passed since receipt of a first dose of pneumococcal vaccine.
  - The highest risk group includes persons with functional or anatomic asplenia (e.g., sickle cell disease or splenectomy), HIV infection, leukemia, lymphoma, Hodgkin’s disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome, or other conditions associated with immunosuppression (e.g., organ or bone marrow transplantation), and those receiving immunosuppressive chemotherapy (including long-term systemic corticosteroids).
  - For children, a second dose of PPSV23 is recommended 5 years after the first dose of PPSV23 for persons aged 2 years and older who are immunocompromised, have sickle cell disease or functional or anatomic asplenia
- If prior vaccination status is unknown for patients in the high-risk group, patients should be given pneumococcal vaccine.
- All persons aged 65 years and older who received PPSV23 when aged <65 years and for whom an additional dose of PPSV23 is indicated when aged ≥65 years, this subsequent PPSV23 should be given ≥1 year after PCV13 and ≥5 years after the most recent dose of PPSV23.
- Because data are insufficient concerning the safety of PPSV23 vaccine when administered three or more times, revaccination following a second dose is not routinely recommended.

Warnings:

- For planning cancer chemotherapy or other immunosuppressive therapy (e.g., for patients with Hodgkin’s disease or those who undergo organ or bone marrow transplantation), the timing of vaccination is critical, (See Timing of Vaccination)
• If the vaccine is used in persons receiving immunosuppressive therapy, the expected serum antibody response may not be obtained and potential impairment of future immune responses to pneumococcal antigens may occur, (See Timing of Vaccination)
• Intradermal administration may cause severe local reactions.

**Dosage and Route**

Administer a single 0.5 mL dose of PPSV23 vaccine, intramuscularly (IM) or subcutaneously (SQ), according to the recommended schedule. *Do not inject intravenously or intradermally.*

  - Always check the package insert prior to administration of any vaccine.

**Anatomical Site**

• IM in the deltoid muscle or lateral mid-thigh; as with other intramuscular injections, use with caution in patients on anticoagulant therapy.
• SQ anterolateral fat of thigh for young children, posterolateral fat of upper arm for children & adults.

**Precautions (See the package insert for a complete listing of precautions):**

• Safety and effectiveness in children below the age of two (2) years have not been established. PPSV23 vaccine is not recommended in this age group.
• It is not known whether PPSV23 vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PPSV23 vaccine should be given to a pregnant woman only if clearly indicated.
• It is not known whether PPSV23 is excreted in human milk; caution should be exercised when PPSV23 vaccine is administered to a nursing woman.

**Contraindications**

Hypersensitivity to any component of the vaccine.

**Adverse Events**

• See the product’s package insert
• See Adverse Events Following Vaccinations page of this section

**Storage and Handling**

• Store in refrigerator at 36°F – 46°F (2°C – 8°C)
References:

MMWR September 4, 2015 / 64(34):944-947: Intervals Between PCV13 and PPSV23 Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP),
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6434a4.htm?s_cid=mm6434a4_w


Immunization Action Coalition, Ask the Experts. Zoster (shingles), “The Zostavax package insert says that clinicians should consider administering zoster vaccine and pneumococcal polysaccharide vaccine (PPSV) at least 4 weeks apart. What does ACIP say about this? http://www.immunize.org/askexperts/experts_zos.asp

PPSV23 Vaccine Package Insert (revised 05/2015)
Rotavirus (RV1) Vaccine, Live, Oral, ROTARIX®

Precautions and Contraindications

Screen all patients for precautions and contraindications to immunization.

Indications and Usage: ROTARIX® is a vaccine indicated for the prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9) in infants and children.

Recommended Schedule

- The vaccination series consists of two 1-mL doses administered orally at 6 to 24 weeks of age. There should be an interval of at least 4 weeks between the first and second doses.
- Maximum age for the first dose is 14 weeks 6 days.

Dosage and Route

FOR ORAL USE ONLY. DO NOT INJECT.

To administer the vaccine:

- Remove plastic cover from vial of lyophilized vaccine.
- Connect transfer adapter onto vial by pushing it downwards until the transfer adapter is properly and securely in place.
- Shake the oral applicator containing the liquid diluent vigorously. The shaken suspension will appear as a turbid liquid with a slow settling white deposit.
- Remove the protective tip cap from the oral applicator.
- Connect the oral applicator into the transfer adapter by pushing it firmly on the device.
- Transfer the entire content of the oral applicator into the vial of lyophilized vaccine.
- With the oral applicator still attached, shake the vial and examine for complete suspension. The reconstituted vaccine will appear more turbid than the diluent alone. This appearance is normal.
- Withdraw the entire mixture back into the oral applicator.
- The infant should be seated in a reclining position. Administer orally the entire content of the oral applicator (on the inside of the cheek). Dispose of applicator and vaccine vial in biohazard waste container.

Anatomical Site

- Mouth/inner cheek

Precautions

- Prior to administering the vaccine, review infant immunization history for hypersensitivity and other reactions to any component of ROTARIX®, including latex rubber contained in the oral applicator.
- Administration of ROTARIX® should be delayed in infants suffering from acute diarrhea or vomiting.
- An increased risk of intussusception following administration of ROTARIX® was observed in some, but not all, postmarketing studies, particularly during the first week following the first dose of vaccine.
- Since ROTARIX® is a live virus, safety and effectiveness in infants with known primary or secondary immunodeficiencies have not been evaluated.
Contraindications

DO NOT administer to infants:

- With a history of severe allergic reaction (e.g. anaphylaxis) after a previous dose of rotavirus vaccine or exposure to a vaccine component.
- With a history of uncorrected congenital malformation of the gastrointestinal tract (such as Meckel’s diverticulum) that would predispose the infant for intussusception.
- With a history of intussusception.
- With Severe Combined Immunodeficiency Disease (SCID).

Adverse Events

- See the product’s package insert
- See Adverse Events Following Vaccinations page of this section

Storage and Handling

- Store in refrigerator at 36°F – 46°F (2°C – 8°C) (DO NOT FREEZE).
- Administer within 24 hours of reconstitution.
- May be stored at room temperature up to 25°C (77°F) after reconstitution.
- Discard reconstituted vaccine if not used within 24 hours.
- Discard if the vaccine has been frozen.
- Protect from light.

Other Important Notes

- The ACIP recommends that ROTARIX® be given during the current routine well-baby visits at 2 and 4 months of age.
- Breast-feeding is not a contraindication for vaccination. No restrictions were placed on infants’ liquid consumption, including breast-milk, either before or after vaccination.
- In the event that the infants spits out or regurgitates most of the vaccine dose, a single replacement dose of ROTARIX® may be considered at the same vaccination visit.
- Rotavirus shedding in stool occurs after vaccination with peak excretion occurring around day 7 after dose 1 of ROTARIX®.
- CPT 90680
Tuberculin Testing and Live Vaccines

Recommendations for use of the tuberculin skin test are independent of those for immunization. Tuberculin testing at any age is not required before administration of live-virus vaccines. A tuberculin skin test (TST) can be applied at the same visit during which these vaccines are administered. Measles vaccine temporarily can suppress tuberculin reactivity for at least 4 to 6 weeks. The effect of live-virus varicella, yellow fever, and live-attenuated influenza vaccines on tuberculin skin test reactivity is not known. In the absence of data, the same TST spacing recommendation should be applied to these vaccines as described for MMR. There is no evidence that inactivated vaccines, polysaccharide vaccines or recombinant or subunit vaccines or toxoids interfere with immune response to TST.

Tuberculin Skin Testing (TST) and Rotavirus Vaccine (RV1)

- Apply TST at same visit as RV1 (preferred strategy)
- Apply TST first and administer RV1 when TST is read (least favored option because receipt of RV1 is delayed) (least preferred strategy)
- Delay TST at least 4 weeks if RV1 is given first.
Rotavirus (RV5) Vaccine, RotaTeq®

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunization.

Recommended Schedule
- The vaccination series consists of three ready-to-use liquid doses of RotaTeq® administered orally at 6 to 12 weeks of age, with the subsequent doses administered at 4 to 10-week intervals. The third dose should not be given after 32 weeks of age.

Dosage and Route FOR ORAL USE ONLY. DO NOT INJECT.
To administer the vaccine:
- Tear open the pouch and remove the dosing tube
- Clear the fluid from the dispensing tip by holding tube vertically and tapping the cap
- Puncture the dispensing tip by screwing cap clockwise until it becomes tight
- Remove cap by turning it counterclockwise
- Administer dose by gently squeezing liquid into infant’s mouth toward the inner cheek until dosing tube is empty

Anatomical Site
- Mouth/inner cheek

Precautions
- Immunocompromised populations. No safety or efficacy data are available from clinical trials regarding the administration of RotaTeq® to infants who are potentially immunocompromised including:
  o Infants with blood dyscrasias, leukemia, lymphomas of any type or other malignant neoplasms affecting the bone marrow or lymphatic system.
  o Infants on immunosuppressive therapy (including high-dose systemic corticosteroids). RotaTeq® may be administered to infants who are being treated with topical corticosteroids or inhaled steroids.
  o Infants with primary and acquired immunodeficiency states, including HIV/AIDS or other clinical manifestations of infection with human immunodeficiency viruses; cellular immune deficiencies; and hypogammaglobulinemic and dysgammaglobulinemic states. There are insufficient data from clinical trials to support administration of RotaTeq® to infants with indeterminate HIV status who are born to mothers with HIV/AIDS.
  o Infants who have received a blood transfusion or blood products, including immunoglobulins within 42 days.
• **Gastrointestinal Illness.** No safety or efficacy data are available for administration of RotaTeq® to infants with a history of gastrointestinal disorders including infants with active acute gastrointestinal illness, infants with chronic diarrhea and failure to thrive, and infants with a history of congenital abdominal disorders, and abdominal surgery. Caution is advised when considering administration of RotaTeq® to these infants.

• **Intussusception.** An increased risk of intussusception following administration of RotaTeq® was observed in some, but not all, postmarketing studies, particularly during the first week following the first dose of vaccine.

• **Febrile illness.** Low-grade fever (<100.5 F) itself and mild upper respiratory infection do not preclude vaccination.

**Precautions (continued)**

• **Immunodeficient close contacts.** Caution is advised when considering whether to administer RotaTeq® to individuals with immunodeficient close contacts such as:
  o Individuals with malignancies or who are otherwise immunocompromised
  o Individuals with primary immunodeficiency; or
  o Individuals receiving immunosuppressive therapy.

**Contraindications**

**DO NOT** administer to infants:

• With a history of severe allergic reaction (e.g. anaphylaxis) after a previous dose of rotavirus vaccine or exposure to a vaccine component.
• With Severe Combined Immunodeficiency Disease (SCID).
• With a history of intussusception.

**Adverse Events**

• See the product’s package insert
• See Adverse Events Following Vaccinations page of this section

**Storage and Handling**

• Store in refrigerator at 36°F – 46°F (2°C – 8°C)
• Administer as soon as possible after being removed from refrigerator
• Protect from light

**Other Important Notes**

• The ACIP recommends that RotaTeq® be given during the current routine well-baby visits at 2, 4, and 6 months of age.
• There are no restrictions on the infant’s consumption of food or liquid, including breast milk, either before or after vaccination with RotaTeq®.
• Re-administration of a dose of RotaTeq® to an infant who regurgitates, spits out or vomits during or after administration of vaccines is not recommended. The infant should receive the remaining recommended doses of RotaTeq® at appropriate intervals.
Tuberculin Testing and Live Vaccines

Recommendations for use of the tuberculin skin test are independent of those for immunization. Tuberculin testing at any age is not required before administration of live-virus vaccines. A tuberculin skin test (TST) can be applied at the same visit during which these vaccines are administered. Measles vaccine temporarily can suppress tuberculin reactivity for at least 4 to 6 weeks. The effect of live-virus varicella, yellow fever, and live-attenuated influenza vaccines on tuberculin skin test reactivity is not known. In the absence of data, the same TST spacing recommendation should be applied to these vaccines as described for MMR. There is no evidence that inactivated vaccines, polysaccharide vaccines or recombinant or subunit vaccines or toxoids interfere with immune response to TST.

Tuberculin Skin Testing (TST) and Rotavirus Vaccine (RV5)

- Apply TST at same visit as RV5 (preferred strategy)
- Apply TST first and administer RV5 when TST is read (least favored option because receipt of RV5 is delayed) (least preferred strategy)
- Delay TST at least 4 weeks if RV5 is given first.
Protocol for Administration of Tetanus Diphtheria and Tetanus Diphtheria Acellular Pertussis (Td/Tdap) Vaccines
Children Aged 7 Years and Older and Adults

Precautions and Contraindications
Screen all patients for precautions and contraindications to immunization.

Recommended Routine Schedule
Td/Tdap Vaccine Schedule for Children Aged 7 Years and older, unless a contraindication

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Recommended Age</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Td</td>
<td>7 years of age</td>
<td>May be used for age 7 years and older not receiving previous doses of DTaP, DT, or Td for the primary series. Tdap is preferred as first dose if not fully vaccinated.</td>
</tr>
<tr>
<td>Tdap/Td</td>
<td>11 through 12 years of age</td>
<td>1st booster dose, administer Tdap vaccine. Thereafter, administer Td every 10 years.</td>
</tr>
</tbody>
</table>

Recommended Immunization Schedule for Persons Aged 7 through 18 years
For those who fall behind or start late, see the Catch-up Schedule

Vaccine: Tetanus, Diphtheria or Tetanus, Diphtheria, Pertussis (Td/Tdap)

- For children aged 7 through 10 years of age who are not fully vaccinated against pertussis (i.e., 5 doses of DTaP vaccine or 4 doses of DTaP vaccine if the fourth dose was administered on or after the fourth birthday) and for whom no contraindication to pertussis vaccine exists, administer one dose of Tdap vaccine. If additional doses of tetanus- and diphtheria-toxoid containing vaccines are needed in the catch-up series, use Td vaccine, according to the catch-up immunization schedule. Children who receive Tdap vaccine when aged 7 through 10 years (as part of the catch up series) may be given an additional Tdap for the routine recommended adolescent dose when aged 11 through 12 years of age. Td vaccine should next be given 10 years after receiving Tdap vaccine.

- Administer one dose of Tdap vaccine to adolescents aged 11 through 18 years who have completed the recommended childhood DTaP/ DTP vaccination series. Td booster doses should be administered every 10 years, thereafter. Tdap vaccine can be administered regardless of the interval since the last tetanus- or diphtheria-toxoid containing vaccine.

*ACIP Recommendations for children 7 to 9 years of age differ from the package inserts. [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm)
Catch-Up Schedule for Persons Aged 7 through 18 Years
Who Start Late or Who Are More Than 1 Month Behind

Vaccine: Tetanus, Diphtheria (Td) or Tetanus, Diphtheria Acellular Pertussis (Tdap).
See the “Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind—United States, 2014” for more information, http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf.

- An inadvertent dose of DTaP vaccine administered to children aged 7 through 10 years may count as part of the catch-up series. This dose can count as the adolescent Tdap dose, or the child can later receive a Tdap booster at age 11 through 12 years.
- An inadvertent dose of DTaP vaccine administered to an adolescent aged 11 through 18 years may count as part of the catch-up series. This dose should be counted as the adolescent Tdap dose.
- Children aged 7 through 10 years who are not fully immunized with the childhood DTaP vaccine series, should receive Tdap vaccine as the first dose in the catch-up series. They may be given an additional Tdap for the routinely recommended adolescent dose at 11-12 years of age. Td should be administered 10 years after the Tdap dose.
- Those persons aged 7 through 18 years who were never vaccinated against tetanus, diphtheria, or pertussis or who have unknown vaccination status should receive a series of three vaccinations containing tetanus and diphtheria toxoids. The first of these three doses should be a single dose of Tdap vaccine.
- The information below provides catch-up schedules and minimum intervals for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Tdap vaccine should be substituted for a single dose of Td vaccine in the catch-up series.
  o Administer Tdap as dose 1 at a minimum age of 7 years.
  o Administer Td as dose 2 with a minimum interval of 4 weeks between dose 1 to dose 2
  o Administer Td as dose 3 with a minimum interval between dose 2 to dose 3 of:
    ▪ 4 weeks, if first dose of DTaP/DT was administered at younger than age 12 months
    ▪ 6 months, if first dose of DTaP/DT was administered at age 12 months or older and then no further doses are needed for catch-up
  o For some children, administer Td as dose 4 with a minimum interval between dose 3 to dose 4 of 6 months, if first dose of DTaP/DT was administered at younger than age 12 months.

*ACIP Recommendations for children aged 7 through 9 years of age differ from the package inserts.
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm.
Additional Information

Preventing Spread of Pertussis to Infants by Vaccinating Their Adolescent Contacts: Administer a single dose of Tdap to adolescents (e.g., parents, siblings, child-care providers, and health care personnel) who have or anticipate having close contact with an infant aged less than 12 months, if they have not received Tdap previously, and ideally at least 2 weeks before beginning close contact with the infant. Tdap can be administered regardless of the interval since the last tetanus or diphtheria toxoid containing vaccine.

During Pertussis Outbreaks: Administer a single dose of Tdap vaccine to children and adolescents aged 10 through 18 years who have never received Tdap vaccine.

Primary Vaccination Series for Persons Aged

19 Years and Older

Vaccine: Tetanus, Diphtheria (Td) or Tetanus, Diphtheria Acellular Pertussis (Tdap) *

(Subscribe a single dose of Tdap vaccine for any of the Td doses)

- Administer dose 1 at a minimum age of 19 years.
  - BOOSTRIX® is licensed for use in individuals aged 10 years and older.
  - ADACEL® is licensed for use in individuals aged 10 through 64 years. **
- Administer dose 2 at a minimum interval of 4 weeks between dose 1 to dose 2
- Administer dose 3 at a minimum interval of 6 months through 12 months between dose 2 to dose 3

Footnotes:

*Adults with an unknown or incomplete history of a complete primary vaccination series with tetanus- and diphtheria-toxoid--containing vaccines should begin or complete a primary vaccination series. A primary series for adults is 3 doses of tetanus- and diphtheria-toxoid containing vaccines; administer the first 2 doses at least 4 weeks apart and the third dose 6 through 12 months after the second. However, a single dose of Tdap can substitute for any one of the doses of Td in the 3-dose primary series. For incompletely vaccinated adults (i.e., less than 3 doses), administer the remaining doses. The booster dose of tetanus- and diphtheria-toxoid containing vaccine should be administered to adults who have completed a primary series and if the last vaccination was received 10 or more years previously. Tdap is preferred for the first booster dose, but Td vaccine may be used. Td vaccine should next be given 10 years after receiving Tdap vaccine except for pregnant women who should receive a dose of Tdap during each pregnancy. For adults who have not received Tdap previously, Tdap can be administered regardless of interval since the most recent tetanus- or diphtheria-toxoid containing vaccine.

**ACIP Recommendations in 2012 stated that either Tdap vaccine brand may be used for adults aged 65 years and older, [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6125a4.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6125a4.htm).
Vaccine: Tetanus, Diphtheria and Tetanus, Diphtheria Pertussis (Td/Tdap)

- Adults aged 19 years and older: Administer a single dose of Tdap vaccine to all adults who have not previously received Tdap or for whom vaccine status is unknown. Tdap can be administered regardless of the interval since the last tetanus- or diphtheria-toxoid containing vaccine. *

- Adults aged 19 years and older: Administer 1 dose of Td booster every 10 years (substitute a 1 time dose of Tdap vaccine for Td)

- Pregnancy: Administer one dose of Tdap vaccine during each pregnancy for adolescents aged 11 through 18 years and for adults aged 19 years and older, regardless of the patient’s prior history of receiving Tdap or Td vaccine.

- Adult contacts and caregivers of infants: Administer a single dose of Tdap vaccine to adult household contacts and caregivers of infants less than 12 months who have never received Tdap vaccine, regardless of the interval since the last tetanus or diphtheria toxoid containing vaccine.

- Health care personnel: Administer a single dose of Tdap vaccine to health care workers who have direct patient contact who have never received Tdap vaccine, regardless of the interval since the last tetanus or diphtheria toxoid containing vaccine.

- Age appropriate doses of Td/Tdap may be indicated for adults with the following special indications:
  - Immunocompromising conditions (e.g. those caused by human immunodeficiency virus (HIV) infections, medications, radiation)
  - Diabetes, heart disease, chronic pulmonary disease, chronic alcoholism
  - Asplenia (including elective splenectomy and terminal complement component deficiencies)
  - Chronic liver disease
  - Kidney failure, end-stage renal disease, receipt of hemodialysis

*Footnote:

Administer a single dose of Tdap to adults (e.g., parents, siblings, grandparents, child-care providers, and health care personnel) who have or anticipate having close contact with an infant aged less than 12 months, if they have not previously received Tdap and ideally at least 2 weeks before beginning close contact with the infant. Tdap can be administered regardless of the interval since the last tetanus or diphtheria toxoid containing vaccine.
**Td/Tdap - Adults with a Complete Primary Vaccination Series with**  
**Tetanus- and Diphtheria-toxoid Containing Vaccines**  
**(Additional Information)**

**Health-care personnel:** Health-care personnel in hospitals or ambulatory care settings who have direct patient contact should receive a single dose of Tdap as soon as feasible if they have not previously received Tdap. Tdap can be administered regardless of the interval since the last tetanus or diphtheria toxoid containing vaccine. Pregnant health care personnel need to get repeat doses during each pregnancy, preferably early in the 27 through 36 weeks gestation period, regardless of number of years since prior Td or Tdap. All healthcare personnel should then receive Td boosters every 10 years thereafter.

**Pregnant Women:**

- **Pregnant women and pertussis vaccination.** *Administer one dose of Tdap vaccine during each pregnancy for adolescents aged 11 through 18 years and for adults aged 19 years and older, regardless of the interval since prior Tdap or Td vaccination.* Tdap should preferably be administered early in the 27 through 36 week gestation period (to maximize passive antibody transfer to the infant).

- **Routine post-partum Tdap:** Pregnant women who previously have not received a dose of Tdap (including women who are breastfeeding) should receive Tdap immediately after delivery. If Tdap cannot be administered immediately after delivery, it should be given before discharge from the hospital or birthing center. If Tdap cannot be administered before discharge, it should be given as soon as feasible. The dose of Tdap replaces the next decennial dose of Td.

- **Pregnant women due for a tetanus booster:** A Tdap booster vaccination is indicated during each pregnancy and should be administered early in the 27 through 36 week gestation period (to maximize passive antibody transfer to the infant).

- **Wound management for pregnant women:** As part of standard wound management care to prevent tetanus, a tetanus toxoid-containing vaccine might be recommended for wound management in a pregnant woman if 5 years or more have elapsed since last receiving Td. If a Td booster is indicated for a pregnant woman, Tdap should be administered.

- **Pregnant women with unknown or incomplete tetanus vaccination:** Administer three vaccinations containing tetanus and reduced diphtheria toxoids at 0, 4 weeks, and 6 through 12 months. Tdap should replace one dose of Td, preferably early in the 27 through 36 week gestation period (to maximize passive antibody transfer to the infant).

**Simultaneous administration:** Tdap can be administered with other vaccines that are indicated. Each vaccine should be administered using a separate syringe at a different anatomic site.

**Preventing Spread of Pertussis to Infants by Vaccinating Their Adult Contacts:**

Administer a single dose of Tdap vaccine to adult household contacts and caregivers of infants aged less than 12 months (e.g., parents, grandparents, adult household members, childcare providers, health care personnel, etc.). Tdap can be administered regardless of the interval since the last tetanus or diphtheria toxoid containing vaccine.

**During Pertussis Outbreaks:** Administer a single dose of Tdap vaccine to persons 19 years of age and older who have never received Tdap vaccine. Tdap can be administered regardless of the interval since the last tetanus or diphtheria toxoid containing vaccine.
Wound Management and Tetanus-containing Vaccines  
(Ages 7 years and older)

Antibiotic prophylaxis against tetanus is neither practical nor useful in managing wounds; proper immunization plays the more important role.

Clean Minor Wounds:
- Immunization history is unknown or less than 3 doses of a tetanus-containing vaccine
  - Children and adolescents, 7 through 18 years of age
    - Administer Tdap (one time dose, preferably the first dose in the catch-up series). If additional doses are needed, use Td vaccine as recommended in the catch-up immunization schedule. Schedule follow-up visits to complete the primary immunization series for tetanus containing vaccines
    - For children 7 through 10 years who receive a dose of Tdap as a part of the catch-up series, an adolescent Tdap vaccine dose at age 11 through 12 years may be administered. Td vaccine should be administered instead 10 years after the Tdap dose.
  - Adults, 19 years of age and older
    - Administer Tdap (one time dose) or Td. Schedule follow-up visits to complete the primary immunization series for tetanus containing vaccines.

- Immunization history is known for a complete primary series (i.e. three or more doses of DTaP, DT, Tdap, or Td):
  - No tetanus-containing vaccine dose is needed if it has been less than 10 years since the last tetanus-containing vaccine dose.
  - Administer Tdap (one time dose) or Td if it has been 10 or more years since the last tetanus-containing vaccine dose. Tdap is preferred for those persons who have not received Tdap previously. Administer Td to those individuals who have previously received Tdap.

All Other Wounds (Such as, but not limited to, wounds contaminated with dirt, feces, soil, and saliva; puncture wounds e.g. stepping on a tack or a rusty nail; avulsions; and wounds resulting from missiles, crushing, burns, and frostbite). Patients whose wounds require extensive cleaning because of dirt or need surgical debridement because of devitalized tissue or foreign material should be referred to the nearest emergency room.

- Immunization history is unknown or less than 3 doses of a tetanus-containing vaccine - REFER PATIENT TO THE NEAREST EMERGENCY ROOM OR THEIR PRIVATE PHYSICIAN, as these patients need both a tetanus-containing vaccine and Tetanus Immune Globulin (TIG) administered by the same provider.
- Immunization history is known for a complete primary series (i.e., three or more doses of DTaP, DT, Tdap, or Td):
  - No tetanus-containing vaccine dose is needed if it has been less than 5 years since the last tetanus-containing vaccine dose.
  - Administer Tdap (one time dose) or Td if it has been 5 or more years since the last tetanus containing vaccine dose. Tdap is preferred for those persons who have not received Tdap previously. Administer Td to those individuals who have previously received Tdap.
ACIP Recommendations for Tdap administration of children 7 to 9 years of age differ from the package insert. [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm)

**Dosage and Route**

*Shake vial well before withdrawing each dose.* Discard vial of vaccine if it cannot be resuspended.

Give Td / Tdap vaccine 0.5 mL intramuscularly (IM).

Shake the vial well to distribute the suspension uniformly before withdrawing for administration. (Do not use if resuspension does not occur with vigorous shaking.)

Always check the package insert prior to administration of any vaccine.

**Anatomical Site**

The preferred site is into the deltoid muscle. The vaccine should not be injected into the gluteal area or areas where there is a major nerve trunk.

**Precautions**

- Patient’s current health status and medical history should be reviewed in order to determine whether any contraindications exist and to assess the benefits and risks of vaccination.
- If Td or Tdap vaccine is administered to immunocompromised persons, including persons receiving immunosuppressive therapy, the expected immune response may not be obtained.

**Contraindications**

Individuals with:

- Anaphylactic reaction to previous dose of Td, Tdap, any other tetanus-toxoid, diphtheria-toxoid or pertussis containing vaccine, to latex, or to any other component of the vaccine (see package insert for specific components).
- Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not due to another identifiable cause within 7 days of previous dose of DTP or DTaP.

**Adverse Events** – See the product’s package insert

**Storage and Handling**

- Store in refrigerator at 36°F – 46°F (2°C – 8°C)
- DO NOT FREEZE; discard if product has been frozen.

**Notes:**

FDA lowered the age of licensure for Adacel vaccine administration from age 11 years to 10 years in March 2014,” [http://www.immunize.org EXPRESS/issue1114.asp](http://www.immunize.org EXPRESS/issue1114.asp) and [http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm392016.htm](http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm392016.htm).

The minimum age of 10 years for administration of both Adacel and BOOSTRIX is described in the “Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2017”: [https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf](https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf)
References:

Immunization Action Coalition (IAC): Needle Tips: ACIP Votes to Update Recommendations for HPV, Tdap, MenB and HepB Vaccines; Volume 26-Number 4; December 2016.

MMWR “Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis (Tdap) Vaccine from the Advisory Committee on Immunization Practices, 2010.” January 14, 2011/60(01); 13-15
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm

“Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2017”:

CDC Immunization of Health-Care Personnel: Recommendations of the ACIP
MMWR, 2011; 60(RR-7), http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm

“Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States, 2017”:

Package Inserts

- Tdap vaccine: http://www.immunize.org/packageinserts/pi_tdap.asp
- Td vaccine: http://www.immunize.org/packageinserts/pi_tetanus.asp
- Tdap vaccine: http://www.immunize.org/packageinserts/pi_tdap.asp
Varicella (VAR) Vaccine

Precautions and Contraindications

Screen all patients for precautions and contraindications to immunization.

Recommended Schedule

Varicella vaccine can be given to individuals 12 months of age and older:

- **All children <13 years of age should be administered routinely two doses of varicella-containing vaccine,** with the first dose administered at age 12 through 15 months and the second dose at age 4 through 6 years (i.e., before a child enters kindergarten or first grade).
  - The second dose can be administered before age 4 years provided at least 3 months have elapsed since the first dose.
  - 3 months. However, if the second dose was administered at least 4 weeks after the first dose, the second dose can be accepted as valid.
- **A second dose catch-up varicella vaccination is recommended for children, adolescents, and adults who previously had received one dose,** to improve individual protection against varicella and for more rapid impact on school outbreaks. Catch-up vaccination can be implemented during routine health care provider visits and through school and college entry requirements. Catch-up second dose can be administered at any interval longer than one month after the first dose.
- **Two doses of single-antigen varicella vaccine are recommended for adolescents (aged 13 years through 18 years) and adults (aged 19 years and older) without evidence of immunity to varicella** or a second dose if they have received only one dose. For persons aged 13 years and older, the minimum interval between doses is 4 weeks.
  - Evidence of immunity to varicella in adolescents and adults includes any of the following (see MMWR 2007;56[No. RR-4], available at [http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf)):
    - Written documentation of 2 doses of varicella vaccine at least 4 weeks apart;
    - U.S.-born before 1980 (although for health-care personnel and pregnant women, birth before 1980 should not be considered evidence of immunity);
    - History of varicella based on diagnosis or verification of varicella by a health-care provider (for a patient reporting a history of or having an atypical case, a mild case, or both, health-care providers should seek either an epidemiologic link to a typical varicella case or to a laboratory-confirmed case or evidence of laboratory confirmation, if it was performed at the time of acute disease);
    - History of herpes zoster based on diagnosis or verification of herpes zoster by a health-care provider; or
    - Laboratory evidence of immunity or laboratory confirmation of disease.
- **Two doses of single-antigen varicella vaccine are recommended for healthcare personnel (aged 13 years and older) without evidence of immunity to varicella** or a second dose if they have received only one dose. For persons aged 13 years and older, the minimum interval between doses is 4 weeks.
  - Healthcare Personnel evidence of immunity to varicella includes any of the following:
    - Written documentation of 2 doses of varicella vaccine at least 4 weeks apart,
    - Diagnosis or verification of a history of varicella disease by a health-care provider, or
    - Diagnosis or verification of a history of herpes zoster by a health-care provider.
• Laboratory evidence of immunity or laboratory confirmation of the disease (commercial assays can be used to assess disease-induced immunity, but they often lack sensitivity to detect vaccine-induced immunity, i.e., they might yield false-negative results).

**Confirmation of Laboratory Evidence of Immunity after Documented Immunization with Two Doses of Varicella Vaccine**

- For new employees in Local Health Departments, it is not necessary to confirm laboratory evidence of immunity to varicella if an individual has written documentation of two doses of varicella vaccine at least 4 weeks apart.
- For existing employees in Local Health Department, it is not necessary to periodically (e.g., every five years) confirm laboratory evidence of immunity to varicella if an individual has written documentation of 2 doses of varicella vaccine at least 4 weeks apart.
- For other individuals, it is not necessary to confirm laboratory evidence of immunity to varicella if an individual has written documentation of two doses of varicella vaccine at least 4 weeks apart.

**Dosage and Route**

- 0.5 mL subcutaneously (SQ or SC)

**Anatomical Site**

- Outer aspect of the deltoid of the upper arm or in the higher anterolateral area of the thigh.

**Precautions**

- Prior to administering the vaccine, obtain a vaccination history to determine any reactions to any vaccine.
- For those of childbearing age, pregnancy should be avoided for 3 months following vaccination.

**Contraindications**

**DO NOT** administer varicella vaccine to individuals with:

- A history of anaphylactic reactions to neomycin.
- A history of hypersensitivity to gelatin or any other component of the vaccine.
- Blood dyscrasias, leukemia, lymphomas of any type, malignant neoplasms
- Primary and acquired immunodeficiency states, including AIDS
- Active untreated tuberculosis
- Women who are pregnant
- An active febrile illness with fever > 101.3°F.
- Immunosuppressive therapy including high-dose systemic corticosteroids.

**Adverse Events**

- See the product’s package insert
- See Adverse Events Following Vaccinations page of this section
Tuberculin Testing and Live Vaccines

Recommendations for use of the tuberculin skin test are independent of those for immunization. Tuberculin testing at any age is not required before administration of live-virus vaccines. A tuberculin skin test (TST) can be applied at the same visit during which these vaccines are administered. Measles vaccine temporarily can suppress tuberculin reactivity for at least 4 to 6 weeks. The effect of live-virus varicella, yellow fever, and live-attenuated influenza vaccines on tuberculin skin test reactivity is not known. In the absence of data, the same TST spacing recommendation should be applied to these vaccines as described for MMR. There is no evidence that inactivated vaccines, polysaccharide vaccines or recombinant or subunit vaccines or toxoids interfere with immune response to TST.

Tuberculin Skin Testing (TST) and Varicella (VAR)

- Apply TST at same visit as VAR (preferred strategy)
- Apply TST first and administer VAR when TST is read (least favored option because receipt of VAR is delayed) (least preferred strategy)
- Delay TST at least 4 weeks if VAR is given first.

Storage and Handling

- Store all live vaccines (MMR, MMRV, and varicella) in the freezer at 5°F, and protect from light, keep in original box with top closed.
- Reconstituted varicella vaccine, must be discarded, if not used within 30 minutes.
Recombinant Zoster Vaccine (RZV), SHINGRIX®

**Precautions and Contraindications**
Screen all patients for precautions and contraindications to immunization.

**Recommended Schedule:**
Recombinant zoster vaccine is recommended by the Advisory Committee on Immunization Practices (ACIP) for these age groups:

- Adults Aged 50 Years and Older
  - **SHINGRIX®** (RZV) vaccine is indicated for prevention of herpes zoster (shingles) and related complications for immunocompetent adults aged 50 years and older.
  - RZV vaccine is recommended (per ACIP) for the prevention of herpes zoster (shingles) and related complications for immunocompetent adults aged 50 years of age and older who previously received zoster vaccine live, ZVL (ZOSTAVAX®). * RZV vaccine should not be given less than 2 months after receipt of ZVL.
  - RZV vaccine is preferred (per ACIP) over ZVL vaccine for the prevention of herpes zoster and related complications in adults aged 50 years and older.
  - RZV vaccine is recommended (per ACIP) in adults aged 50 years and older with chronic medical conditions (e.g., chronic renal failure, diabetes mellitus, rheumatoid arthritis, and chronic pulmonary disease).
  - RZV vaccine is recommended (per ACIP) in adults aged 50 years and older taking low-dose immunosuppressive therapy (e.g., less than 20 mg/day of prednisone or equivalent or using inhaled or topical steroids) and persons anticipating immunosuppression or who have recovered from an immunocompromising illness.
- Adults Aged 60 Years and Older - administer either RZV or ZVL (RZV is preferred).

**Dosage and Route**
Administer 0.5 mL of reconstituted RZV intramuscularly (IM) (see package insert).

**SHINGRIX®** vaccine is administered as a series of two doses. Administer the first dose at month 0 followed by a second dose administered anytime between 2 and 6 months later.

The vaccine series need not be restarted if more than 6 months have elapsed since the first dose; however, the efficacy of alternative dosing regimens has not been evaluated, data regarding the safety of alternative regimens are limited, and individuals might remain at risk for herpes zoster during a longer than recommended interval between
doses 1 and 2. If the second dose of RZV is given less than 4 weeks after the first, the second dose should be repeated. Two doses of the vaccine are necessary regardless of prior history of herpes zoster or prior receipt of ZVL.

**Anatomical Site** - Intramuscular injection in the deltoid region of the upper arm.

**Contraindications**
DO NOT administer SHINGRIX® to individuals with a history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX®. (see package insert 11 DESCRIPTION).

**Warnings and Precautions**
- Preventing and Managing Allergic Vaccine Reactions: Prior to administration, the healthcare provider should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX®.
- Current herpes zoster infection. RZV is not a treatment for herpes zoster or postherpetic neuralgia and should not be administered during an acute episode of herpes zoster.
- Pregnancy and breastfeeding. There are no available data to establish whether RZV is safe in pregnant or lactating women and there is currently no ACIP recommendation for RZV use in this population. Consider delaying vaccination with RZV in such circumstances
- Moderate or severe illness with or without fever (temporary deferral)

**Adverse Reactions**
- Local adverse reactions in individuals aged 50 years and older were pain (78%), redness (38.1%), and swelling (25.9%)*
- General adverse reactions in individuals aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%)*
- *About 1 out of 6 individuals who got recombinant zoster vaccine experienced side effects that prevented them from doing regular activities. Symptoms went away on their own in about 2 to 3 days. Side effects were more common in younger individuals.
- **To report SUSPECTED ADVERSE REACTIONS, contact VAERS at 1-800-822-7967 or http://www.vaers.hhs.gov.

**Storage and Handling**
- SHINGRIX® is supplied as two components: A single vial of adjuvant suspension component and a single vial of lyophilized gE antigen component.
- Storage before Reconstitution
  - Adjuvant suspension component vials: Store refrigerated between 36°F and 46°F (2°C and 8°C). Protect vials from light. Do not freeze. Discard if the adjuvant suspension has been frozen.
  - Lyophilized gE antigen component vials: Store refrigerated between 36°F and 46°F (2°C and 8°C). Protect vials from light. Do not freeze. Discard if the antigen component has been frozen.
• Storage after Reconstitution: After reconstitution, administer **SHINGRIX®** immediately or store refrigerated between 36°F and 46°F (2°C and 8°C) and use within 6 hours. Discard reconstituted vaccine if not used within 6 hours. Do not freeze. Discard if the vaccine has been frozen.

• Prepare **SHINGRIX®** by reconstituting the lyophilized varicella zoster virus glycoprotein E (gE) antigen component with the accompanying AS01B adjuvant suspension component. The reconstituted vaccine should be an opalescent, colorless to pale brownish liquid.

• To reconstitute the vaccine (See the Package Insert):
  - Cleanse both vial stoppers. Using a sterile needle and sterile syringe, withdraw the entire contents of the vial containing the adjuvant suspension component by slightly tilting the vial (blue-green cap). Vial 1 of 2.
  - Slowly transfer entire contents of syringe into the lyophilized gE antigen component vial (brown cap). Vial 2 of 2.
  - Gently shake the vial to thoroughly mix contents until powder is completely dissolved.

• After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine and administer intramuscularly.

**Other Important Notes**

• Immunosuppressive therapies may reduce the effectiveness of **SHINGRIX®**

• Whereas RZV is licensed for all persons aged ≥50 years, immunocompromised persons and those on moderate to high doses of immunosuppressive therapy were excluded from the efficacy studies (ZOE-50 and ZOE-70), and thus, ACIP has not made recommendations regarding the use of RZV in these patients.

• **SHINGRIX®** can be administered concomitantly, at different anatomic sites, with other adult vaccines.

• Adults with a history of herpes zoster (shingles) should receive RZV. If a patient is experiencing an episode of herpes zoster, vaccination should be delayed until the acute stage of the illness is over and symptoms abate.

• Before vaccination, providers should counsel RZV recipients about expected systemic and local reactogenicity.
  - Reactions to the first dose did not strongly predict reactions to the second dose.
  - Vaccine recipients should be encouraged to complete the series even if they experienced a grade 1-3 reaction to the first dose of RZV.
  - *Grade 3 side effects prevent an individual from doing their regular activities. (See VIS: RZV 2/12/2018*  

• The vial stoppers are not made with natural rubber latex.

**Resources:**


Food and Drug Administration. **SHINGRIX®** (Package Insert). Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration: 2017


Vaccine Information Statement (VIS): Recombinant Zoster (Shingles) Vaccine, RZV: What You Need to Know; U.S. Department of Health and Human Services (CDC); 2/12/2018
Zoster (ZOS) Vaccine Live, ZOSTAVAX®

**Precautions and Contraindications**
Screen all patients for precautions and contraindications to immunization.

**Recommended Schedule:**
Eligible persons:
- Zoster vaccine is indicated for prevention of herpes zoster (shingles) in individuals 60 years of age and older.

**Dosage and Route**
Administer entire amount (approximately 0.65 mL) of reconstituted zoster vaccine subcutaneously (see package insert). Do not inject intravascularly.

Zoster vaccine is administered as a single dose. Reconstitute the vaccine using only the diluent supplied, and use all of the diluent. The supplied diluent is free of preservatives.

**Anatomical Site**
- Subcutaneously in the outer aspects of the deltoid

**Precautions**
- Moderate or severe illness with or without fever (temporary deferral)

**Contraindications**
ZOSTAVAX® should not be administered to individuals:
- With a history of anaphylactic/anaphylactoid reaction to gelatin, neomycin, or any other component of the vaccine (see WARNINGS).
- With a history of primary or acquired immunodeficiency states including leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system; or AIDS or other clinical manifestations of infection with human immunodeficiency viruses (see WARNINGS).

https://www.cdc.gov/vaccines/hcp/vis/vis-statements/shingles-recombinant.html

Footnotes to the “Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States, 2018”:
• Immunosuppressive therapy, including high-dose corticosteroids.
• Active untreated tuberculosis.
• Women who are or may become pregnant (see PRECAUTIONS, Pregnancy).

WARNINGS
• Vaccination with a live attenuated vaccine, such as ZOSTAVAX®, may result in a more extensive vaccine-associated rash or disseminated disease in individuals who are immunosuppressed. Safety and efficacy of ZOSTAVAX® have not been evaluated in individuals on immunosuppressive therapy, or in individuals receiving daily topical or inhaled corticosteroids or low-dose oral corticosteroids.
• Neomycin allergy commonly manifests as a contact dermatitis, which is not a contraindication to receiving this vaccine.
• Persons with a history of anaphylactic reaction to topically or systemically administered neomycin should not receive ZOSTAVAX® (see CONTRAINDICATIONS).
• ZOSTAVAX® is not a substitute for VARIVAX® [Varicella Virus Vaccine Live (Oka/Merck)] and should not be used in children.

Adverse Events
• See the product’s package insert.
• See Adverse Events Following Vaccinations page of this section

Storage and Handling
• Reconstitute the vaccine using only the diluent supplied. The supplied diluent is free of preservatives
• ZOSTAVAX® is stored frozen and should be reconstituted immediately upon removal from the freezer. Before reconstitution, protect from light.
• The vaccine should be administered immediately after reconstitution, to minimize loss of potency. Discard reconstituted vaccine if it is not used within 30 minutes.
• The diluent should be stored separately at room temperature or in the refrigerator.
• To reconstitute the vaccine: Withdraw the entire contents of the diluent vial into a syringe. Inject all of the diluent in the syringe into the vial of lyophilized vaccine and gently agitate to mix thoroughly.
• Do not freeze reconstituted vaccine.

Other Important Notes
• Withdraw the entire contents into a syringe and inject the total volume of reconstituted vaccine subcutaneously; preferably in the upper arm

Tuberculin Testing and Live Vaccines
Recommendations for use of the tuberculin skin test are independent of those for immunization. Tuberculin testing at any age is not required before administration of live-virus vaccines. A tuberculin skin test (TST) can be applied at the same visit during which these vaccines are administered. Measles vaccine temporarily can suppress tuberculin reactivity for at least 4 to 6 weeks. The effect of live-virus varicella, yellow fever, and live-attenuated influenza vaccines on tuberculin skin test reactivity is not known. In the absence of data, the same TST spacing recommendation should be applied to these vaccines as described for MMR. There is no evidence that inactivated vaccines, polysaccharide vaccines or recombinant or subunit vaccines or toxoids interfere with immune response to TST.
Tuberculin Skin Testing (TST) and Zoster Vaccine (ZOS)

- Apply TST at same visit as ZOS (preferred strategy)
- Apply TST first and administer ZOS when TST is read (least favored option because receipt of ZOS is delayed) (least preferred strategy)
- Delay TST at least 4 weeks if ZOS is given first.
**Perinatal Hepatitis B Prevention Program and Case Management Protocol**

Kentucky Administrative Regulation, 902 KAR 2:020, requires all licensed health professionals and facilities to report hepatitis B infection in pregnant women to the local or state health department. The Perinatal Hepatitis B Prevention Program consists of surveillance, tracking, and a reminder/recall program for infants born to hepatitis B surface antigen (HBsAg)-positive women.

Each local health department (LHD) must designate one person as the Perinatal Hepatitis B Prevention Coordinator for case management of these infants.

**Screening and Reporting**

- Kentucky Revised Statute 214.160, [http://www.lrc.ky.gov/statutes/statute.aspx?id=8792](http://www.lrc.ky.gov/statutes/statute.aspx?id=8792), requires that all pregnant women shall be screened for hepatitis B surface antigen (HBsAg) during every pregnancy. This testing shall be completed regardless of past test results or hepatitis B immunization status.

- If a woman has a positive HBsAg screening, notification to the local or state health department “shall be considered a priority and shall be made within one (1) business day per 902 KAR 2.020”, [http://www.lrc.ky.gov/kar/902/002/020.htm](http://www.lrc.ky.gov/kar/902/002/020.htm).

- If a woman has a positive HBsAg screening, that woman must have further serological testing completed for confirmation of infection, unless she is known to have chronic hepatitis B infection.
  - CDC recommended additional tests shown in the “Screening and Referral Algorithm for Hepatitis B Virus (HBV) Infection among Pregnant Women” on page 2, to include: hepatitis B e antigen (HBeAg, associated with a higher risk of infectivity when positive), quantitative HBV DNA concentration, and alanine aminotransferase (ALT). Assure that medical providers are aware of CDC recommendations for immediate referral of a pregnant woman to a hepatitis specialist when results on those additional lab tests are reported as:
    - HBeAg-positive
    - HBV DNA concentration of 20,000 IU/mL or greater
    - ALT of 19 IU/L or greater

- See Table 1 for correct interpretation of the results of the following serological markers that may also be ordered by medical providers: HBsAg, antibody to hepatitis B core antigen (total anti-HBc and IgM anti-HBc).

- The American Association for the Study of Liver Diseases (AASLD) suggests maternal antiviral therapy when the maternal HBV DNA is >200,000 IU/mL. All HBsAg positive pregnant women should receive information concerning HBV that discusses the potential use of antiviral therapy, and the importance of prophylaxis for their infant.
Women who present to the delivering hospital with an unknown HBsAg status must have lab tests drawn at the time of delivery to determine their HBsAg status. The results must be recorded on the Perinatal Hepatitis B Prevention Form for Infants (EPID 399) form prior to discharge and sent to the health department in the county of residence of the mother, whether located in Kentucky or in another state.

If it is not possible to determine the mother’s HBsAg status (e.g., when a parent or person with lawful custody safely surrenders an infant confidentially shortly after birth), the vaccine series should be completed according to a recommended schedule for infants born to HBsAg-positive mothers. The final dose in the series should not be administered before age 24 weeks (164 days). These infants should receive post vaccination serologic testing (PVST) at age 9-12 months, and revaccination if necessary.

Positive results must be reported in the National Electronic Disease Surveillance System (NEDSS) or on a Hepatitis B Infection in Pregnant Women or Child (EPID 394) form. Forward all HBsAg-positive results on pregnant women, reported on the EPID 394 form, to the Kentucky Perinatal Hepatitis B Prevention Coordinator by mail or fax, within one business day of results being reported:

Mail the results to:

Perinatal Hepatitis B Prevention Coordinator  
275 East Main Street, HS2E-B  
Frankfort, KY 40621

Fax the results to 502-564-4760
Screening and Referral Algorithm for Hepatitis B Virus (HBV) Infection among Pregnant Women

**HbsAg**

- **Yes**
  - Report HbsAg positive pregnant women to Prenatal Hepatitis B Prevention Program
  - Identify all household and sexual contacts and recommend screening by primary care provider

- **No**
  - Assess if at high risk* for acquiring HBV infection
    - Consider vaccination during pregnancy or postpartum
    - Repeat HbsAg testing when admitted for delivery
  - No further action needed

**Order Additional Tests:**
- HbsAg (Hepatitis B antigen)
- HBV DNA Concentration
- ALT (alanine aminotransferase)

- **No**
  - Refer for care postpartum

- **Yes**
  - Refer to specialist immediately during pregnancy

*High risk for HBV infection includes household or sexual contacts of HbsAg-positive patients, injection drug users, more than one sex partner during the past six months, evaluation or treatment for a sexually transmitted disease, HIV infection, chronic liver disease, or end-stage renal disease, and international travel to regions with HbsAg prevalence of ≥2%.


[Link to PDF](https://www.cdc.gov/hepatitis/hbv/pdfs/prenatalhbsagtesting.pdf)
<table>
<thead>
<tr>
<th>Test</th>
<th>Results</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg Anti-HBc</td>
<td>Negative</td>
<td>Susceptible to infection</td>
</tr>
<tr>
<td>HBc Anti-HBs</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>HBsAg</td>
<td>Negative</td>
<td>Immune due to vaccination</td>
</tr>
<tr>
<td>Anti-HBc Anti-HBs</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Positive with ≥10 mIU/mL</td>
<td></td>
</tr>
<tr>
<td>HBsAg Anti-HBc</td>
<td>Negative</td>
<td>Immune and recovered from past hepatitis B virus (HBV) infection</td>
</tr>
<tr>
<td>HBc Anti-HBs</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>HBsAg Anti-HBc</td>
<td>Positive</td>
<td>Acutely infected</td>
</tr>
<tr>
<td>HBc IgM anti-HBc</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>Anti-HBs</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>HBsAg Anti-HBc</td>
<td>Positive</td>
<td>Chronically infected</td>
</tr>
<tr>
<td>HBc IgM anti-HBc</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>HBsAg Anti-HBc</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>HBc Anti-HBs</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>HBsAg Anti-HBc</td>
<td>Negative</td>
<td>Four interpretations are possible**</td>
</tr>
<tr>
<td>HBc Anti-HBs</td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td></td>
</tr>
</tbody>
</table>
Table 1: Interpretation of Hepatitis B Serologic Tests

+ For infants born to hepatitis B-infected mothers, postvaccination serologic testing (PVST), consisting of testing for HBsAg and quantitative anti-HBs, should be ordered at age 9 through 12 months (or 1 through 2 months after the final dose of the vaccine series, if delayed) [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm?s_cid=mm6439a6_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm?s_cid=mm6439a6_w).

Postvaccination quantitative anti-HBs antibody testing, when it is recommended for other persons, should be performed 1 to 2 months following the last dose of the hepatitis B vaccine series.

** 1. May be recovering from acute HBV infection.

2. May be distantly immune, and the test is not sensitive enough to detect a very low level of anti-HBs in serum.

3. May be susceptible with a false positive anti-HBc.

4. May be chronically infected and have an undetectable level of HBsAg present in the serum.

Taken from *Epidemiology and Prevention of Vaccine Preventable Diseases* (Pink Book) 13th edition (2015), page 153.
## Table 2: Hepatitis B Post Exposure Management of Infants with Birth Weight of 2,000 Grams or More

### HEPATITIS B (HepB) VACCINE SCHEDULES FOR NEWBORNS INFANTS BY MATERNAL HEPATITIS B SURFACE ANTIGEN (HBsAg) STATUS*

<table>
<thead>
<tr>
<th>Maternal HBsAg Status</th>
<th>Monovalent (Single-antigen) HepB vaccine</th>
<th>Monovalent (Single-antigen) HepB and Combination Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dose</td>
<td>Age</td>
</tr>
<tr>
<td>Positive</td>
<td>1†</td>
<td>Birth (12 hours or less)</td>
</tr>
<tr>
<td></td>
<td>HBIG§</td>
<td>Birth (12 hours or less)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1 through 2 months</td>
</tr>
<tr>
<td></td>
<td>3¶</td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown**</td>
<td>1†</td>
<td>Birth (12 hours or less)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1 through 2 months</td>
</tr>
<tr>
<td></td>
<td>3¶</td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>1†,++</td>
<td>Birth (24 hours or less)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1 through 2 months</td>
</tr>
<tr>
<td></td>
<td>3¶</td>
<td>6 through 18 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*See Table 3 for hepatitis B vaccine schedules for preterm infants weighing less than 2,000 grams

†Either RECOMBIVAX HB* or ENGERIX-B® should be used for the birth dose. PEDIARIX® cannot be administered at birth or before age 6 weeks.

§ Hepatitis B immune globulin (HBIG) (0.5 mL) should be administered intramuscularly in a separate anatomical site from the hepatitis B vaccine, ideally in a separate limb.

¶ The final dose in the vaccine series should not be administered before age 24 weeks (164 days). For infants born to hepatitis B-infected mothers, postvaccination serologic testing (PVST), consisting of testing for HBsAg and quantitative anti-HBs, should be ordered at age 9 through 12 months (or 1 through 2 months after the final dose of the vaccine series, if delayed).

** When the maternal HBsAg status is unknown, the mother should have blood drawn and tested for HBsAg after admission for delivery. If the mother is found to be HBsAg-positive, the infant should receive HBIG as soon as possible but no later than 7 days after birth.

For medically stable infants weighing ≥ 2000 grams at birth and born to HBsAg-negative mothers, the first dose of vaccine should be administered within 24 hours of birth (new recommendation in 2018). Only single-antigen HepB vaccine should be used for the birth dose.

Adapted from the 2015 Red Book (Hepatitis B chapter), the Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2017*.
Table 3. Hepatitis B Post Exposure Management of Preterm Infants, Birth Weight Less Than 2,000 grams, by Maternal Hepatitis B Surface Antigen (HBsAg) Status

<table>
<thead>
<tr>
<th>Maternal HBsAg Status</th>
<th>Recommendations</th>
</tr>
</thead>
</table>
| Positive              | • Administer HBIG* and monovalent (single-antigen) hepatitis B vaccine within 12 hours of birth.  
• Do not count the birth dose as part of the vaccine series  
• Administer 3 additional hepatitis B vaccine doses with either monovalent HepB vaccine at 1, 2 through 3, and 6 months of age, or a hepatitis B containing combination vaccine at 2, 4, and 6 months of age (PEDIARIX®)  
• For infants born to hepatitis B-infected mothers, postvaccination serologic testing, consisting of testing for HBsAg and quantitative anti-HBs, should be ordered at age 9 through 12 months (or 1 through 2 months after the final dose of the vaccine series, if delayed) |
| Unknown               | • Administer HBIG and monovalent (single-antigen) hepatitis B vaccine within 12 hours of birth.  
• Test mother for HBsAg status  
• Do not count the birth dose as part of the vaccine series.  
• Administer 3 additional hepatitis B vaccine doses with either monovalent HepB vaccine at 1, 2 through 3, and 6 months of age, or a hepatitis B containing combination vaccine at 2, 4, and 6 months of age (PEDIARIX®)  
• For infants born to hepatitis B-infected mothers, postvaccination serologic testing, consisting of testing for HBsAg and quantitative anti-HBs, should be ordered at age 9 through 12 months (or 1 through 2 months after the final dose of the vaccine series, if delayed). |
| Negative              | • Delay first dose of hepatitis B vaccine until age 1 month if medically stable or at hospital discharge.  
• Complete the hepatitis B vaccine series with either monovalent HepB vaccine at 1, 2 through 3, and 6 months, or a hepatitis B containing combination vaccine at 2, 4 and 6 months (PEDIARIX®) |

* Hepatitis B immune globulin (HBIG) (0.5 mL) should be administered intramuscularly in a separate anatomical site from the hepatitis B vaccine, ideally in a separate limb.

The final dose in the vaccine series should not be administered before age 24 weeks (164) days. For infants born to hepatitis B-infected mothers, postvaccination serologic testing, consisting of testing for HBsAg and quantitative anti-HBs, should be ordered at age 9 through 12 months (or 1 through 2 months after the final dose of the vaccine series, if delayed).
RESPONSIBILITIES

Kentucky Perinatal Hepatitis B Prevention Coordinator

- Maintains the Kentucky Perinatal Hepatitis B prevention database.
- Serves as a resource for the local health departments.
- Develops templates and educational materials for the local health departments to use in case management for the parent and providers.

Local Health Department Perinatal Hepatitis B Prevention Coordinator

- Determine pregnancy status on all reports of HBsAg-positive women aged 11 through 46 years.
- Follow-up with the reporting provider of an HBsAg-positive pregnant woman to obtain more information needed for case management. The Coordinator should ensure that the provider is aware of the pregnant woman’s HBsAg-positive status and of the additional CDC recommended tests in the “Screening and Referral Algorithm for Hepatitis B Virus (HBV) Infection among Pregnant Women”.
- Complete an EPID 394 form or enter the case information into NEDSS on all HBsAg-positive pregnant women.
- Initiate a case management form (EPID 395 form).
- Forward a copy of the EPID 394 form to the Kentucky Perinatal Hepatitis B Prevention Coordinator at the Kentucky Department for Public Health in Frankfort.
- Contact the HBsAg-positive woman as soon as a case is identified. Provide education and counseling about protecting the liver, the prevention of perinatal hepatitis B infection for the infant, and protecting others from exposure to the hepatitis B virus. For educational materials, visit http://www.cdc.gov/hepatitis. A letter may be sent (PHBPP-1 form).
- Determine sexual and household contacts of the HBsAg-positive woman and offer them education, testing and/or hepatitis B immunizations. Testing should not unduly delay or impede immunization efforts. Document contacts and outcomes in NEDSS or on the EPID 395 form. Refer all HBsAg-positive patients to a medical provider to monitor outcomes or progress of HBV infection. Document if referral was completed.
- Send a reminder letter or call mother one month prior to delivery. (PHBPP-2 form)
- Notify the delivering hospital of the mother’s HBsAg status. (PHBPP-3 form)
- Once an infant is born to an HBsAg-positive mother, verify that the infant received HBIG and hepatitis B vaccine after delivery per the EPID 399 form from the delivering hospital.
- Review all EPID 399 forms for missing information. All sections of the EPID 399 form must be completed. The EPID 399 form should be sent to the local health department in the mother’s county of residence for case management, whether located in Kentucky or in another state.
- Contact the hospital if the due date is two weeks past for follow-up.
• Notify the infant’s provider for follow-up care, and refer them to the American Academy of Pediatrics recommendations in the 2015 Red Book for Post Exposure Management of Infants born to HBsAg-positive mothers and to the 2015 “Update: Shortened Interval for Postvaccination Serologic Testing of Infants Born to Hepatitis B-Infected Mothers,” http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm?s_cid=mm6439a6_w from CDC. A case management form can be sent to this provider. (PHBPP 4, and PHBPP-5 forms).

• Ensure the infant, born to an HBsAg-positive mother, receives three or more doses of the hepatitis B vaccine series and postvaccination serological testing (PVST). Send reminder letters and/ or make phone calls to the mother and the provider two to four weeks prior to each vaccination dose and for serology testing due dates (PHBPP-6, PHBPP-7, and PHBPP-8 forms).

• HBsAg negative infants with anti-HBs less than 10 mIU/mL should be revaccinated with a single dose of HepB vaccine and receive PVST one to two months later. Infants whose anti-HBs remains less than 10 mIU/mL following single dose revaccination should receive two additional doses of HepB vaccine, followed by PVST one to two months after the final dose.
  o Based on clinical circumstances or family preference, HBsAg-negative infants with anti-HBs less than 10 mIU/mL may instead be revaccinated with a second, complete 3-dose series, followed by PVST performed one to two months after the final dose of vaccine.

• Send a final letter to mother with dates immunizations were received and results of PVST for the infant’s immunization record. (PHBPP-9 form)

• Case is closed if the results of PVST indicate that the infant is HBsAg-negative and anti-HBs-positive. The results must be attached to the final printout.

• If infant is HBsAg-positive, results must be reported to the local health department or KDPH within one business day of the report of a positive result in accordance with 902 KAR 2:020.

• Send updates by the 15th of each month to the Kentucky Perinatal Hepatitis B Prevention Coordinator by mail or fax.
  o Mail the updates and lab results to:
    Perinatal Hepatitis B Prevention Coordinator
    275 East Main Street, HS2E-B
    Frankfort, KY 40621
  o Fax the updates and lab results to 502-564-4760
HBsAg-positive women identified at or after delivery

Infants born to women for whom HBsAg testing results during pregnancy are not available but other evidence suggestive of maternal HBV infection exists (e.g., presence of HBV DNA, HBeAg-positive, or mother known to be chronically infected with HBV) should be managed as if born to a HBsAg-positive mother. The infant should receive both HepB and HBIG within 12 hours of birth.

If it is not possible to determine the mother’s HBsAg status (e.g., when a parent or person with lawful custody safely surrenders an infant confidentially shortly after birth), the vaccine series should be completed according to a recommended schedule for infants born to HBsAg-positive mothers. The final dose in the series should not be administered before age 24 weeks (164 days). These infants should receive postvaccination serologic testing at age 9-12 months, and revaccination of necessary.

In some cases, HBV infection is detected at the time of delivery of the infant. In this case, the delivery hospital should contact the LHD of the county of residence for the infant and complete the EPID 399 form.

The LHD Perinatal Hepatitis B Prevention Coordinator shall confirm that the infant has received Hepatitis B vaccine and HBIG. HBIG should be given as soon as possible ideally within 12 hours of birth, but within seven days of birth, at a separate anatomical site from the hepatitis B vaccine, ideally in a separate limb. The LHD Perinatal Hepatitis B Prevention Coordinator then begins case management for infants born to an HBsAg-positive woman.
Table 4: Postvaccination Serological Test Results and Follow-Up

<table>
<thead>
<tr>
<th>Serology Test Results</th>
<th>Follow-up</th>
</tr>
</thead>
</table>
| HBsAg-negative and anti-HBs-positive (10 mIU/mL or greater) | None  
Infant is immune |
| HBsAg-negative and anti-HBs-negative (less than 10 mIU/mL) | Infant did not develop immunity.  
HBsAg negative infants with anti-HBs less than 10 mIU/mL should be revaccinated with a single dose of HepB vaccine and receive post vaccination serologic testing 1-2 months later. Infants whose anti-HBs remains less than 10 mIU/mL following single dose revaccination should receive two additional doses of HepB vaccine, followed by PVST 1-2 months after the final dose.  
- Based on clinical circumstances or family preference, HBsAg-negative infants with anti-HBs less than 10 mIU/mL may instead be revaccinated with a second, complete 3-dose series, followed by post vaccination serologic testing (PVST) performed 1-2 months after the final dose of vaccine. |
| HBsAg-positive and anti-HBs-negative | Infant is infected with Hepatitis B virus and will need medical follow up. Send a report to Kentucky Perinatal Hepatitis B Prevention Coordinator in accordance with 902 KAR 2:020 and CSG protocol titled “Reportable Diseases Deadlines for Health Professionals and for Local Health Departments”. |

Information from MMWR 2005, Vol. 54 and ACIP VFC Resolution 2/17-1

Managing Missed Vaccination/ Serology Appointment

- Send a reminder card for missed appointments.
- Send a letter, conduct home visit and/or make a telephone call to the parent or guardian.
- Send a certified letter for continued non-compliance. If there is no response to that letter, the infant is considered lost to follow-up.
- Send updates to the Kentucky Perinatal Hepatitis B Coordinator by the 15th of each month.
Lost to Follow-up

In the nine to 18 months that it takes to complete the newborn case management, some patients will move without providing the LHD with new contact information. To find patients, LHDs may use Women Infants and Children (WIC) and Medicaid databases to locate updated demographics. Additional tips for locating these patients can include:

- Call telephone information (411)
- Internet search engines (e.g., Google or white pages)
- Directories that list occupants of each household; most STD programs have directories like this.
- Old phone numbers listed in patient paperwork. Sometimes relatives or friends may still be at that number.
- Transpose the digits of telephone numbers and addresses.
- Search older health department records.

A patient can be classified as “lost to follow-up” and the file closed once the following conditions are met and the Kentucky Perinatal Hepatitis B Coordinator believes further investigation would be fruitless. Examples include:

- Failed phone contact after three calls.
- Failed home visit.
- Failed mail deliveries including returned certified letters.
- Parent refuses to participate in case management with the Perinatal Hepatitis B Prevention Program.

Document all attempts to find infants and their parents. If an infant is lost to follow-up and the infant is later located, the case should be reopened and follow-up continued from that point. Consult the Kentucky Perinatal Hepatitis B Prevention Coordinator for assistance.

Optional Forms and Templates for Perinatal Hepatitis B Prevention Program (PHBPP)

See CSG Forms Section, [https://chfs.ky.gov/agencies/dph/dpqj/hcab/Documents/FormsListing.doc](https://chfs.ky.gov/agencies/dph/dpqj/hcab/Documents/FormsListing.doc), for the following forms:

- EPID-395: EPID 395: Kentucky PHBPP Case Management Worksheet
- PHBPP-1: PHBPP Introduction Letter (for the Mother)
- PHBPP-2: Reminder Letter Prior to Delivery
- PHBPP-3: Notification Letter to Hospital about an HBsAg + Pregnant Woman
- PHBPP-4: Letter to the Infant’s Primary Care Physician
- PHBPP-5: PHBPP for Infants Follow-up Form
- PHBPP-6: Vaccination Reminder Letter to the Mother
- PHBPP-7: PVST Reminder Letter to the Mother
- PHBPP-8: PVST Reminder Letter to the Primary Care Provider
- PHBPP-9: Notification Letter to the Mother that Infant is Immune
References and Additional Resources

Perinatal Transmission Guidelines and Recommendations at the CDC’s Website at
https://www.cdc.gov/hepatitis/hbv/index.htm

Educational materials at http://www.cdc.gov/hepatitis/Partners/Perinatal/EducationalMaterials.htm

ACIP VFC Resolution 2/17-1, “Vaccines to Prevent Hepatitis B”

Update: Shortened Interval for Postvaccination Serologic Testing of Infants Born to
Hepatitis B-Infected Mothers, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm?s_cid=mm6439a6_w

CDC Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on
Immunization Practices (ACIP). MMWR, 2018, Vol. 67/No.1

Footnotes to the “Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger,
UNITED STATES, 2018”:
ADVERSE EVENTS FOLLOWING VACCINATION

Adverse events have been reported following the administration of all vaccines. These events range from frequent, minor, local reactions to extremely rare, severe, systemic illness.

More complete information on adverse reaction to a specific vaccine may be found in the ACIP recommendations for each vaccine.

Events that occur after receipt of vaccine purchased with public (federal, state, and/or local government) funds must be reported on the Vaccine Adverse Event Reporting System (VAERS Form) by the administering health provider. There are three ways to report to VAERS, http://vaers.hhs.gov/esub/index:

1) Report Online via a secure website at https://vaers.hhs.gov/esub/step1

Vaccine Adverse Events Reporting System
P. O. Box 1100

Rockville, MD 20849-1100

To ensure that the Kentucky Immunization Program is aware of these events, please fax a copy to 502-564-4760.

Refer to the VAERS Table of Reportable Events Following Vaccination or the Pink Book for additional vaccine information and information regarding adverse events that are required to be reported.
# Lab

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Laboratory Testing

Overview:

Laboratory tests may involve the testing of body fluids such as blood and urine, or other tissues, secretions, and substances. Laboratory tests provide clinicians and health providers with clues and indicators to possible health problems. Information from lab tests can help to identify changes in health condition, diagnose diseases or conditions, plan treatment for a disease or condition, evaluate treatment response, and help to monitor diseases and conditions over time.

Laboratory tests usually have a reference range or value(s) of what is considered normal. Such ranges or values are usually based upon the testing results from healthy people and may incorporate factors such as age, gender, ethnicity, geography, season and other variables. Laboratory ranges and values may vary slightly from lab to lab for the same test due to differences in the method of the test, equipment used in the testing, and the population of people tested to establish the range.

Many national public health organizations and authorities such as the Centers for Disease Control and Prevention (CDC), American Diabetes Association (ADA), and National Lipid Association and the National Cholesterol Education Program (NCEP) have provided national laboratory references and values to help guide health care providers and professionals. Values and ranges on some of the more common public health laboratory tests are represented in the table from those nationally recognized organizations and associations, as well as tests provided from our Kentucky Department for Public Health (KDPH) state reference laboratory; Division of Laboratory Services (DLS). Refer to the following website; http://chfs.ky.gov/dph/info/lab/, for a comprehensive “Reference List of Tests” and information on DLS testing and services. The Division of Laboratory Services can be contacted at 502-564-4446.
# Laboratory Tests and Guidelines

Tests and procedures with asterisks (**) denote tests and procedures not provided by the DLS (Not all-inclusive)

<table>
<thead>
<tr>
<th>Laboratory Test/Procedure</th>
<th>Findings and Directives</th>
<th>Follow-up Recommendations &amp; Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cholesterol (total)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-19 years</td>
<td>Venous specimens should <strong>not</strong> be drawn on pediatric patients – if risk factors are positive, a referral should be made.</td>
<td>See Pediatrics Section for Guidelines. Refer to the Expert Panel Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: Classification of cholesterol levels in pediatric patients Acceptable: &lt;170 mg/dL Borderline: 170–199 mg/dL High: &gt;200 mg/dL</td>
</tr>
<tr>
<td><strong>Cholesterol (total) cont.</strong></td>
<td>Normal: &lt;200 mg/dL</td>
<td>See Individual Program Guidelines Normal: 1. Repeat every 5 years or at clinician’s discretion 2. Provide preventive counseling</td>
</tr>
<tr>
<td>&gt;20 years, male or female</td>
<td>Abnormal: &gt;200 mg/dL</td>
<td>Abnormal: 1. Schedule a fasting Lipid Profile or refer for medical management 2. Refer high-risk (&gt;240 mg/dL) for MNT 3. Identify with patient modifiable risk factors 4. Discuss lifestyle changes individualized to patient needs and modifiable risk factors (provide resource information)</td>
</tr>
</tbody>
</table>

For lab values and management guidelines specific for patients with diabetes, see Diabetes Section and refer to the National Lipid Association and the National cholesterol Education Program (NCEP)

| Chlamydia/Gonorrhea Screening | Negative, Positive, or Equivocal (Submit another specimen) | See STD Section for Guidelines. |

| **Glucose** 2 – 20 years | Normal: | See Pediatrics Section. |
### Commonly Performed Lab Tests and Procedures continued (Not all-inclusive)

<table>
<thead>
<tr>
<th>Laboratory Test/Procedure</th>
<th>Findings and Directives</th>
<th>Follow-up Recommendations &amp; Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Glucose - Gestational</strong></td>
<td>50 gm Oral Glucose Load</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 hour after 50 gm load Plasma Glucose</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Normal: &lt;140 mg/dL</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>100 gm Glucose Tolerance Test</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diagnostic Criteria: Two or more of the venous plasma concentrations listed below must be met or exceeded for positive diagnosis.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fasting: 95 mg/dL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 hour: 180 mg/dL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 hour: 155 mg/dL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 hour: 140 mg/dL</td>
<td></td>
</tr>
<tr>
<td><strong>Glucose - Postpartum</strong></td>
<td>Fasting glucose</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Normal: &lt;100 mg/dL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Abnormal: &gt;100 mg/dL</td>
<td></td>
</tr>
<tr>
<td><strong>Glucose (for patients not diagnosed with diabetes)</strong></td>
<td>Plasma or Plasma Equivalent Value</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Normal: Fasting: &lt;100 mg/dL</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** The Glucose Tolerance Test (GTT) should be performed in the morning after an overnight fast of at least 3 days of unrestricted diet (≥150 g carbohydrates per day) and unlimited physical activity. The patient should remain seated and should not smoke throughout the test.

See Gestational Diabetes Guidelines in the Prenatal Section.


See Gestational Diabetes Guidelines in the Prenatal Section.

Normal: 1. Repeat periodic screening.
**Hemoglobin/Hematocrit**

<table>
<thead>
<tr>
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<th>Findings and Directives</th>
<th>Follow-up Recommendations &amp; Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hemoglobin/Hematocrit</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-3 days (cap)</td>
<td>Normal: 14.5-22.5 g/dL</td>
<td>1. Screen for WIC Services</td>
</tr>
<tr>
<td>1-2 wk</td>
<td>Normal: 12.5-18.5 g/dL</td>
<td>2. For Hgb &gt;9.0, Hct &gt;27.0 but less than the recommended normals, repeat screen in 1–3 months.</td>
</tr>
<tr>
<td>1-6 months</td>
<td>Normal: 10.0-13.0 g/dL</td>
<td>3. Refer for medical evaluation when Hgb ≤9.0, Hct ≤27.0.</td>
</tr>
<tr>
<td>7 mo-2 yrs</td>
<td>Normal: 10.5-13.0 g/dL</td>
<td>4. Refer to appropriate age section for follow-up.</td>
</tr>
<tr>
<td>2-5 yrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-12 yrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-18 yrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Waived Hemoglobin A1C**
(Performed by LHD or health care provider)
NOTE: Waived fingerstick Hgb A1C testing is not for the screening or diagnosis of diabetes

**Normal Reference Range**
4.0-6.5 %

**Abnormal:**
Fasting: ≥100 mg/dL
Random (Casual): ≥140 mg/dL

**Note:**
Meter must yield a plasma equivalent value if capillary specimen performed

**Abnormal:**
1. Refer all positive results to physician for follow-up.
2. Provide counseling on nutrition, exercise, risk factor reduction, food preparation and purchasing.
3. Refer for Medical Nutrition Therapy.

Refer to the National Institute of Diabetes and Digestive and Kidney Disease website for:
http://www.niddk.nih.gov/health-information/health-topics/diagnostic-tests/a1c-test-diabetes/Pages/index.aspx

Commonly Performed Lab Tests and Procedures continued (Not all-inclusive)
<table>
<thead>
<tr>
<th>Age/Gender</th>
<th>Hematocrit</th>
<th>Abnormal Hematocrit</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-18 yrs Male &gt;18 yrs</td>
<td>11.5-13.0</td>
<td>34-39</td>
</tr>
<tr>
<td>Female &gt;18 yrs</td>
<td>11.5-15.5</td>
<td>35-45</td>
</tr>
<tr>
<td>Pregnant Female: Trimester 1</td>
<td>13.0-16.0</td>
<td>37-49</td>
</tr>
<tr>
<td>Trimester 2</td>
<td>12.0-16.0</td>
<td>36-46</td>
</tr>
<tr>
<td>Trimester 3</td>
<td>13.5-17.5</td>
<td>41-53</td>
</tr>
<tr>
<td>12.0-16.0</td>
<td>36-46</td>
<td></td>
</tr>
</tbody>
</table>

**Hepatitis B**
(For Prenatal and LHD employees)

Screen individuals with the following risk factors:

1. Prenatal patient for initial screen, obtain HBsAg.
2. Prenatal patient with known exposure to HBsAg positive partners, obtain HBsAg, Anti-HBs, and Anti-HBc.
3. LHD Employee-Post-vaccine testing, obtain Anti-HBs at 1–2 mos. post-vaccine.
4. Employee Percutaneous or permucosal exposure: obtain baseline and 6 mos. (Anti-HBs)
5. Percutaneous or permucosal exposure, test source patient; obtain HBsAg.

**Non-reactive (Negative)**

**Repeatedly Reactive (Positive)**

Refer to the Mayo Medical Laboratories website for clinical interpretation; component of the Complete Blood Count (CBC) in the test catalog.

Refer to Reportable Disease Desk Reference.

Screen Household and sexual contacts of prenatal patients who screen positive. Test for Anti-HBc and Anti-HBs.

Infants born to HBsAg positive mothers should be tested 3–9 mos. after their third dose of hepatitis vaccine. (Obtain Anti-HBs if testing post-immunization therapy.)
Commonly Performed Lab Tests and Procedures continued *(Not all-inclusive)*

<table>
<thead>
<tr>
<th>Laboratory Test/Procedure</th>
<th>Findings and Directives</th>
<th>Follow-up Recommendations &amp; Guidelines</th>
</tr>
</thead>
</table>
| HIV Testing & Counseling (Male and Female) | **Non-reactive (Negative)**  
| | **Repeatedly Reactive (Positive)**  
| | **POSITIVE RESULTS ARE SIGNIFICANT.** | See HIV Section for Guidance.  
| | | Occupational – LHD Employee  
| | | Percutaneous or permucosal exposure: recommended testing schedule is Baseline, 6 weeks, 3 months, 6 months, and 1 year. |
**Lead Screening**
(Blood lead screening for ‘at-risk’ children ages 6 months to 6 years and prenatal patients)

<table>
<thead>
<tr>
<th>Normal:</th>
<th>Lead Poisoning (≥15 µg/dL level for public health action): Confirmed Lead Level of ≥15 µg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>While no amount of lead in the blood is normal, for children less than 72 months of age, CDC recommends assuring blood lead levels at 0–4.9 µg/dL to minimize neurological effects.</td>
<td></td>
</tr>
</tbody>
</table>

**High Risk:**
Lead level of 5–14.9 µg/dL

**See Lead Section for guidance.**

---

**Lipid Profile, Fasting**

<table>
<thead>
<tr>
<th>Normal:</th>
<th>Normal:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol &lt;200 mg/dL</td>
<td>1. Repeat screen in 5 years and at clinician’s discretion</td>
</tr>
<tr>
<td>HDL Cholesterol(male) ≥60 mg/dL</td>
<td>2. Provide preventive counseling</td>
</tr>
<tr>
<td>HDL Cholesterol(female) ≥60 mg/dL</td>
<td><strong>Borderline/High Risk:</strong></td>
</tr>
<tr>
<td>LDL Cholesterol &lt;100 mg/dL</td>
<td>1. Refer for Medical Evaluation</td>
</tr>
<tr>
<td>Triglycerides &lt;150 mg/dL</td>
<td>2. Refer high-risk (&gt;240 mg/dL) for Medical Nutrition Therapy (MNT) at clinician’s discretion.</td>
</tr>
</tbody>
</table>

**Borderline Risk:**
Total Cholesterol 200-239 mg/dL
HDL Cholesterol(male) 40-59 mg/dL
HDL Cholesterol(female) 50-59 mg/dL
LDL Cholesterol 130-159 mg/dL
Triglycerides 150 -199 mg/dL

**High Risk:**
Total Cholesterol ≥240 mg/dL
HDL Cholesterol(male) < 40 mg/dL
HDL Cholesterol(female) < 50 mg/dL
LDL Cholesterol >160 mg/dL
Triglycerides >200 mg/dL

---

**Note:**
Screen individuals for the following indications:

- Persons with total blood cholesterol of 200 mg/dL or greater
- Persons diagnosed with diabetes
- Persons with multiple (2+) risk factors for CVD (family history of premature CVD, hypertension, hyperlipidemia, diabetes, substance abuse including alcohol; cigarette smoking; obesity; signs and symptoms of diabetes and CVD; age-men ≥45 and women >55 years; Race-African Americans; and physical inactivity).
- Obtain at least every 5 years in adults age 21 and over
<table>
<thead>
<tr>
<th>Laboratory Test/Procedure</th>
<th>Findings and Directives</th>
<th>Follow-up Recommendations &amp; Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Newborn Screening</strong> (Birth to 6 months of age)</td>
<td><strong>Findings and Directives for all Metabolic Screening Disorders</strong></td>
<td>No further action necessary</td>
</tr>
<tr>
<td><strong>MS/MS tests by Category</strong></td>
<td><strong>Normal</strong></td>
<td>Laboratory will make immediate referral to university specialist. NBS follow-up staff will notify PCP of referral and provide educational materials for PCP and parents.</td>
</tr>
<tr>
<td><strong>Amino Acid Disorders:</strong> Argininosuccinate Acidemia, Citrullinemia, Homocystinuria, Maple Syrup Urine Disease, Phenylketonuria, Tyrosinemia, Argininemia, Hyperphenylalaninemia, Hypermethioninemia, Nonketotic Hyperglycinemia</td>
<td><strong>Abnormal</strong></td>
<td>Results that apply to all disorders in the Newborn Screening panel. Follow-up guidelines will be the same for all disorders with these results.</td>
</tr>
<tr>
<td><strong>Fatty Acid Disorders:</strong> Carnitine uptake defect, Long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHAD), Medium-chain acyl-CoA dehydrogenase deficiency (MCAD), Short-chain acyl-CoA dehydrogenase deficiency (SCAD), Trifunctional protein deficiency, Very long-chain acyl-CoA dehydrogenase deficiency (VLCA), Carnitine acylcarnitine translocase deficiency, Carnitine palmitoyl transferase deficiency, Glutaric academia type II.</td>
<td><strong>Unsatisfactory, and Normal but &lt;24 Hours of Age are results that apply to all disorders in the Newborn Screening panel. Follow-up Guidelines will be the same for all disorders with these results.</strong></td>
<td>Rescreen as directed in report</td>
</tr>
<tr>
<td><strong>Organic Acid Disorders:</strong> 3-methylcrotonyl-CoA-Carboxylase Deficiency, Beta-ketothiolase, Glutaric acidemia type 1, Isovaleric acidemia, 3-hydroxy 3-methylglutaric aciduria, Methylmalonic acidemia, methylmalonic acidemia mutase deficiency, Propionic Acidemia, Multiple carboxylase deficiency, 2-Methyl-3-Hydroxybutyric aciduria, 3-Methylglutaconic aciduria, Isobutyryl-CoA dehydrogenase deficiency, Malonic acidemia, Ethylmalonic encephalopathy, 2-Methylbutyryl-CoA dehydrogenase deficiency.</td>
<td><strong>Unsatisfactory</strong></td>
<td>Rescreen</td>
</tr>
<tr>
<td><strong>Endocrine Disorders</strong> Congenital Adrenal Hyperplasia, Congenital Hypothyroidism</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hemoglobinopathies</strong> HbSS, HbSC, HBSβ0, HbSβ+</td>
<td><strong>&lt;24 hours of age</strong></td>
<td>Transfusion Management: Rescreen for all disorders 72 hrs after transfusion.</td>
</tr>
<tr>
<td><strong>Transfusion</strong></td>
<td></td>
<td>90 days after transfusion, rescreen for any disorder that</td>
</tr>
<tr>
<td><strong>Other Disorders Utilizing Red Blood Cell Analysis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biotinidase Deficiency</td>
<td></td>
<td></td>
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<tr>
<td>Galactosemia</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Other Disorders</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cystic Fibrosis</td>
</tr>
<tr>
<td>SCID</td>
</tr>
<tr>
<td>Krabbe</td>
</tr>
<tr>
<td>Pompe</td>
</tr>
<tr>
<td>MPS-1</td>
</tr>
</tbody>
</table>

Submit filter paper specimen to the Division of Laboratory Services, make sure filter paper is “in-date”, not expired. Allow specimen to dry for at least 3 hours before mailing and mail to Lab within 24 hours of obtaining.

relies on red blood cell analysis such as **hemoglobinopathies, galactosemia**, and **biotinidase**.

See Specific Test Reports-
Follow-up as clinically indicated
**Pregnancy Test, urine**  
(performed by LHD or health care provider) | **Negative or Positive** | See pregnancy test guidelines in Family Planning Section.  
---|---|---  
**Rubella** | **Negative : Consistent with NO immunity** | **Equivocal, Borderline or Uncertain Immune status** | **Positive: Consistent with Immunity**  
| Negative immune status:  
1. Determine pregnancy status by history, date of LMP, and/or pregnancy test if necessary.  
2. Offer one MMR vaccine to persons regardless of age who have never been immunized against MMR.  
3. If patient is under age 21 and has never had MMR vaccine, can offer first and booster doses of MMR.  
4. Counsel to avoid pregnancy for at least 28 days. | Equivocal immune status: An equivocal value on two specimens 14 days apart may indicate a vaccine booster is needed. See management above (negative). | Positive immune status:  
1. Inform patient of evidence of protection against rubella  
2. Inquire about history of vaccination against measles and mumps  
3. Manage as above if no evidence of protection against measles and mumps |
<table>
<thead>
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<th>Follow-up Recommendations &amp; Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Syphilis- IGGE</strong></td>
<td>Non-reactive</td>
<td>See STD Section for Guidance.</td>
</tr>
<tr>
<td>Reactive: Confirmatory testing performed at the State Lab, may include VDRL and TPPA as recommended by CDC guidelines. See Specific Report.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Equivocal:</strong> Confirmatory testing performed at the State Lab, may include VDRL and TPPA as recommended by CDC guidelines. See Specific Report.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Urinalysis</strong> (performed by LHD or health care provider)</td>
<td>Positive or Negative</td>
<td>Recommend medical evaluation for acute or chronic conditions.</td>
</tr>
<tr>
<td>Positive dipstick for Leukocytes, Nitrates, Glucose, Ketone bodies, Protein or Blood.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Vaginal Wet Mount</strong> (performed by LHD or health care provider)</td>
<td>Normal</td>
<td>Refer to LHD Lab procedure manual and STD section</td>
</tr>
<tr>
<td>Abnormal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White Blood Cells</td>
<td></td>
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<tr>
<td>Bacterial Overgrowth</td>
<td></td>
<td></td>
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<tr>
<td>Clue Cells</td>
<td></td>
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<tr>
<td>Trichomonas</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yeast/budding yeast</td>
<td></td>
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</tr>
</tbody>
</table>
Recommendations of Lab Tasks Checklists
Waived/PPM/Moderate Laboratories

The Director/Site Coordinator is a Local Health Department (LHD) staff member who coordinates local activities and communications related to CLIA compliance. The Director/Site Coordinator oversees the quality of specific laboratory sites and serves as the local level contact person for the State Lab staff.

The following lab tasks may be assigned to relevant staff within the local health department:

**General Instructions**

- Follow the most recent package insert of manufacturer's instructions. Kit instructions may change slightly from lot to lot date the insert with the date the shipment was received as documentation. Any changes must be reflected in the procedure. Director/Site coordinator and staff must read and resign revised procedure with changes and trained as applicable on major changes.
- Perform quality control or calibration as specified by the kit manufacturer. Maintain the QC documentation for two years.
- Use the test kits/reagents in the form they are received; do not alter reagent strips by cutting them in order to test more samples per strip.
- Store and handle all tests according to the manufacturer's instructions. Never use outdated reagents.
- Inform the OIG office of any change in status of the lab (e.g., change in the medical director, practice name, address, etc.). Consult with the LHD's region assigned Laboratory surveyor.
- Follow all OSHA regulations that pertain to laboratory testing (e.g., Bloodborne Pathogens regulations).
- Document training of new testing personnel in their personnel file-training for each test and test method is required. Training should be documented before personnel begin any unsupervised testing.
- Complete Corrective Action Incident reports. Reports are used as an tool to report any nonconformity or situation outside the normal operating policy or procedure. Reports are reviewed initially and at 3 months for remedial action and resolutions as necessary. Consult with the state lab's technical staff as needed.
- Review reference lab specimen referral criteria. Obtain copy of CLIA certificate for all reference laboratories used by the LHD. Confirm specimen collection requirements and follow up all testing results.
- Send specimens for confirmatory testing when required by the manufacturer-for example, rapid group A strep kits may require a throat culture if the patient's test result is negative.
Recommendations for Waived PPM Mode rate Complexdy Laboratories
Director/Site Coordinator Responsibilities

The Director/Site Coordinator is a local health department staff member who coordinates local activities and communications related to CLIA compliance.

Director/Site Coordinator Responsibilities

- Oversee the quality of specific laboratory sde(s)
- Serve as the local level contact person for the state lab staff, taking responsibility for sharing information with lab staff and providing staff with lab updates.
- Serve as member and/or coordinator of the Quality Assurance Committee
- Assure all activities of the Quality Assurance Plan are performed and documented.
  - Assure that a copy of the QA committee meeting minutes is forwarded to the laboratory Director for review.
  - Director/Site Coordinator will review a sampling of patient records (CH-12) monthly to assure all relevant elements are documented. Suggest using a Quality Assessment Record Search Form (PHLOK-5 Form).
  - Monitor and evaluate Incident Report, remedial action, and resolution as necessary.
  - Monitor and evaluate all proficiency testing and method validation survey results. Perform related remedial action and documentation with a Corrective Action/Incident Report within 5 working days for unacceptable results or unsatisfactory performance.
  - Review any instructional information distributed with survey results and make any applicable changes.
  - Review reference lab specimen referral criteria, and change /necessary to remain compliant with the reference lab.
  - Ensure all required employee competency evaluations are performed and documented.
Shipping Laboratory Specimens to
Division of Laboratory Services (DLS)

- Packaging and Shipping information can be found in the Administrative Reference.

Resources:


http://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/basics/tests-diagnosis/con-20020865
http://www.lrc.state.ky.us/kar/902/004/030reg.htm

CSG Family Planning Section
CSG HIV Section
CSG Immunization Section
CSG Lead Section
CSG Pediatric Section
CSG Prenatal Section
CSG STD Section
# Lead

**Kentucky Childhood Lead Poisoning Prevention Program (KYCLPPP)**

Table of Contents

## CLINICAL PROTOCOLS

- Lead Poisoning Prevention Screening Guide
- Verbal Risk Assessment for Lead Poisoning
- Blood Lead Testing
- Completion of Laboratory Submission Forms

## FOLLOW UP INTERVENTION ON ELEVATED BLOOD LEAD LEVELS

- Guidelines for Follow-Up on Blood Lead Levels
- Lead Poisoning Prevention and Management
- Home Visits and Environmental Management
Childhood Lead Poisoning Prevention Program (CLPPP)

Lead Poisoning Prevention Screening Guide

Child enrolled in Medicaid?  

- **YES**
- **NO**

Review Lead Poisoning Verbal Risk Assessment* to determine patient lead based health hazard risks

Are there any lead hazard sources identified?

- **YES**  
  Answers “Yes” or “Don’t Know” to one or more questions on Lead Poisoning Verbal Risk Assessment*.

- **NO**  
  Answers “No” to all questions on the Lead Poisoning Verbal Risk Assessment.

**HIGH RISK:** Ensure **blood** lead screening for all at-risk patients. Refer to your LHD EPSDT policy for screens/reimbursement. Upon receipt of the elevated results, notify parents/prenatal patient and follow case intervention and health education guidelines set forth by the KY Department for Public Health and the Childhood Lead Poisoning Prevention Program. All Medicaid children require a blood lead test at ages 12 and 24 months and any time 25-72 months of age if not previously tested (SEE NOTE).

**LOW RISK:** Individual has no known risk factors for lead at this time. Administer Lead Poisoning Verbal Risk Assessment *at next preventative visit.
*American Academy of Pediatrics (AAP) recommends lead poisoning verbal risk assessment to be performed at ages 6, 9, 12, 18, and 24 months, and ages 3, 4, 5, and 6 years (72 months of age and younger) with a blood lead test performed for “Yes or Don’t Know” response to any question. AAP recommends and Medicaid requires blood lead testing at ages 12 and 24 months.

NOTE: According to the Centers for Medicare & Medicaid Services’ Early and Periodic Screening, Diagnosis and Treatment (EPSDT) guidelines, all preventive EPSDT examinations must include a blood lead laboratory test for children at 12 and 24 months of age and anytime under the age of 72 months if not previously tested. Refer to your LHD EPSDT policy for screens/reimbursement.

PRENATAL: See CSG Prenatal section for lead screening guidelines for at-risk patients
LEAD POISONING VERBAL RISK ASSESSMENT Children

72 months of age and younger

The Lead Poisoning Verbal Risk Assessment questions should be reviewed at every preventive visit for all children ages 6 months through 6 years to determine the patient’s exposure risk to lead hazard. The American Academy of Pediatrics (AAP) recommends that the verbal risk assessment be performed at ages 6, 9, 12, 18, and 24 months, and ages 3, 4, 5, and 6 years. A blood lead test should be performed for any yes or don’t know response to any question on the assessment. AAP recommends blood lead testing for children ages at ages 12 and 24 months.

Pregnant Women (See also the prenatal section for Lead Screening Guidelines/ Follow-Up)

Review each of these questions at the positive pregnancy test visit or initial prenatal visit to determine if patient is at-risk for lead hazards. Document in the medical record at the positive pregnancy test/initial prenatal visit and anytime that the assessment was done, any positive response(s), and action taken according to the class chart guidelines located in the Prenatal section.

The Lead Poisoning Verbal Risk Assessment questions are included on Health Risk Assessments ACH 25, 90 and 91. A copy of the Lead Poisoning Verbal Risk Assessment should be used at preventive visits and can be found at http://chfs.ky.gov/NR/rdonlyres/894A7D46-2E98-4CA6-B30E-4BE48B465FF7/0/LEADPoisoningVerbalRiskAssessmentQuestionnaireJUNE2016.pdf and reviews common lead hazards.

Document in the patient’s medical record when Lead Poisoning Verbal Risk Assessment was completed, any positive response(s) and action(s) taken:

- A “Yes” or “Don’t Know” response to any question on the Lead Poisoning Verbal Risk Assessment will warrant a blood lead screening test at that time, regardless of the child’s payer source or zip code area.
- Any child having a positive risk factor but not having an elevated blood lead level (EBLL) should be provided lead poisoning preventive education and tested at least annually, (< 72 months of age) as long as any risk factor exists.
BLOOD LEAD TESTING

Blood lead testing should be provided for at-risk patients. At-risk patients include children seventy-two (72) months of age and younger and pregnant women who:

1. Are enrolled in Medicaid.
2. Have a yes or don’t know response to any question on the Lead Poisoning Verbal Risk Assessment.

Medicaid requires blood lead testing for enrolled children at ages 12 and 24 months of age and for all children < 72 months of age who do not have a documented blood lead test.

BLOOD LEAD SPECIMEN COLLECTION GUIDELINES

Contamination errors are common in trace metal analysis and precautions must be taken to eliminate or reduce them.

All LHD staff obtaining blood lead specimens must view CDC’s Blood Lead Collection Guidelines at: [http://www.cdc.gov/nceh/lead/training/blood_lead_samples.htm](http://www.cdc.gov/nceh/lead/training/blood_lead_samples.htm) as indicated in the Training Requirements: Administrative Reference (AR)/Training Guidelines and Program Descriptions.

All LHD staff obtaining blood lead specimens must be familiar with their analyzing labs’ requirements on blood lead specimen collection (check with the LHD analyzing lab) as indicated in the Training Requirements: AR/ Training Guidelines and Program Descriptions.

All LHDs using LeadCare devices must be familiar with its specific user manual instructions on its use, KY Clinical Laboratory Improvement Amendments (CLIA) obligations and state (KRS 211.902) reporting requirements. A LeadCare device is not acceptable for confirming an elevated blood lead >5 micrograms per deciliter (µg/dL). LeadCare devices can only be used as a screening tool and is not a diagnosis tool.

COMPLETION OF LABORATORY SUBMISSION FORMS

Please fill out lab requisition forms accurately and completely, including your agency as the provider.

A. SCREENING

This should be checked for:

• initial capillary sample;
• first venous sample (venous samples should always be taken on pregnant women)
• re-screenings of children with levels > 5 μg/dL
• screening tests being repeated due to clot, insufficient quantity, or any other reason the sample could not be analyzed (incorrect collection technique)

B. CONFIRMATORY (Confirm blood lead level per follow-up guidelines)

• the second capillary sample when the first capillary sample was > 5 μg/dL
• venous samples submitted as confirmatory samples after a first capillary sample was equal to or greater than 5 μg/dL, and
• confirmatory tests being repeated due to clot, insufficient quantity, or any other reason the sample could not be analyzed.

C. MEDICAL FOLLOW-UP

• follow-up blood lead tests on all children who have been identified with an EBLL and;
• medical follow-up tests being repeated due to clot, insufficient quantity, or any other reason the sample could not be analyzed.

NOTE: Venipunctures are considered a confirmed specimen. For EBLLs, provide follow-up as indicated in the “Guidelines for Follow-Up on Blood Lead Levels.”

NOTE: See Administrative Reference for payment procedures.
### Initial Elevated Results

<table>
<thead>
<tr>
<th>Blood Lead Level</th>
<th>Assessment</th>
<th>Interventions</th>
<th>Follow-Up</th>
</tr>
</thead>
</table>
| 1-4.9 µg/dL      | Not considered an elevated lead level | • Lead Poisoning Prevention Education  
  • If a screening test is completed at the LHD, anticipatory guidance and education should be reviewed with parent/guardian to include:  
  o What is lead  
  o The effects of lead  
  o Potential lead sources  
  o Temporary measures to control exposure  
  o Dietary interventions,  
  o Proper hand washing and housecleaning techniques | • Continue to review risk assessment questions at each preventive health visit up to < 72 months of age. |
| 5-9.9 µg/dL      | Confirm BLL immediately if initial test was capillary.  
 Confirmatory tests should occur well before 12 weeks. | • Ensure BLL is confirmed.  
 • DO NOT wait to confirm. This only prolongs potential exposure. |
| 10-14.9 µg/dL    | Confirm BLL if initial test is capillary. | • Ensure BLL is confirmed  
 • Refer to PCP within 48 hours for |
<p>| 15-44.9 µg/dL    | Venous is considered | • Confirm BLL ASAP with a venous specimen if the initial test was capillary. |</p>
<table>
<thead>
<tr>
<th>&gt; 70 µg/dL</th>
<th>Confirmed.</th>
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<tbody>
<tr>
<td>• <strong>MEDICAL EMERGENCY</strong>: Confirm BLL ASAP with a venous specimen if the initial test was capillary.</td>
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<tr>
<td>• Ensure BLL if confirmed</td>
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<tr>
<td>• Refer to PCP within 24 hours for medical evaluation.</td>
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<tr>
<td>Blood Lead Level</td>
<td>Assessment</td>
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</table>
| 5–14.9 µg/dL     | Considered an elevated blood lead level (EBLL). Complete case management forms* | **Home Visit:**  
- A Visual Investigative Home Visit* must be made within **30 DAYS OR SOONER** of confirmed EBLL result to help families visually identify potential lead hazards.  
- A review on how to minimize the child’s lead hazard exposure should be completed during this home visit.  
**Lead Poisoning Prevention Education:**  
- Review with parent/guardian:  
  - What is lead  
  - The effects of lead  
  - Potential lead sources  
  - Temporary measures to control exposure  
  - Dietary interventions,  
  - Proper hand washing and housecleaning techniques  
**Referrals:**  
- Refer for WIC services  
- Refer for Medical Nutrition Therapy | *Follow-up tests should be repeated every 12 weeks (or as ordered by physician if more frequent) until blood lead level is < 5 µg/dL.  
- Establish a tracking system that ensures retesting and follow-up intervention.  
- Environmental: Lead hazards have been addressed. |

*Fax case management and home visit forms to KYCLPPP once these interventions have occurred. **Do not** send a home visit form without the environmentalist’s section.
<table>
<thead>
<tr>
<th>Blood Lead Level</th>
<th>Assessment</th>
<th>Interventions</th>
<th>Follow-up</th>
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<tr>
<td>&gt;15 μg/dL</td>
<td>Considered an elevated blood lead level (EBLL).</td>
<td><strong>Home Visit:</strong>&lt;br&gt;• A Visual Investigative Home Visit* must be made within 1 WEEK OR SOONER of confirmed EBLL result to help families visually identify potential lead hazards.&lt;br&gt;• A review on how to minimize the child’s lead hazard exposure should be completed during this home visit.</td>
<td>• Repeat blood lead tests at 1–2 month intervals until blood lead level is &lt; 5 μg/dL for 6 months (or as ordered by the physician if more frequent).&lt;br&gt;• Establish a tracking system that ensures follow-up retesting and interventions.</td>
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</table>
Referrals:

- Refer for WIC services
- Refer for Medical Nutrition Therapy (to occur within two weeks to ensure prevention of further lead absorption).
- Refer case to LHD environmentalist for a Certified Risk Assessment (this is different than a home visit) within two weeks of LHD receiving confirmed EBLL results.
- Refer to a primary care provider (PCP) for medical evaluation. For EBLLs >25 μg/dL, please provide PCP with information on lead specialist consult.

*Fax case management and home visit forms to KYCLPPP once these interventions have occurred. Do not send a home visit form without the environmentalist’s section.
LEAD POISONING PREVENTION AND EBLL MANAGEMENT

EBLL FOLLOW-UP INTERVENTION

According to the Centers for Disease Control and Prevention (CDC), case management of children and pregnant women with elevated blood lead levels (EBLLs) involves the coordination, provision and oversight of services required to reduce blood lead levels to below a level of concern. A hallmark of effective case management is the ongoing communication with caregivers and other service providers. This is a cooperative approach to solving any problems that may arise during efforts to decrease the patient’s EBLL by reducing or eliminating lead based health hazard exposure in the patient’s environment.

Case management is much more than a simple referral to other service providers. There are eight components, which should be under the purview of a registered nurse:

- Client identification and outreach
- Individual assessment and diagnosis
- Service planning and resource identification
- The linking of clients to needed services
- Service implementation and coordination
- The monitoring of service delivery
- Advocacy
- Evaluation

When a blood lead result is >5 ug/dL, education on what lead is, sources of lead and how to minimize exposure should be provided to the family. Follow-up interventions should be initiated for every child and pregnant woman having a confirmed EBLL of >5 ug/dL. Children and pregnant women with EBLLs become “health department patients” when an EBLL is identified through LHD screening or are referred by the primary care physician, even if they are or have been receiving direct clinical services elsewhere. They will remain a health department patient until case closure.

Until an electronic system is established, report forms are used to coordinate communication between the LHD lead case managers and KYCLPPP to ensure EBLLs receive appropriate and timely care. KYCLPPP monitors incoming lab data and compares with incoming LHD EBLL reports. Appropriate follow- up interventions need to be dated when completed. A physical address must be included to enter the data into the state data system.
The KYCLPPP Follow-Up Intervention Report form must be filled out completely for all children and pregnant women having a confirmed EBLL of $\geq 5 \mu g/dL$. The original report form is to be placed in the patient’s chart and a copy should be faxed to KYCLPPP. Updates on EBLLs and interventions should be made on the back of the form and a copy faxed to KYCLPPP. Staff should write the current BLL and date of specimen collection clearly on the notes page.

ENVIRONMENTAL MANAGEMENT FOR EBLL PATIENTS Visual

Investigative Home Visits

Environmental Management through home visits is one component of the ongoing process related to the elimination of lead poisoning as a public health problem.

Environmental intervention through visual investigation:

- Help the family visually identify potential lead hazards in the child’s environment
- Provide the family with educational materials/recommendations in an effort to reduce lead hazard exposure and help guide the family in taking corrective action
- Work to reduce patient’s EBLL to less than 5 $\mu g/dL$ by reducing/eliminating lead exposure
- Ensure that EBLL patient’s receive timely and appropriate care.

Certified Risk Assessment/Lead Inspections

According to KRS 211.905, for confirmed BLLs $> 15 \mu g/dL$, an inspection (with sampling) of the property where an EBLL child seventy-two (72) months of age or younger routinely spends more than six hours per week must be completed to determine the existence of lead-based hazards.

Priority of this inspection should be given to the child’s primary place of residence. The environmental investigations may include the visual investigative home visit as well as the comprehensive lead hazard risk assessment/lead inspection (certified risk assessment) to determine the existence of lead based hazards. (Only persons certified in Kentucky can complete the environmental lead risk assessment).

Collaboration of the environmentalist and the lead case manager ensures appropriate and timely environmental intervention for EBLL clients. Interventions during environmental investigations include:

- Informing the patient/parent/guardian/caregiver of child’s EBLL; review level of understanding; monitoring of blood lead levels,
• Reviewing what lead poisoning is and common sources of lead and provide a review of lead poisoning preventive educational materials;

• Reviewing lead poisoning prevention (increase Calcium, Iron and Vitamin C, low-fat diet, house cleaning techniques, minimizing the child’s exposure);

• Reviewing patient’s physical status, including behavior problems/changes, nutritional status and specific habits such as placing fingers in mouth or eating dirt or paint chips;

• Establishing who is providing patient’s primary and acute health care;

• Visualize the patient’s home environment and child’s play areas to help the family identify potential sources of lead and discuss preventive strategies to reduce the patient’s lead hazard exposure;

• Ensure the well-being of the child by referring to appropriate agencies; services may include social services for emergency or temporary housing agencies and community partners to help correct potential lead health hazards.

Environmental intervention is initiated for all cases referred into or already receiving services in a health department clinic with a confirmed EBLL > 5μg/dL and for pregnant women with a BLL of 10 μg/dL or greater.
Upon receipt of confirmed EBLL results, LHD staff are responsible for collaboration and referrals to the environmentalist for the appropriate environmental intervention. For children identified as having BLLs of:

- >5 \(\mu g/dL\), a Visual Investigative Home Visit is to be completed at the patient’s primary residence to help families in visually identifying potential sources of lead-based health hazard exposure.

- >15\(\mu g/dL\): In addition to the visual investigative home visit, a referral should be made to the environmentalist to ensure a lead hazard inspection/risk assessment with sampling is completed by a certified risk assessor.

**Investigation of the Primary Address:**

Part I of the visual investigative home visit form should be initiated by LHD lead case or home visiting staff. This equips the environmentalist with information in best identifying potential sources of current and past lead hazard exposure. Investigations should be conducted within the appropriate timeframes according to CDC’s recommendations. (See Table 1). However, KYCLPPP recommends a timeframe of **30 days or sooner** for BLLs 5-14.9\(\mu g/dL\). Early intervention helps families in identifying potential lead hazard sources, ways on minimizing exposure and in providing a review of lead poisoning preventive education with the parent/guardian/caregiver. This works to ensure prevention of further lead hazard exposure and further elevation of the BLL.

**Table 1: Time Frames for Environmental Investigation**

<table>
<thead>
<tr>
<th>Blood Lead Level</th>
<th>Time Frame for Assessment</th>
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<tbody>
<tr>
<td>5-14.9(\mu g/dL)</td>
<td>30 days for confirmed BLL in this range</td>
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<tr>
<td>15-19.9 (\mu g/dL)</td>
<td>2 weeks; &amp; refer for comprehensive lead risk assessment</td>
</tr>
<tr>
<td>20-44.9 (\mu g/dL)</td>
<td>1 weeks; &amp; refer for comprehensive lead risk assessment</td>
</tr>
<tr>
<td>45-69.9 (\mu g/dL)</td>
<td>48 hours; &amp; refer for comprehensive lead risk assessment</td>
</tr>
<tr>
<td>&gt;70 (\mu g/dL)</td>
<td>24 hours; &amp; refer for comprehensive lead risk assessment</td>
</tr>
</tbody>
</table>


A thorough visual investigation of the child’s home helps families to identify possible sources of lead. The investigation should visualize both the interior and exterior environment of the child with attention given to those areas that are **child accessible**, painted surfaces, dust and soil. Other potential sources of lead should be considered during the assessment (i.e., water, family occupation, hobbies, etc.) (See *Lead Poisoning Verbal Risk Assessment* for a list of common sources: http://chfs.ky.gov/NR/rdonlyres/894A7D46-2E98-4CA6-B30E-4BE48B4651F7/0/LEADPoisoningVerbalRiskAssessmentQuestionnaireJUNE2016.pdf).
At the time of the Visual Investigative Home Visit, preventive education should be reviewed with the parents/guardians/caregiver. **Preventive education** includes discussing the child’s potential source(s) of lead hazards, how to prevent the patient’s access and further exposure to those sources, an increase in the child’s hand washing with soap and water (especially prior to eating/snacking and sleep times), and house cleaning techniques such as damp dusting, wet mopping, and daily vacuuming of the home. Temporary measures to reduce further exposure are not required within a specific timeframe, however it is recommended to immediately keep the child from accessing potential lead hazard sources.

If the child’s BLL should increase to a confirmed elevated blood lead level of $>15\mu g/dL$, a lead inspection/risk assessment (certified risk assessment) is required to identify child-accessible lead-based hazards. The case should be referred to the environmentalist.

If there are suspected or identified lead hazards, intervention should include educating the family on how to use temporary measures to prevent child access to the sources. Temporary measures may include but are not limited to:

- Blocking child access to potential hazardous area with a barrier (i.e. door, child gate, furniture
- Use of duct or masking tape and plastic or cardboard to cover an area of chipping/peeling surface until permanent work can be conducted;
- Daily damp dust, wet mop and vacuum with a HEPA vacuum especially in the child’s play area;
- Wipe child’s toys clean, keep toys in clean, dry tote, and placing tote in cleaned play area and limiting the child’s play to only this area (especially if child is crawling and/or in hand-to-mouth exploration stage);
- Keep child’s hands washed with soap and water (germ gel does not remove lead), wash hands before snacks and meals and before any sleep times, nap or bedtime (especially if child is crawling and/or in hand-to-mouth exploration stage);
- Leaving shoes outside or placing shoes in a tote or shelf out of the child’s reach to keep lead dust/paint chips from being tracked in from outside.
- Exploring the possibility to relocate children and pregnant women from the home while renovation/remediation work is in progress.
- Ensure the family is using lead safety work practices during renovations, providing containment areas (walk off areas, plastic off door areas, remove shoes/clothing before entering living spaces, daily clean up and vacuuming of work and walk off areas). Brochures on renovation can be found and ordered at: [http://www2.epa.gov/lead/brochures-and-posters](http://www2.epa.gov/lead/brochures-and-posters).
If the BLL remains elevated and is not decreasing within 8-12 weeks, environmental intervention may need to be conducted at another property where the child routinely spends more than six hours per week.

**Follow-Up Home Visits**

Follow-up home visits ensure preventive measures for lead poisoning prevention are continuing.

Follow-up home visits are also indicated when:

a. child fails to return for blood lead monitoring  
b. blood lead levels remain elevated  
c. blood lead levels are increasing  
d. at any other time the case manager feels a home visit would be beneficial
<table>
<thead>
<tr>
<th>Assessment</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family’s verbal understanding of lead poisoning and prevention</td>
<td>Reinforce previous health education</td>
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<tr>
<td>Home environment: determine whether temporary measures are continuing</td>
<td>Reinforce previous recommendations. Provide education as indicated.</td>
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<tr>
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<tr>
<td>Determine whether permanent measures have occurred/are planned.</td>
<td>Stress importance of workers using safety precautions and appropriate clean-up procedures during abatement. Encourage pregnant women and children to be kept away from work areas.</td>
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<td></td>
<td>While extensive work is being done, it is preferable to move the family out of the home.</td>
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</tbody>
</table>

**CASE CLOSURE**

Case closure is determined according to the case’s highest confirmed blood level and can be closed as follows:

- **For BLLs 5-14.9 µg/dL** – Case closure occurs when BLL is less than 5 µg/dL, repeat at-risk blood testing as indicated.
- **For BLLs 15µg/dL and greater** – Case closure occurs when BLL is less than 5 µg/dL for at least six months, environmental hazards have been addressed; there are no new environmental hazards or as ordered by the physician.

For prenatal EBLLs, case closure occurs at the pregnant woman at the time of the delivery of the newborn. **If the prenatal patient’s BLL is > 25 µg/dL**, the mother will need to follow-up with their PCP. The newborn will need to be tested at delivery using a cord blood sample. Case Management follow-up should be initiated for newborns with BLLs > 5µg/dL.

A case may also be designated as **administrative closure** if all directives, as enumerated in the “Follow-up/Internal Tracking/Referral” section, have been completed. The case manager must follow and document all procedures for closure in a “lost to follow up” case closure.
Cases where all directives have been completed and there has been no contact or follow-up appointment completed by the patient or child’s family, the case will need to be referred to Department for Community Based Services (DCBS) to ensure medical follow-up. Please see Administrative Reference (AR) Volume I, Abuse, Neglect and Violence section/ Department for Community Based Services.

When a case is closed to follow-up, please provide the date, reason for case closure, and any actions/interventions or comments on the case report form in area provided. If a case has been closed and a new EBLL is identified, please open a new case and send a new Report Form with initial BLL and updated information. Please do not continue on old file and write reopened.

KYCLPPP forms available @ http://chfs.ky.gov/dph/CSG_Forms.htm. Forms should be filed in the patient’s chart and a copy is to be faxed to KYCLPPP : (502) 564-5766

Sources/ Manuals:


3. CDC Response to Advisory Committee on Childhood Lead Poisoning Prevention (ACLPPP): Recommendations in “Low Level Lead Exposure Harms Children: A Renewed Call of Primary Prevention” (CDC, 2012).

Resources:

Centers for Disease Control and Prevention: https://www.cdc.gov/nceh/lead/


Environmental Protection Agency: www.epa.gov/lead


• EPA. Protect Your Family from Lead in Your Home (http://www2.epa.gov/lead/protect-your-family-lead-your-home-real-estate-disclosure) (2013)

Newborn Metabolic Screening

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**CLINICAL PROTOCOLS**

Newborn Screening LHD Clinical Protocol

**CASE MANAGEMENT**

Case management of abnormal screening

Coordination for Metabolic Foods and Formulas
Clinical Responsibility of the LHD in the Newborn Screening Program

1. Collecting or verifying the Newborn Metabolic Screen
   a. For infants receiving well child/EPSDT services at the LHD, the LHD should verify and chart the results of the Newborn Screening Test at the first well child visit; if those results have not been received, the LHD should contact the State Newborn Screening Lab at 502-782-7732 or 502-782-7734 to obtain those results and put them in the infant’s chart.
   b. Initial Screening should occur at the LHD when an infant has not received the newborn screen as a result of:
      - home delivery;
      - early hospital discharge (release less than 24 hours); or
      - the parent has been notified that the newborn screen needs to be repeated.
   c. If a newborn screening test is drawn at the LHD, it is the LHD’s responsibility to monitor and chart the outcome of the newborn screening test until no further testing is required or the infant has been linked to a university specialist and a local medical home.

2. Repeat Newborn Metabolic Screenings
   a. If the initial Newborn Screening lab is unsatisfactory or abnormal; or, if the repeat lab is unsatisfactory or abnormal a letter requesting repeat test(s) will be generated by the State Lab. These letters are sent to the infant’s health caregiver/submitter (physician, hospital, primary care provider or LHD).
   b. Repeat at the request of the DPH Follow-up Program: If a repeat newborn screening test has been requested and not received, the newborn screening follow-up staff will send a letter to the infant’s mother or guardian notifying them of the continued need for repeat testing. The LHD may need to perform a newborn screen on an infant if a repeat has been requested. Notification from the State Lab or the Newborn Screening Program shall be presented by the parent at the time of the request.
   c. If repeat testing has been recommended by the State Lab, the LHD should continue to monitor and/or obtain those results during subsequent visits until a normal result is received or a referral has been made to a university specialist for diagnostic evaluation.
   d. Repeat newborn screens should not be performed on infants who are six (6) months of age or older. This includes sickle cell testing. The State Lab does not accept filter paper newborn screening specimens on patient over six (6) months of age unless they fall under one or both categories:
      o Prematurity
      o Adoption
   e. For anyone older than six (6) months of age that does not fit the above criteria, the LHD should recommend a laboratory evaluation by a reference laboratory, other than State Lab, for the specific disorder in question.
   f. If the State Lab has recommended a repeat newborn screen and the parent/guardian refuses for the repeat to be performed, please have the parent/guardian sign a refusal of treatment form and fax it to the Newborn Screening Follow-up Program at (502) 564-1510. If you have questions, call the Newborn Screening Follow-up Program at (502) 564-3756 ext 4367.
LHD role in Case Management of Newborn Metabolic Screening

1. For infants with positive or equivocal diagnoses:
   a. The LHD may be asked to assist in locating the patient. State Newborn Screening Follow-up Program and the Lab refer infants with abnormal results to the primary care provider and the appropriate university specialist who will, in many cases, need to locate the patient/family within hours. The DPH Newborn Screening staff will contact the LHD if their assistance is necessary.
   b. The LHD may be asked to assist in finding a medical home for these children. These children need a primary care provider who can diagnose and treat acute illnesses, be available after hours, and have the capability to admit the child to the hospital if needed.

2. Coordination of care:
   LHD’s may be called upon to assist these families with locating and obtaining specialized metabolic foods and formula for Infants with a positive definitive diagnosis by the specialist of an inborn error of metabolism or genetic condition. These infants will have a physician order by the specialist for specialized food and formula for treatment that is administered under the direction of a physician.
   a. Infants with positive or equivocal tests should be evaluated for WIC eligibility as some specialized metabolic formulas can be obtained through WIC.
   b. LHDs may contact the Metabolic Foods and Formula Program at (502) 564-3756 ext 4367 to help arrange special foods and formula for infants per 902 KAR 4:035:
      • Who are uninsured;
      • Whose coverage of specialized food and formula has been denied by their insurance company; or
      • Whose coverage limits have been exceeded.
Pediatrics
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CLINICAL PROTOCOLS

Well Child/Pediatric Preventive Health Care

Birth through 15 Months..........................................................................................................-

16 Months through 10 Years...................................................................................................

11 Years through Birth Month of 21st Year.............................................................................

CASE MANAGEMENT

Clinical Protocols for Management of Abnormal Screenings....................................................
<table>
<thead>
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<th>AGE</th>
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<th>4 M</th>
<th>6 M</th>
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**HISTORY** 1,2 (Comprehensive initial and interval history including medical, dietary, developmental, lead, TB, Fluoride and oral health, and health risk assessment, as described in HP13 and 14)

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**DEVELOPMENTAL ASSESSMENT** 3

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**PHYSICAL EXAM** 4 (comprehensive)

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**SENSORY SCREENING**

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**IMMUNIZATIONS** 5

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**LABORATORY (routine)**

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**LABORATORY (patient at risk)**

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<td>S</td>
<td></td>
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<tr>
<td>RECOMMENDED Fluoride Varnish at eruption of first tooth and at 6 month intervals to age 6 years.(^8)</td>
<td></td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>X or R</td>
<td>S</td>
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</tr>
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</table>

X=TO BE PERFORMED
S=SUBJECTIVE BYHX
O=OBJECTIVE BY A STANDARD TESTING METHOD
R=TO BE PERFORMED FOR AT RISK PATIENTS
X\(^a\)= AAP recommends (not required) use of a standardized developmental screening tool at these times
Footnotes refer to the key on the following page.
The shaded area is the range during which a service may be provided, with X indicating the preferred age for service.

1. A history and physical exam can help determine whether an infant and toddler are developing normally or otherwise. If on completion of history and physical exam parameters are noted outside of normal ranges for any conditions, the child should be referred for further evaluation; follow Clinical Protocols for Management of Abnormal Screenings in the Case Management Section for critical abnormalities.

2. A comprehensive history should be completed on the initial visit that identifies medical, immunization, dietary/nutritional, developmental, lead, TB, mother’s hepatitis B and hepatitis C status, fluoride, and oral health risks. An interval history should be completed each visit after the initial visit; the HRA for these periodic pediatric visits is to include the dietary questions, risks for SHS, lead, TB, fluoride, oral health, and abuse and neglect. The WIC-75 dietary information may be used in addition to the HRA but is only required for the WIC Certification visit and not every pediatric periodicity visit. For infants born to mothers confirmed to be infected with hepatitis C virus (HCV) (e.g., positive HCV RNA confirmation test), provide Quantitative HCV RNA testing at ages two months or four months and provide age-appropriate immunizations including hepatitis B (HepB) immunizations. Quantitative HCV RNA testing should then be repeated at a subsequent visit in four to six months, independent of the initial HCV RNA test result if the first test is reported as negative. An anti- HCV antibody test (anti-HCV) can be an alternative but should be provided no sooner than age 18 months because anti-HCV from the mother can interfere with those test results until that age.

See the 5-Screening and Referral Guidance for Infants Born to Mothers with Hepatitis C Virus (HCV) Infection.

3. A comprehensive pediatric preventative visit shall include assessment of the parent’s developmental/behavioral concerns with the history, and assessment for age-specific developmental benchmarks during the physical exam, according to the age-appropriate benchmarks in this section. Assessment of the developmental benchmarks by history and exam should be documented as part of the patient’s record. If developmental delay is suspected based on an assessment of a parent’s developmental/behavior concern or if delays are suspected after a screening of developmental benchmarks, a written referral is made to the appropriate source for further evaluation. (See Clinical Protocols for Management of Abnormal Screening in this section.)

4. A Comprehensive physical examination should be done at appropriate intervals by appropriate staff, and according to the age specific preventive health guidelines for services. The exam should include and
document: General Appearance, Nutritional Status, vital signs, Mental status, head-to-toe physical exam including all systems – see Chapter on Physical exam in the CSG.

5. At every health visit, all children 6 months to 6 years of age are evaluated, using the questions on the “Verbal Risk Assessment for Lead Poisoning” to determine their exposure to and risk of poisoning. (See Lead Section).

6. If an infant or toddler comes under care for the first time at any point of the Well Child EPSDT schedule, or if any items are not accomplished at the suggested age, the schedule should be brought up to date. Immunizations should be brought up to date according to the Recommended Childhood and Adolescent Immunization Schedule (See Immunization section). For infants born to mothers confirmed to be infected with HCV, provide age appropriate immunizations, including Hepatitis B vaccinations.

7. For guidance regarding metabolic/sickle cell screening, refer to Newborn Metabolic Screening Section in the Administrative Reference.

8. Infants or Toddlers who are not drinking fluoridated water or who are not taking vitamins with fluoride should be given a fluoride supplement. Fluoride Varnish should be applied at eruption of the first tooth and at 6-month intervals to age 6 years. Families should be counseled for risk factors for dental caries are: bottle weaning after 12 months of age, excessive/long-term use of sippy cup with sugary beverages, white spot lesions on teeth.

9. Age appropriate Health Education/Anticipatory Guidance for issues regarding General Health, Nutrition, Safety, and Psychosocial Issues should be given with each patient contact. The Well Child Care provider should provide Basic Nutritional Counseling. Parents and caregivers should be advised to place infants on their backs, in a separate bed, free of soft bedding, in a smoke-free environment when putting infants to sleep. Anticipatory guidance should follow AAP’ Bright Futures for this age grouping and includes but is not limited to safe sleep, abusive head trauma, infant car seats, second hand smoke, choking hazards, falls, home safety, and other topics according to risk. Referrals for Medical Nutritional Therapy should be made to a Registered Dietitian for the following conditions: Metabolic/Genetic Conditions, Failure to Thrive, Diabetes, Lead Poisoning, Obesity, Eating Disorders, Anemia, and Early Childhood Caries.
# WELL CHILD/PEDIATRIC PREVENTIVE HEALTH CARE

(16 months through 10 years)

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## HISTORY

1-2 (Comprehensive initial and interval history including medical, dietary, developmental, lead, TB, fluoride and oral health, and health risk assessment. as described in HP13 and 14)

|       | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  |

## DEVELOPMENTAL ASSESSMENT

3

|       | X* | X  | X* | X  | X  | X  | X  | X  | X  | X  | X  |

## PHYSICAL EXAM

(comprehensive)

|       | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  |

## MEASUREMENTS

| HEIGHT/WEIGHT | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  |
| BMI           | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  |
| HEAD CIRCUMFERENCE | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  |
| TEMPERATURE   | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  |
| RESPIRATIONS  | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  |
| HEART RATE    | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  |
| BLOOD PRESSURE | R  | R  | R  | R  | X  | X  | X  | X  | X  | X  | X  |

## PELVIC EXAM

- Testicular exam

## SENSORY SCREENING

| VISION     | S  | S  | S  | O  | O  | O  | S  | R  | S  | R  | O  |
| HEARING    | S  | S  | S  | O  | O  | O  | S  | R  | S  | R  | O  |
| IMMUNIZATIONS

5

| X  | X  | X  | X  | X  | X  | X  | X  | X  | X  | X  |

## LABORATORY (routine)

| SICKLE CELL DISEASE

11

| R  | R  | X  | R  | R  | R  | R  | R  | R  | R  | R  | R  |
| LEAD

5

| R  | R  | X  | R  | R  | R  | R  | R  | R  | R  | R  | R  |
| HCT/HGB | R  | R  | R  | R  | R  | R  | R  | R  | R  | R  | R  |

## LABORATORY (patient at risk)

| FLUORIDE

7

| R  | R  | R  | R  | R  | R  | R  | R  | R  | R  | R  | R  |
| GLUCOSE

9

<p>| R  | R  | R  | R  | R  | R  | R  | R  | R  | R  | R  | R  |
| HEPATITIS C antibody test | R  | R  | R  | R  | R  | R  | R  | R  | R  | R  | R  |</p>
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X=TO BE PERFORMED  
S=SUBJECTIVE BY HX  
O=OBJECTIVE BY A STANDARD TESTING METHOD  
R=TO BE PERFORMED FOR AT RISK PATIENTS  
X*= AAP recommends (but not required) use of a standardized developmental screening tool at these ages  

Footnotes refer to the key on the following page.  
The shaded area is the range during which a service may be provided, with X indicating the preferred age for service.

1. A history and physical exam can help determine whether an infant and toddler are developing normally or otherwise. If on completion of history and physical exam parameters are noted outside of normal ranges for any conditions, the child should be referred for further evaluation; follow Clinical Protocols for Management of Abnormal Screenings in the Case Management Section for critical abnormalities.

2. A comprehensive history should be completed on the initial visit that identifies medical, immunization, dietary/nutritional, developmental, lead, TB, mother’s hepatitis B and hepatitis C status, fluoride, and oral health risks. An interval history should be completed each visit after the initial visit; the HRA for these periodic pediatric visits is to include the dietary questions, risks for SHS, lead, TB, fluoride, oral health, and abuse and neglect. The WIC-75 dietary information may be used in addition to the HRA but is only required for the WIC Certification visit and not every pediatric periodicity visit. For infants born to mothers confirmed to be infected with hepatitis C virus (HCV) (e.g., positive HCV RNA confirmation test), provide Quantitative HCV RNA testing at ages two months or four months and provide age-appropriate immunizations including hepatitis B (HepB) immunizations. Quantitative HCV RNA testing should then be repeated at a subsequent visit in four to six months, independent of the initial HCV RNA test result if the first test is reported as negative. An anti- HCV antibody test (anti-HCV) can be an alternative but should be provided no sooner than age 18 months because anti-HCV from the mother can interfere with those test results until that age. See the 5-Screening and Referral Guidance for Infants Born to Mothers with Hepatitis C Virus (HCV) Infection.

3. A comprehensive pediatric preventative visit shall include assessment of the parent’s developmental/behavioral concerns with the history, and assessment for age-specific developmental benchmarks during the physical exam, according to the age-appropriate benchmarks in this section. Assessment of the developmental benchmarks by history and exam should be documented as part of the patient’s record. If developmental delay is suspected based on an assessment of a parent’s developmental/behavior concern or if delays are suspected after a screening of developmental
benchmarks, a written referral is made to the appropriate source for further evaluation. (See Clinical Protocols for Management of Abnormal Screening in this section.)

4. A Comprehensive physical examination should be done at appropriate intervals by appropriate staff, and according to the age specific preventive health guidelines for services. The exam should include and document: General Appearance, Nutritional Status, vital signs, Mental status, head-to-toe physical exam including all systems – see Chapter on Physical exam in the CSG.

5. A comprehensive history indicating lead exposure on a child, 6 months to 6 years of age, warrants a blood sample to be collected immediately. If lead level is less than 5ug/dL retest at next periodicity schedule only if risk factor changes. Refer to Lead Poisoning Prevention and Management Section.

6. If a toddler or preschooler comes under care for the first time at any point of the Well Child/EP/SDT schedule, or if any items are not accomplished at the suggested age, the schedule should be brought up to date. For immunizations, refer to the Recommended Childhood and Adolescent Immunization Schedule – United States, approved by the Advisory Committee on Immunization Practices (www.cdc.gov/nip/acip) or the American Academy of Pediatrics (www.aap.org) or the Immunization section.

7. Toddlers and pre-school children who are not drinking fluoridated water or who are not taking vitamins with fluoride should be given a fluoride supplement. Fluoride Varnish should be applied at eruption of the first tooth and at 6-month intervals to age 6 years. Families should be counseled for risk factors for dental caries are: bottle weaning after 12 months of age, excessive/long-term use of sippy cup with sugary beverages, white spot lesions on teeth.

8. Recommend children receive dental sealant on their permanent molars as soon as the teeth come in– before decay attacks the teeth. The first permanent molars called “6 year molars” (2nd and 3rd grade) come in between the ages 5 and 7. The second permanent molars “12 year molars” (6th grade) come in when a child is between 11 and 14 years of age. Intra and extra oral piercing, use of tobacco and frequent intake of sugary beverages are never recommended at any age. Recommend use of lip protectant with SPF of 15 or greater to be applied to the lips.

9. Cholesterol and Glucose screens should only be completed for at risk patients. Refer to Clinical Protocols for Management of Abnormal Screenings in this section.

10. A Tuberculin Skin Test (TST) should be administered to at-risk children with any of the High-Risk indicators on the Tuberculin Skin Test Recommendations. (See TB Section)

11. Age appropriate Health Education/Anticipatory Guidance for issues regarding General Health, Nutrition, Safety, and Psychosocial Issues should be given with each patient contact. The Well Child Care provider should provide Basic Nutritional Counseling. Anticipatory Guidance for this age group should include but is not limited to child safety seats, second hand smoke, home safety, poisoning, bike/ATV safety, fire safety, falls, bullying, child abuse prevention and other topics according to risk. Referrals for Medical Nutritional Therapy should be made to a Registered Dietitian for the following conditions: Metabolic/Genetic Conditions, Failure to Thrive, Diabetes, Lead Poisoning, Obesity, Anemia, and Early Childhood Caries.
## WELL CHILD/PEDIATRIC PREVENTIVE HEALTH CARE

(11 Yrs through Birth Month of 21st Year)

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<th>13 Y</th>
<th>14 Y</th>
<th>15 Y</th>
<th>16 Y</th>
<th>17 Y</th>
<th>18 Y</th>
<th>19 Y</th>
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<td>HISTORY</td>
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</tbody>
</table>
[Comprehensive initial and interval history including medical, dietary, developmental, lead, TB, Fluoride and oral health, and health risk assessment. as described in HP13 and 14] | X | X | X | X | X | X | X | X | X | X | X |
| DEVELOPMENTAL ASSESSMENT | X* | X | X* | X | X | X | X | X | X | X | X |
| PHYSICAL EXAM | X | X | X | X | X | X | X | X | X | X | X |

### MEASUREMENTS

| IGH/WEIGHT | X | X | X | X | X | X | X | X | X | X | X |
| HEAD CIRCUMFERENCE | X | X | X | X | X | X | X | X | X | X | X |
| TEMPERATURE | X | X | X | X | X | X | X | X | X | X | X |
| RESPIRATIONS | X | X | X | X | X | X | X | X | X | X | X |
| HEART RATE | X | X | X | X | X | X | X | X | X | X | X |
| BLOOD PRESSURE | X | X | X | X | X | X | X | X | X | X | X |
| PELVIC EXAM/PAP | R | R | R | R | R | R | R | R | R | R | R |
| BREAST EXAM | S | S | S | S | S | S | S | S | X | X | X |
| TESTICULAR EXAM | X | X | X | X | X | X | X | X | X | X | X |

### SENSORY SCREENING

| ION | S | O | S | S | O | S | S | O | S | S | S |
| HEARING | S | O | S | S | O | S | S | O | S | S | S |
| IMMUNIZATIONS | X | X | X | X | X | X | X | X | X | X | X |

### LABORATORY (Routine)

| KLE CELL DISEASE |
| LEAD |
| HCT/HGB | R | R | R | R | R | R | R | R | R |

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*July 2019*
<table>
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<td>CHOLESTEROL&lt;sup&gt;15&lt;/sup&gt;</td>
</tr>
<tr>
<td>STD&lt;sup&gt;16&lt;/sup&gt;</td>
</tr>
<tr>
<td>TUBERCULIN&lt;sup&gt;14&lt;/sup&gt;</td>
</tr>
<tr>
<td>HEALTH EDUCATION (Age Appropriate.)&lt;sup&gt;17&lt;/sup&gt;</td>
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<tr>
<td>DENTAL REFERRAL&lt;sup&gt;13&lt;/sup&gt;</td>
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</table>

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S=SUBJECTIVE BY HX
O=OBJECTIVE BY A STANDARD TESTING METHOD
R=TO BE PERFORMED FOR AT RISK PATIENTS

The shaded area is the range during which a service may be provided, with X indicating the preferred age for service.

1. A history and physical exam can help determine whether an infant and toddler are developing normally or otherwise. If on completion of history and physical exam parameters are noted outside of normal ranges for any conditions, the child should be referred for further evaluation; follow Clinical Protocols for Management of Abnormal Screenings in the Case Management Section for critical abnormalities.

2. A comprehensive history should be completed on the initial visit that identifies medical, immunization, dietary/nutritional, developmental, lead, TB, fluoride, and oral health risks. An interval history should be completed each visit after the initial visit; the HRA for these periodic pediatric visits is to include the dietary questions, risks for SHS, lead, TB, fluoride, oral health, and abuse and neglect.

3. A comprehensive pediatric preventative visit shall include assessment of the parent’s developmental/behavioral concerns with the history, and assessment for age-specific developmental benchmarks during the physical exam, according to the age-appropriate benchmarks in this section. Assessment of the developmental benchmarks by history and exam should be documented as part of the patient’s record. If developmental delay is suspected based on an assessment of a parent’s developmental/behavior concern or if delays are suspected after a screening of developmental benchmarks, a written referral is made to the appropriate source for further evaluation. (See Clinical Protocols for Management of Abnormal Screening in this section.)

4. A Comprehensive physical examination should be done at appropriate intervals by appropriate staff, and according to the age specific preventive health guidelines for services. The exam should include
and document: General Appearance, Nutritional Status, vital signs, Mental status, head-to-toe physical
exam including all systems – see Chapter on Physical exam in the CSG.
5. A history and physical exam can help determine whether a pre-teen or adolescent is developing
normally or otherwise. If on completion of history and physical exam parameters are noted outside of
normal ranges, follow Clinical Protocols for Management of Abnormal Screenings in the Case
Management Section for critical abnormalities.
6. If a preteen or adolescent comes under care for the first time at any point of the Well Child/EPSDT
schedule, or if any items are not accomplished at the suggested age, the schedule should be brought
up to date. For immunizations, refer to the schedule approved by the Advisory Committee on
Immunization Practices (www.cdc.gov/nip/acip) or the American Academy of Pediatrics
(www.aap.org) or the Immunization section.
7. Pap smears are not suggested under the ACOG guidelines until age 21 unless the clinician thinks
there is a reason to complete a pap smear during the pelvic exam. (Refer to the Cancer
Screening/Follow-up Section for risk factors, screening, and follow-up information).
8. Ideally, female adolescents HCT/HGB screen should occur after the onset of the 1st menses.
9. All menstruating adolescents should be screened annually (regularity, dysmenorrhea, etc.).
10. All females should be taught to do breast self-exam (BSE) beginning at age 20. The required method
for performing the clinical breast exam and teaching BSE is the MammaCare Method. Counseling
shall be documented in the medical record at the initial and annual visits. (Refer to Cancer
Screening/Follow-up Section for risk factors, screening, and follow-up information).
11. An adolescent with an abnormal breast exam should be referred for examination and/or follow-up
treatment. (Refer to Cancer Screening/Follow-up Section)
12. Testicular exams to identify undescended testicles are an important part of a physical exam for 11–20
year old males and should be completed three times within this age span. If service is declined,
documentation is required.
13. If pre-teens and adolescents are not drinking fluoridated water or are not taking vitamins with
fluoride, they should be given a fluoride supplement. Recommend children receive dental sealant on
their permanent molars as soon as the teeth come in–before decay attacks the teeth. The first
permanent molars called “6 year molars” (2nd and 3rd grade) come in between the ages 5 and 7. The
second permanent molars “12 year molars” (6th grade) come in when a child is between 11 and 14
years of age. Intra and extra oral piercing, use of tobacco and frequent intake of sugary beverages
are never recommended at any age. Recommend use of lip protectant with SPF of 15 or greater to
be applied to the lips.
14. A TST should be administered to at-risk children with any of the High-Risk indicators on the
Tuberculin Skin Test Recommendations. (See TB Section)
15. Cholesterol and Glucose screens should only be completed for at risk patients.
16. All sexually active patients should be screened for STD and offered HIV counseling and testing.
17. Age appropriate Health Education/Anticipatory Guidance for issues regarding General Health,
Nutrition, Safety, and Psychosocial Issues should be given with each patient contact. The Well Child
Care provider should provide Basic Nutritional Counseling. Anticipatory Guidance for this age group
should include but is not limited to safety belt and helmet use, smoking and substance abuse, second
hand smoke, bullying, pregnancy prevention, STI, dating violence and stalking, and other counseling
according to age and risks. Referrals for Medical Nutritional Therapy should be made to a Registered
Dietitian for the following conditions: Metabolic/Genetic Conditions, Failure to Thrive, Diabetes,
Lead Poisoning, Obesity, Eating Disorder, Anemia, and Dental Caries.
# PEDIATRIC AGE APPROPRIATE DEVELOPMENTAL BENCHMARKS

<table>
<thead>
<tr>
<th></th>
<th>1 MO</th>
<th>2 MO</th>
<th>4 MO</th>
<th>6 MO</th>
<th>9 MO</th>
<th>12 MO</th>
</tr>
</thead>
<tbody>
<tr>
<td>FINE</td>
<td>Moves arms and legs</td>
<td>Eyes follow you and shows interest in objects</td>
<td>Reaches for objects</td>
<td>Reaches and transfers objects. Puts objects in mouth.</td>
<td>Feeds self</td>
<td>Points with index finger. Drinks from a cup. Feeds self</td>
</tr>
<tr>
<td>GROSS</td>
<td>Lifts head for short time when on stomach</td>
<td>Lifts head and upper chest with support in the arms when on stomach</td>
<td>Holds head erect but raises body on hands when on stomach</td>
<td>Rolls over, sits with support. Stands when placed in standing position</td>
<td>Can sit without support</td>
<td>Pulls to stand. May take a few steps alone</td>
</tr>
<tr>
<td>LANGUAGE</td>
<td>Makes throaty noises</td>
<td>Coos and babbles in response to voices</td>
<td>Laughs and squeals out loud</td>
<td>Turns to sound vocalizes single commands such as Dad, Ba-Ba</td>
<td>Says Mama and Dada</td>
<td>Can say words in addition to mama and dada</td>
</tr>
<tr>
<td>SOCIAL</td>
<td>响应声音和哭泣，或因惊吓而动</td>
<td>Shows pleasure in contact with adults</td>
<td>Smiles, squeals, blows bubbles</td>
<td>May have stranger anxiety</td>
<td>Responds to name</td>
<td>Plays pat-a-cake, peek-a-boo</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>15 MO</th>
<th>18 MO</th>
<th>2 YR</th>
<th>3 YR</th>
</tr>
</thead>
<tbody>
<tr>
<td>FINE</td>
<td>Drinks from a cup. Stacks 2 blocks. Feeds self with fingers.</td>
<td>Scribbles and imitates drawing with a crayon</td>
<td>Can stack 6 blocks, make straight or circular marks with a crayon</td>
<td>Copies circle and a cross</td>
</tr>
<tr>
<td>GROSS</td>
<td>Walks well, stoops, climbs stairs</td>
<td>Walks backwards, runs stiffly, throws a ball</td>
<td>Can go up stairs one at a time. Can kick a ball</td>
<td>Jumps up and down, kicks a ball, rides a tricycle</td>
</tr>
<tr>
<td>LANGUAGE</td>
<td>Has vocabulary of 3-6 words.</td>
<td>Mimics words and objects</td>
<td>Has a vocabulary of at least 20 words and uses 2 word phrases</td>
<td>Knows his name, age, and sex, colors</td>
</tr>
<tr>
<td>SOCIAL</td>
<td>Indicates what he/she wants by pointing and grunting</td>
<td>Makes gestures and imitates others. Listens to a story</td>
<td>Shows affection and blows kisses</td>
<td>Imitates adults and follows 2 step commands</td>
</tr>
<tr>
<td>---------</td>
<td>----------------------------------------------------</td>
<td>---------------------------------------------------</td>
<td>---------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>4 YR</td>
<td>Builds a tower of 10 blocks, thumb wiggle</td>
<td>Copies a square and a triangle, draws self</td>
<td>Draws a 6-part person</td>
<td></td>
</tr>
<tr>
<td>5 YR</td>
<td>Hops, jumps on 1 foot</td>
<td>Balances on one foot for 5 seconds</td>
<td>Writes letters, can do heel to toe steps</td>
<td></td>
</tr>
<tr>
<td>6 YR</td>
<td>Throws an overhand ball</td>
<td>Draws a 3-part person, prints and knows some letters, may be able to skip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LANGUAGE</td>
<td>Sings a song</td>
<td>Knows name, address, and phone #.</td>
<td>Knows all letters and counts</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Can tell you his first and last name</td>
<td>Counts on fingers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SOCIAL</td>
<td>Can talk about daily activities and discuss thing in his/her name</td>
<td>Plays make believe and dress-up</td>
<td>Understands right and wrong</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Differentiate fantasy/reality concepts</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## PEDiATRIC AGE SPECIFIC/APPROPRIATE DEVELOPMENTAL BENCHMARKS
### LATE CHiLDHOOD 8–10 YEARS

<table>
<thead>
<tr>
<th>STAGES</th>
<th>Increasing Awareness of Outside World</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHYSICAL</strong></td>
<td>Height and Weight</td>
</tr>
<tr>
<td></td>
<td>BMI (if available)</td>
</tr>
<tr>
<td></td>
<td>Scoliosis Screening, Dental-mixed dentition (primary and permanent teeth)</td>
</tr>
<tr>
<td></td>
<td>Tanner Stage</td>
</tr>
<tr>
<td><strong>PSYCHO-SOCIAL</strong></td>
<td>Personal competence and building confidence in self</td>
</tr>
<tr>
<td><strong>MENTAL HEALTH</strong></td>
<td>Same sex friends assume greater importance</td>
</tr>
<tr>
<td></td>
<td>Seeking of increasing independence from family becomes obvious</td>
</tr>
<tr>
<td></td>
<td>Easily influenced by peers with increase in risk-taking behaviors</td>
</tr>
</tbody>
</table>

### EARLY ADOLESCENCE 11–15 YEARS

<table>
<thead>
<tr>
<th>STAGES</th>
<th>Dramatic Physical Changes: Who am I Physically?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHYSICAL</strong></td>
<td>Height and Weight</td>
</tr>
<tr>
<td></td>
<td>BMI (if available)</td>
</tr>
<tr>
<td></td>
<td>Tanner Stage</td>
</tr>
<tr>
<td></td>
<td>Acne and Common Dermatoses</td>
</tr>
<tr>
<td></td>
<td>Dental, permanent teeth erupted</td>
</tr>
<tr>
<td></td>
<td>Sexual Activity</td>
</tr>
<tr>
<td></td>
<td>Substance Abuse</td>
</tr>
<tr>
<td><strong>PSYCHO-SOCIAL</strong></td>
<td>Demand Privacy (modesty)</td>
</tr>
<tr>
<td><strong>MENTAL HEALTH</strong></td>
<td>Preoccupation with appearance</td>
</tr>
<tr>
<td></td>
<td>Present/self oriented</td>
</tr>
<tr>
<td></td>
<td>Morality driven by rules i.e., right/wrong, good/bad</td>
</tr>
<tr>
<td></td>
<td>Anxious about large number of changes in life</td>
</tr>
</tbody>
</table>

### MIDDLE ADOLESCENCE 15–18 YEARS

<p>| STAGES            | Search for Clearer sense of Self and to Find Place in Larger Community: Who am I? |</p>
<table>
<thead>
<tr>
<th>PHYSICAL</th>
<th>PSYCHO-SOCIAL MENTAL HEALTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height and Weight</td>
<td>Friends assume greater importance and provide feelings of security/less time with family</td>
</tr>
<tr>
<td>BMI (if available)</td>
<td>Extreme sensitivity to peer group social norms and fads</td>
</tr>
<tr>
<td>Tanner Stage</td>
<td>Sexual identity (homosexual/heterosexual)</td>
</tr>
<tr>
<td>Acne and Common Dermatoses</td>
<td>Future oriented in thinking</td>
</tr>
<tr>
<td>Dental</td>
<td>Broaden perspective to include societal issues/while seeking greater privacy</td>
</tr>
<tr>
<td>Sexual Activity</td>
<td>Question rules and authority increases risk taking behaviors</td>
</tr>
<tr>
<td>Substance Abuse</td>
<td>Opinionated and challenging increasing conflicts</td>
</tr>
</tbody>
</table>

**LATE ADOLESCENCE 18–20 YEARS**

<table>
<thead>
<tr>
<th>STAGES</th>
<th>Emergency of Realistic Self Image and Adult Behavior: Where am I going?</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHYSICAL</td>
<td>Height and Weight</td>
</tr>
<tr>
<td></td>
<td>BMI (if available)</td>
</tr>
<tr>
<td></td>
<td>Tanner Stage</td>
</tr>
<tr>
<td></td>
<td>Acne and Common Dermatoses</td>
</tr>
<tr>
<td></td>
<td>Dental</td>
</tr>
<tr>
<td></td>
<td>Sexual Activity</td>
</tr>
<tr>
<td></td>
<td>Substance Abuse</td>
</tr>
<tr>
<td></td>
<td>Decision about college/workforce, military</td>
</tr>
<tr>
<td></td>
<td>Focuses on achieving greater autonomy from family/more accepting of parents</td>
</tr>
<tr>
<td></td>
<td>Increased high-risk behaviors peak</td>
</tr>
<tr>
<td></td>
<td>Development of mature sexual identity</td>
</tr>
<tr>
<td></td>
<td>Seek mature emotional intimacy</td>
</tr>
<tr>
<td></td>
<td>Draw from increasing life experiences for options and to make decision</td>
</tr>
</tbody>
</table>
# CLINICAL PROTOCOLS FOR MANAGEMENT OF ABNORMAL SCREENINGS

(Birth through 20 years)

The demographic, health and behavior information that is routinely collected using the HRA, Health History, and Physical Exam in preventive health care screening visits provides the health care provider with valuable information in determining the patient’s health status and potential health risk issues. If on completion of history and physical exam parameters are noted outside of normal ranges for any conditions, the child should be referred for further evaluation. The list below, while not all inclusive, provides guidance on critical referral points that must be addressed. Other abnormalities should be referred according to the clinical judgment of the practitioner providing the Health History/HRA, Physical, and Developmental Exam.

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>CRITICAL REFERRAL POINTS</th>
<th>ACTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CHILD ABUSE/ NEGLECT</strong></td>
<td><strong>Signs of Physical Abuse:</strong></td>
<td></td>
</tr>
<tr>
<td>(Emotional, Physical, Sexual, or Neglect)</td>
<td>TEN-4 Rule -- Bruise anywhere on a child (\leq 4) months; Bruise in the aggregate TEN (Torso, Ears, or Neck) region in child (\leq 4) years</td>
<td>1. Assure child safety</td>
</tr>
<tr>
<td></td>
<td>Unexplained or recurring Cigarette Burns, Fractures, Abrasions/Lacerations, Bite Marks, or Scars on Body (anywhere)</td>
<td>2. Report suspected abuse to Dept. for Community Based Services</td>
</tr>
<tr>
<td></td>
<td>Vaginal Lacerations (External/Internal)</td>
<td>3. Refer and link to medical provider/PCP</td>
</tr>
<tr>
<td></td>
<td>Rectal Excoriations</td>
<td>4. Refer to mental health services as indicated</td>
</tr>
<tr>
<td></td>
<td>History of suspected abusive behavior by an Adult (physical, sexual, or mental)</td>
<td></td>
</tr>
<tr>
<td><strong>ABNORMAL PATTERNS OF GROWTH</strong></td>
<td><strong>Low Birth Weight</strong> (birth – 2 years)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>FTT (birth – 2 years</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Physical Indicators:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Head Circumference:</strong> (Birth to 3 Years)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(&lt;10)% percentile or (\geq 90)% percentile</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Height:</strong> (Birth to 10 Years)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(&lt;10)% or (\geq 90)% Delayed Growth</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Weight:</strong> (&lt;10)% or (\geq 85) %</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Asymmetry of Extremities</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>FTT (birth – 2 years)</strong></td>
<td></td>
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<td></td>
<td>Asymmetry of Extremities</td>
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<td></td>
<td><strong>Low Birth Weight</strong> (birth – 2 years)</td>
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<td><strong>FTT (birth – 2 years)</strong></td>
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<td><strong>Physical Indicators:</strong></td>
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<td></td>
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<td></td>
<td>(&lt;10)% or (\geq 90)% Delayed Growth</td>
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</tr>
<tr>
<td></td>
<td><strong>Weight:</strong> (&lt;10)% or (\geq 85) %</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Asymmetry of Extremities</td>
<td></td>
</tr>
<tr>
<td>SUSPECTED DEVELOPMENTAL DELAY</td>
<td><strong>FAILURE TO PASS DEVELOPMENTAL SCREENING</strong></td>
<td><strong>CRITICAL REFERRAL POINTS</strong></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Failure to pass developmental screening</td>
<td><strong>Physical Indicators:</strong></td>
<td></td>
</tr>
<tr>
<td>Congenital Anomaly(ies) and/or Genetic Syndrome</td>
<td>Near Syncope</td>
<td></td>
</tr>
<tr>
<td>Organic Disease</td>
<td>Light headedness</td>
<td></td>
</tr>
<tr>
<td>Seizures/Convulsions/Epilepsy</td>
<td>Unexplained seizures</td>
<td></td>
</tr>
<tr>
<td>Deafness</td>
<td>Overweight/obesity or diabetes with cardiac symptoms</td>
<td></td>
</tr>
</tbody>
</table>

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**CLINICAL PROTOCOLS FOR MANAGEMENT OF ABNORMAL SCREENINGS (continued)**

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>CRITICAL REFERRAL POINTS</th>
<th>ACTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CARDIOVASCULAR DISEASE/CHOLESTEROL</strong> (2 through 20 Years)</td>
<td><strong>Physical Indicators:</strong></td>
<td>1. Refer and link to PCP for medical evaluation and follow-up</td>
</tr>
<tr>
<td></td>
<td>Near Syncope</td>
<td>2. Provide basic nutrition counseling and case management regarding food purchasing, food preparation habits and eating patterns. Evaluate progress at return visits</td>
</tr>
<tr>
<td></td>
<td>Light headedness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unexplained seizures</td>
<td></td>
</tr>
</tbody>
</table>
## DENTAL/ORAL

**Physical Indicators:**
- Cavities, Prolonged Bottle Use (>6 mo.)
- Red Swollen Gums, Leukoplakia, Gingivitis, Oral Cyst/Lesions, Pain, halitosis, loose teeth, Mal-alignment
- Smokeless Tobacco
- Unfluoridated Water.

1. Referral for dental visit as indicated
2. Apply fluoride varnish at the eruption of the first tooth and repeat every 6 months.
3. Anticipatory guidance on weaning from bottle, no juice in bottles, nutrition, oral care/dental hygiene, and tobacco product use
4. Test of home water for Fluoride as indicated, and providing Fluoride supplementation as indicated

## GENETIC DISORDERS

**Physical indicators including, but not limited to:**
- Positive newborn screening
- White patch hair
- Heavy eyebrow
- Characteristics of eyes
- Unusual face/skull structure
- Webbed neck, cleft palate, lip
- Hirsutism (especially in females)
- Deafness
- Tall/short stature
- Pectus excavation/carinatum
- Unusual hands/feet; Extra/ missing digits/short digits; Webbing
- Structural Defects or Injuries:
  - Deformed External/Internal Ear
- Confirmed diagnosis of genetic disorder
- Family history

1. Refer and link to PCP for medical evaluation
2. Refer to Genetic Services as indicated for evaluation, diagnosis, counseling
3. Refer to First Steps (birth–3 years) if diagnosis is an established risk condition (chfs.ky.gov/dph/firststeps.htm)
4. Refer for dental evaluation for palate, lip deformities
5. Refer diabetes, metabolic disorders for medical nutrition therapy as indicated
### HEARING LOSS

**Physical Indicators:**
- Discharge from Ears
- Enlarged Tender Lymph Nodes
- No Intelligible Speech by 2 years
- Failure to Localize Sound
- Imbedded Foreign Bodies
- Impacted Cerumen
- Recurring Otitis Media

1. Refer and link to PCP for medical evaluation
2. First Steps (birth – 3 years) with confirmed hearing loss diagnosis
3. Anticipatory guidance on S/S of infections, antibiotic therapy, feeding position for infants

### OCULAR PROBLEMS

**Physical Indicators:**
- Abnormal vision screening exam
- Eye Injury, Irritation or inflammation
- Tilts Head or Thrust Head Forward
- Setting sun sign
- Asymmetry in Corneal Reflex
- Absent Red reflex, Pupillary Light Reflex
- Marked Strabismus
- Suspected Blindness

1. Refer and link to PCP for medical evaluation
2. Refer for Ophthalmology evaluation as indicated
3. Refer to First Steps (birth to 3 years) if blindness confirmed
<table>
<thead>
<tr>
<th>CONDITION</th>
<th>CRITICAL REFERRAL POINTS</th>
<th>ACTIONS</th>
</tr>
</thead>
</table>
| **DIABETES**                    | **Physical Indicators:**  
1. The Three POLYS (Cardinal Symptom of Diabetes) particularly if associated with weight loss:  
   a. Polyphagia  
   b. Polyuria  
   c. Polydipsia  
2. Signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, or polycystic ovaries) | 1. Refer and link to PCP for medical evaluation  
2. Diabetic/counseling as indicated                                                                                                                                      |
| **INJURIES**                    | **Age Appropriate Issues:**  
Unsafe sleeping environment  
Abusive Head Trauma  
Choking (All ages, especially <3 years)  
   Food/Foreign Objects  
   Medicine/Poisons  
Motor Vehicle Safety/Child safety restraints/Seat Belt Use (all ages)  
Water (all ages): Temperature, Drowning, Sunburns, Electrical Shock  
Others as indicated by the HRA | 1. If child appears to be in an unsafe environment notify DCBS for possible neglect  
2. Assure counseling and education to family on age appropriate safety and Points to Remember                                                                                 |
| **EATING DISORDERS AND UNDERWEIGHT** | **Physical Indicators:**  
< 10 percentile weight for height  
Lower percentile than earlier measurement or major change in percentile  
Loss > 10% of previous weight  
Absence of Menarche after puberty  
Throat ulcers/Teeth erosion and sensitivity  
Anorexia Nervosa/Bulimia: (11–20 years)  
Distorted body image  
Dieting when not overweight, use of self-induced Emesis, Laxatives, and Diuretics to lose weight | 1. Refer and link to PCP for medical evaluation  
2. Refer to Medical nutrition therapy  
3. Refer for mental health services, dental evaluation as appropriate.  
4. Anticipatory guidance on health risk associated with eating disorders, healthy body image, oral health, & basic nutrition |
| OVERWEIGHT/ OBESEITY | Physical Indicators: | 1. Refer and link for medical evaluation  
2. Refer for medical nutrition therapy  
3. Refer for mental health services if indicated  
4. Anticipatory guidance |
|----------------------|----------------------|----------------------------------------------------------------------------------|
|                      | >85% desired weight for height (<age 2)  
BMI > 85%  
Higher percentile than earlier measurements or major change in percentiles  
High non-fasting cholesterol >200 (11–20 years) | |
| SUBSTANCE ABUSE      | Physical Indicators including, but not limited to:  
Restlessness, Disoriented, Slurred speech  
Agitated/aggressive behaviors  
Dilated pupils  
Needle tracks/scars  
Oral pre-cancerous lesions on lips, tongue, or mucosa. Periodontal disease and/or numerous caries  
Admitted use of Tobacco, Alcohol, Drugs (prescribed/ street), Inhalants, Anabolic Steroids | 1. Assure safety of child and staff  
2. Report suspected abuse/neglect to Dept. for Community Based Services  
3. Refer and link to PCP for medical/dental evaluation, as indicated  
4. Refer and link for mental health and substance abuse services  
5. Counseling & brief intervention for tobacco, alcohol, drugs as indicated |
### CLINICAL PROTOCOLS FOR MANAGEMENT OF ABNORMAL SCREENINGS (continued)

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>CRITICAL REFERRAL POINTS</th>
<th>ACTIONS</th>
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<tbody>
<tr>
<td><strong>RISK BEHAVIORS</strong></td>
<td><strong>Physical Indicators:</strong> (Female and Male)</td>
<td>1. Refer and link to PCP for medical evaluation if physical indicators</td>
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<tr>
<td></td>
<td>STD</td>
<td>2. Report sexual abuse of a minor to Department for Social Services or Kentucky State Police</td>
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<td></td>
<td>Evidence of sexual activity under age 16</td>
<td>3. Follow protocols for STD and Family Planning programs</td>
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<td></td>
<td>Positive pregnancy screening</td>
<td>4. Anticipatory guidance in abstinence, pregnancy prevention, STDs, and HIV</td>
</tr>
<tr>
<td></td>
<td>Oral Human Papilloma Virus, oral lesions</td>
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<td>High-Risk Sexual Activity Behavior</td>
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<td></td>
<td>Non-condom use; Non-contraceptive use</td>
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<td>Multiple Sexual Partners</td>
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<td></td>
<td>Injecting drug user</td>
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<td></td>
<td>Desire for Pregnancy</td>
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<tr>
<td><strong>PSYCHOSOCIAL</strong></td>
<td><strong>Physical indicators:</strong></td>
<td>1. Assure safety of child</td>
</tr>
<tr>
<td></td>
<td>Non-congruent verbalization, mannerism, and expressions</td>
<td>2. If suicidal ideation/self-mutilation is present, call Suicide Crisis Hotline with patient/parent still present (1-800-Suicide)</td>
</tr>
<tr>
<td></td>
<td>Aggressive behavior, acting out</td>
<td>3. Refer and link to PCP for medical evaluation</td>
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<tr>
<td></td>
<td>Flat affect</td>
<td>4. Refer and link to mental health services and local support groups as indicated</td>
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<td>Self-mutilation/Slash scars wrist/arms</td>
<td>5. Refer to appropriate resources (grief counseling in bereavement, parenting classes, and social support groups)</td>
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<td>Rebellion, risk-taking</td>
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<td>Prolonged bereavement</td>
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<td>Depression/Suicidal ideation, threats, attempts</td>
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<td></td>
<td>Inappropriate parent/child interaction</td>
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<td><strong>Signs of Emotional Abuse:</strong></td>
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<td>Unusual/Inappropriate Child Behaviors:</td>
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<tr>
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<td>Conduct, Habit, &amp; Neurotic, Withdrawn</td>
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<td>Poor Peer Relationship</td>
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<td>Psychosomatic Complaints</td>
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<th>INITIAL WORKUP</th>
<th>INITIAL EXAM</th>
<th>RETURN VISITS</th>
<th>15–20 WEEKS</th>
<th>20–24 WEEKS</th>
<th>28 WEEKS</th>
<th>32 WEEKS</th>
<th>35–37 WEEKS</th>
<th>POST-PARTUM VISIT</th>
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<td>Comprehensive history (See ACOG Antepartum/Postpartum Forms)</td>
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<td>Review</td>
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<td>X – third trimester</td>
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<td>Pelvic Exam (See Cancer Screening Section regarding Pap exams)</td>
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<td>Syphilis IGGE (with reflex testing if +)</td>
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<td>HIV (see guidelines)</td>
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<td>Rubella titer</td>
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<td>Blood lead levels (see guidelines)</td>
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<td>If + screen</td>
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<td>@ 24-28 weeks</td>
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<td>If had GDM</td>
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<td>GTT (see guidelines)</td>
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<td>Procedure</td>
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<td>3rd Trimester</td>
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<td>Triple Screen or Quad Screen (see guidelines)</td>
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<td>Ultrasound</td>
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<td>TB skin test</td>
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<td>Dipstick urinalysis</td>
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<td>Urine culture (cc midstream)</td>
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<td>Gonorrhea &amp; Chlamydia &amp; BV cultures</td>
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<td>@ risk</td>
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<tr>
<td>Cystic Fibrosis (see guidelines)</td>
<td>Offer to all</td>
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<td>GBS vaginal culture (see guidelines)</td>
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**COUNSELING**

<table>
<thead>
<tr>
<th>Counseling Area</th>
<th>1st Trimester</th>
<th>2nd Trimester</th>
<th>3rd Trimester</th>
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<tr>
<td>Nutrition/weight gain/vitamins/ folic acid &amp; WIC Referral</td>
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<tr>
<td>Breastfeeding benefits</td>
<td>X</td>
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<tr>
<td>Exercise</td>
<td>X (PN-3)</td>
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<td>Dental care</td>
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<tr>
<td>Smoking, alcohol, &amp; drug, SHS exposure</td>
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<td>Paternity</td>
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<td>Postpartum Blues/Depression</td>
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<tr>
<td>Preterm risk status/prevention/referral</td>
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<tr>
<td>Intimate Partner Violence (Per Trimester)</td>
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<td>X-second trimester</td>
<td>X – third trimester</td>
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<tr>
<td>HIV/AIDS &amp; other prenatal tests</td>
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<tr>
<td>Environmental/work hazards/toxoplasmosis</td>
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<td>Medication use (OTC &amp; Rx)</td>
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<tr>
<td>Referral to HANDS</td>
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<tr>
<td>Enroll with PE/Medicaid/Emerg.Medicaid</td>
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<tr>
<td>Provide Pt with Education forms</td>
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<td>PN-T2</td>
<td>PN-T3</td>
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<tr>
<td>Anticipatory guidance by gestational age/interests/risk factors</td>
<td>X</td>
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</table>

1. **Preterm Birth Prevention**: Patients with a history of previous preterm birth/PPROM, or with a history of cervical incompetence/short, cervical length must be referred to an obstetrician prior to 18-20 weeks to be evaluated for possible use of progesterone to prevent preterm birth.

2. **Immunization Status**: Every pregnant woman should be immunized appropriately if indicated. Influenza illness can cause complications in both mother and baby, so vaccine should be offered in season regardless of the stage of pregnancy. According to ACOG guidelines, pregnant women should...
may receive vaccinations with an inactivated virus, bacterial vaccine, or toxoid; however, exposure to live vaccines should be avoided during pregnancy. Refer to the Immunization Section for details.

3. Prenatal Risk Assessment: Risk factors should be reviewed each trimester. ACOG recommends psychosocial screening on a regular basis to increase the likelihood of successful interventions. Screening should include assessment such as barriers to care, unstable housing, communication barriers, nutrition, tobacco use, substance use, depression, safety, intimate partner violence (IPV), and stress. These factors can contribute to risk of preterm birth, which should also be assessed.

4. Intimate Partner Violence (IPV): Screening should be done by a health care provider who has been educated and trained in domestic violence and who is qualified to document in the medical record. Screening should be for current and past domestic violence that occurred anytime in a woman’s life. If a patient confides that she is being abused, verbatim accounts of the abuse should be recorded in the medical record and appropriate referrals made. The health care provider should inquire about her immediate safety and the safety of the children. ACOG Committee Opinion available at https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Intimate-Partner-Violence

5. Pelvic Exam/Pap Test: A pelvic exam should be completed on every pregnant woman at the initial prenatal exam regardless of whether a pap test is performed. If the patient is due a pap test according to the guidelines, she should provide documentation of her last pap test or else will need to have a pap test completed at the initial prenatal exam. Refer to the Cancer Screening Follow-Up Section for the list of guidelines to determine the need for a Pap test and proper follow-up.

6. Folic Acid – Before pregnancy and during pregnancy, women need 400 micrograms of folic acid daily to help prevent neural tube defects. History should be assessed to determine if a higher dose of folic acid is required.

7. Prenatal Vitamins: Vitamin supplementation should be prescribed/issued during pregnancy, the postpartum period, and the duration of breastfeeding and should meet the dietary reference intakes (see next page). This list is not all-inclusive and generically equivalent prenatal vitamin substitutes may be used. (Note: Prenatal vitamins may not be charged to the WIC program.)

8. Medication use - Prenatal patients should be advised to consult with their health care provider before using nonprescription drugs or herbal remedies during pregnancy. All medications taken during the pregnancy including non-prescription meds, vitamins, and herbal supplements should be noted in the patient record.

9. Alcohol, Tobacco, Other Drug Use (ATOD): All pregnant women should be screened at the first prenatal visit about their past and present use of alcohol, tobacco, secondhand smoke exposure and other drugs (ATOD), including recreational use of prescriptions and over-the-counter medications. This should be documented in the medical record and patients should be educated and referred appropriately. The Level I: Substance Use and Pregnancy Questionnaire (PN-2) has been renamed the Pregnancy Health Risk Screen. This is an optional evidence-based screening questionnaire specifically designed for pregnant women who are at risk for these behaviors. In addition to the ATOD screening, this questionnaire incorporates screening for domestic violence and maternal mental health issues with brief intervention guidelines, as well as suggested actions.
## GUIDELINES FOR PRENATAL VITAMINS

<table>
<thead>
<tr>
<th>Vitamin</th>
<th>1997–2011 Dietary Reference Intakes (DRI)</th>
<th>Minimum Level</th>
<th>Maximum Level</th>
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</thead>
<tbody>
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<td><strong>Vitamin A</strong></td>
<td>Age ≤ 18 750 mcg. RAE (3750 IU)</td>
<td>Age ≤ 18 750 mcg. RAE (3750 IU)</td>
<td>Age ≤ 18 2800 mcg. RAE (14,000 IU)</td>
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<tr>
<td></td>
<td>Age 19 – 50 770 mcg. RAE (3850 IU)</td>
<td>Age 19 – 50 770 mcg. RAE (3850 IU)</td>
<td>Age 19 – 50 3000 mcg. RAE (15,000 IU)</td>
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<tr>
<td><strong>Vitamin D</strong></td>
<td>5 mcg. (200 IU)</td>
<td>5 mcg. (200 IU)</td>
<td>100 mcg. (4000 IU)</td>
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<tr>
<td><strong>Vitamin E</strong></td>
<td>15 mg. (10 IU)</td>
<td>10 mg. (7 IU)</td>
<td>Age ≤ 18 800 mg. (536 IU)</td>
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<td>Age 19 – 50</td>
<td>Age 19 – 50</td>
<td>1000 mg. (670 IU)</td>
</tr>
<tr>
<td><strong>Vitamin K</strong></td>
<td>75 mg (age &lt;18)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>90 mg (ages 19-50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ascorbic Acid/</strong></td>
<td>Age ≤ 18 80 mg.</td>
<td>Age ≤ 18 1800 mg.</td>
<td>Age 19 – 50 2000 mg.</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>Age 19 – 50 85 mg.</td>
<td>70 mg.</td>
<td></td>
</tr>
<tr>
<td><strong>Thiamin</strong></td>
<td>1.4 mg.</td>
<td>1.4 mg.</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Riboflavin</strong></td>
<td>1.4 mg.</td>
<td>1.4 mg.</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Niacin</strong></td>
<td>18 mg.</td>
<td>17 mg.</td>
<td>Age ≤ 18 30 mg.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Age 19 – 50 35 mg.</td>
</tr>
<tr>
<td><strong>Vitamin B6</strong></td>
<td>1.9 mg.</td>
<td>2.0 mg.</td>
<td>Age ≤ 18 80 mg.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Age 19 – 50 100 mg.</td>
</tr>
<tr>
<td><strong>Folic Acid</strong></td>
<td>600 mcg.</td>
<td>400 mcg.</td>
<td>Age ≤ 18 800 mcg.</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>Age 19 – 50 1000 mcg.</td>
</tr>
<tr>
<td><strong>Vitamin B12</strong></td>
<td>2.6 μg.</td>
<td>2.2 μg.</td>
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</tr>
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<td><strong>Biotin</strong></td>
<td>30 mcg.</td>
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<tr>
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<tr>
<td><strong>Calcium</strong></td>
<td>1300 mg. (age 14–18)</td>
<td>250 mg.</td>
<td>2500 mg. (age &gt;18)</td>
</tr>
<tr>
<td></td>
<td>1000 mg. (age 19–50)</td>
<td></td>
<td>3000 mg. (age ≤18)</td>
</tr>
<tr>
<td><strong>Choline</strong></td>
<td>4.5 g. (age ≤18)</td>
<td>3.0 g. (age ≤18)</td>
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</tr>
<tr>
<td></td>
<td>4.5 g. (ages 19-50)</td>
<td>3.5 g. (ages 19-50)</td>
<td></td>
</tr>
<tr>
<td><strong>Copper</strong></td>
<td>1000 mcg.</td>
<td>1000 mcg.</td>
<td>8000 mcg.</td>
</tr>
<tr>
<td><strong>Iodine</strong></td>
<td>220 mcg.</td>
<td>220 mcg.</td>
<td>Age ≤ 18 900 mcg.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Age 19 – 50 1100 mcg.</td>
</tr>
<tr>
<td><strong>Iron</strong></td>
<td>27 mg.</td>
<td>27 mg.</td>
<td>45 mg.</td>
</tr>
<tr>
<td><strong>Magnesium</strong></td>
<td>400 mg. (age 14–18)</td>
<td>100 mg.</td>
<td>1700 mcg.</td>
</tr>
<tr>
<td></td>
<td>350 mg. (age 19–30)</td>
<td></td>
<td>2000 mcg.</td>
</tr>
<tr>
<td></td>
<td>360 mg. (age 31–50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Molybdenum</strong></td>
<td>50 mcg.</td>
<td>50 mcg.</td>
<td>Age ≤ 18 1700 mcg.</td>
</tr>
<tr>
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<td></td>
<td></td>
<td>Age 19 – 50 2000 mcg.</td>
</tr>
<tr>
<td><strong>Phosphorus</strong></td>
<td>Age ≤ 18 1250 mg.</td>
<td>Age ≤ 18 1250 mg.</td>
<td>3500 mg.</td>
</tr>
<tr>
<td></td>
<td>Age 19 – 50 700 mg.</td>
<td>Age 19 – 50 700 mg.</td>
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</tr>
<tr>
<td><strong>Selenium</strong></td>
<td>60 mcg.</td>
<td>60 mcg.</td>
<td>400 mcg.</td>
</tr>
<tr>
<td><strong>Zinc</strong></td>
<td>Age ≤ 18 12 mg.</td>
<td>9 mg.</td>
<td>40 mg. (age &gt;18)</td>
</tr>
<tr>
<td></td>
<td>Age 19 – 50 11 mg.</td>
<td></td>
<td>34 mg. (age ≤18)</td>
</tr>
</tbody>
</table>

**NOTE:** Remember that vitamins are tolerated best after a meal, so do not recommend on an empty stomach.

- Any vitamin that contains 1 mg. or more of folic acid must be provided through a prescription.
- If a prenatal vitamin supplement will not meet all the guidelines established by the DRI, it is best to recommend a vitamin that would fall between the minimum and maximum levels and is approved by the prenatal provider.
- During the second trimester the prenatal supplement should contain at least the following: Iron 30 mg., Zinc 15 mg., Copper 2 mg., Calcium 250 mg., Vitamin B6 2 mg., Folic acid 300 mcg., Vitamin C 50 mg. and Vitamin D 5 mcg.
LHD’s should have a protocol for documenting the distribution of any medication, including vitamins.

References:

5. ACOG FAQ Nutrition During Pregnancy available at [https://www.acog.org/Patients/FAQs/Nutrition-During-Pregnancy](https://www.acog.org/Patients/FAQs/Nutrition-During-Pregnancy)
6. [http://nationalacademies.org/HMD/Activities/Nutrition/SummaryDRIs/DRI-Tables.aspx](http://nationalacademies.org/HMD/Activities/Nutrition/SummaryDRIs/DRI-Tables.aspx)

### RECOMMENDATIONS FOR WEIGHT GAIN DURING PREGNANCY

<table>
<thead>
<tr>
<th>PREPREGNANCY BMI</th>
<th>BMI (kg/m²)</th>
<th>TOTAL WEIGHT GAIN (lbs.)</th>
<th>RATE OF WEIGHT GAIN 2nd &amp; 3rd TRIMESTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight*</td>
<td>&lt; 18.5</td>
<td>28–40</td>
<td>1 (1 – 1.3)</td>
</tr>
<tr>
<td>Normal Weight</td>
<td>18.5 – 24.9</td>
<td>25–35</td>
<td>1 (0.8 – 1)</td>
</tr>
<tr>
<td>Overweight*</td>
<td>25.0 – 29.9</td>
<td>15–25</td>
<td>0.6 (0.5 – 0.7)</td>
</tr>
<tr>
<td>Obese* (Includes All Classes)</td>
<td>≥30</td>
<td>11 – 20</td>
<td>0.5 (0.4 – 0.6)</td>
</tr>
<tr>
<td>Twins²</td>
<td></td>
<td>Normal Weight Status: 37 – 54# Overweight Status: 31 – 50##; Obese Status: 25 – 43##</td>
<td></td>
</tr>
</tbody>
</table>

- Poor weight gain can be a sign of poor fetal growth and must be evaluated by the medical provider, as well as any rapid weight gain (particularly after 24 weeks gestation).
- Determining appropriate weight gain is professional judgment that must be based upon the individual patient’s unique circumstances and weeks of gestation.
- The pregnant woman must be referred to Medical Nutrition Therapy (MNT) for low maternal weight gain, IUGR or oligohydramnios, BMI<18, eating disorders, lead poisoning, anemia, and excessive/inadequate weight gain. Other conditions to consider referring include chronic disease, breastfeeding, HIV/AIDS, hyperemesis gravidarum, homelessness, multiple gestation, overweight, age <17 or >35, and weight loss during pregnancy.

  *Excessive weight gain = greater than eight pounds/month
  *Inadequate weight gain = less than two pounds/month after 1st trimester
References:
**BODY MASS INDEX (BMI)**

*All Pregnant Women*

Body Mass Index (BMI) is a measure that can help determine if a person is at risk for a weight-related illness. To use this chart, find the height in the left-hand column.

Move across the row until you find the weight. The number at the top of the column is the BMI.

<table>
<thead>
<tr>
<th>BMI</th>
<th>19</th>
<th>19.8</th>
<th>20</th>
<th>21</th>
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</tbody>
</table>

Adapted from the CDC Body Mass Index Table and the Institute of Medicine: Nutrition During Pregnancy, National Academy Press, 1990, page 12.

Underweight = BMI < 19.8
Normal = BMI 19.8 – 26.0
Overweight = BMI 26.1 – 29.0
Obese = BMI > 29.1
PRENATAL LEAD SCREENING GUIDELINES

A. Risks of lead exposure in pregnancy
Lead is a naturally occurring toxic element that can cause devastating fetal effects. Lead crosses the placental barrier and the developing nervous system of the fetus is particularly vulnerable to lead toxicity. Some studies have shown that blood lead levels as low as 5 ug/dL may result in adverse pregnancy outcomes including spontaneous abortion, premature birth, stillbirth, birth defects, and decreased intellect and/or behavior problems in the child.

A special concern for pregnant women is that past bone lead accumulation may be released into the blood during pregnancy. Studies have also shown that males exposed to lead may have decreased sperm counts and/or abnormal sperm morphology.

B. Patient assessment and education
All prenatal patients shall be assessed for potential lead poisoning at the initial prenatal work-up visit and be given the PAM-ACH-25. The need for blood testing is based on a yes response to one or more lead risk assessment questions. The questions to determine risk status have been incorporated into the patient handout “What is Lead?” (PAM-ACH-25), that is available on the DPH website.

C. Indications for blood testing
If a prenatal patient answers yes to one or more of the four risk assessment questions at the initial visit, a venous blood specimen should be drawn the same day. A purple top tube should be drawn immediately and sent for analysis. This blood test should be drawn at the same time as the other prenatal lab work.

D. Results of screening test:

<table>
<thead>
<tr>
<th>Level 5 - 14.9 ug/dL</th>
<th>Level &gt; 15 ug/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Exposure</td>
<td>Lead Poisoning</td>
</tr>
<tr>
<td>A. Home visit and counseling to reduce or eliminate known risk factors</td>
<td>A. Home visit and counseling to reduce or eliminate known risk factors</td>
</tr>
<tr>
<td>B. Notify delivering physician of test results and repeat blood specimen in 8 weeks</td>
<td>B. Notify delivering physician of test results and repeat blood specimen in 8 weeks</td>
</tr>
<tr>
<td>C. <strong>At-risk Prenatal Patients</strong> should be followed up by case management</td>
<td>C. <strong>At-risk Prenatal Patients</strong> should be followed up by case management</td>
</tr>
<tr>
<td>D. Refer women for an environmental risk assessment</td>
<td></td>
</tr>
</tbody>
</table>

*Guidelines for home visits, case management, and environmental risk assessments should be referenced from the Lead section.*
Documentation:

Documentation in the medical record should be brief such as “PAM-ACH-25 provided and discussed with no risk factors found” or “PAM-ACH-25 provided and discussed and blood to lab for screening due to positive risk factors.” Any further interventions should also be documented in the patient’s medical record.

Environmental and Clinical Health should work together on all prenatal cases of lead exposure or lead poisoning. Time to correct the problem is very limited and critical in preventing poor pregnancy outcomes. Pregnant women with lead levels above 5 ug/dL should be advised that any children in the household (ages 6 months–6 years) should be referred to the LHD’s Well-Child/EPSDT program or to their primary care provider for lead screening.

HEPATITIS B IN PREGNANCY

KRS 214.160 requires that all pregnant women shall be screened for hepatitis B surface antigen (HBsAg) during every pregnancy. This testing shall be completed regardless of past test results or hepatitis B immunization status and should be completed at the initial prenatal visit. If the woman is high risk for contracting hepatitis B, the serological testing should be repeated in the last trimester.

A. Negative Test and vaccination in pregnancy
   Any pregnant woman with a negative HBsAg who is at risk for developing hepatitis B infection should receive the vaccine as soon as possible. The vaccine is purified surface antigen and poses no known risk to the fetus. See Immunization protocols for specific information on vaccine administration.


Refer to the Perinatal Hepatitis B Prevention Program and Case Management Protocol/Immunization Section of the CSG for more information.

HEPATITIS C IN PREGNANCY

Hepatitis C (HCV) is a viral infection that is spread by direct contact with infected blood. An infected person may or may not have symptoms. Pregnant women with HCV infection should be referred to a subspecialist for further evaluation and management. According to revised KRS 214.160, each pregnant woman in Kentucky shall be screened for hepatitis C. The test results shall be recorded in the woman’s permanent medical record and the permanent medical record of the child or children she was pregnant with at the time of the testing after the child or children are born. The prenatal provider shall verbally inform and document the pregnant woman, or the legal guardian of the child/children, the woman was pregnant with at the time of testing, that KRS 214.160 recommends all children born to HCV–positive women receive serologic testing for the presence of hepatitis C virus antibodies and confirmation RNA bloodwork.

A baby can be infected during birth if the mother has HCV infection. There are no effective preventive measures to decrease the transmission of HCV from an infected mother to the baby during delivery. Pregnant women who are positive for HCV infection should be counseled that a cesarean delivery will not decrease the transmission of the HCV infection from her to the baby. Women who are positive for HCV infection can still breastfeed but should consider abstaining from breastfeeding if their nipples are cracked or bleeding.

References:
1. Protecting Yourself Against Hepatitis B and Hepatitis C. December 2016. Available at https://www.acog.org/Patients/FAQs/Protecting-Yourself-Against-Hepatitis-B-and-Hepatitis-C

PREVENTING PERINATAL HIV/AIDS TRANSMISSION

A pregnant woman who receives prenatal care through the LHD shall be counseled on HIV, including identification of risk factors, and effective ways to reduce risks. Because of recent advances in both antiretroviral and obstetrical interventions, the use of antiretroviral medications during pregnancy and delivery, and to their newborns in the first few weeks of life, can reduce the vertical transmission rate from 25% to 2%.

- All pregnant women should be screened for HIV infection at the initial prenatal visit regardless of risk factors.
- The PAM-ACH 263 or ACOG Patient Fact Sheet PFS005 should be provided on the initial prenatal visit and documented in the medical record.
- Repeat HIV testing in the third trimester, preferable before 36 weeks of gestation, is also recommended for women in areas where there is a high incidence or prevalence of HIV and also for women who are known to be at risk for acquiring HIV.
- **Informed consent before testing is essential.** Women shall be told they are being tested for HIV as part of the routine panel of prenatal tests unless they decline (Opt Out). Patient notification allows a woman to decline testing if she feels it is not in her best interest. Discussing and addressing reasons for refusal could promote health education and trust building and allow some women to accept testing at a later date.
- Documentation of informed consent shall use language the client understands. Pregnant women should be provided with verbal or written information about HIV, including interventions to reduce the risk of transmission from the mother to the infant. No additional written documentation of informed consent beyond that which is required for routine prenatal test is recommended. **Refusal of the HIV test at the initial visit or at the recommended retesting time frame for those individuals at risk should also be documented in the medical record.**
  - For those women who have an established diagnosis of HIV, they should be linked to a specialist in HIV care for ongoing care and co-management.

See HIV/AIDS Section for further information and protocols.

References:

2. Patient Fact Sheet available at: [http://www.acog.org/~media/For-Patients/pfs005.pdf?dmc=1](http://www.acog.org/~media/For-Patients/pfs005.pdf?dmc=1)
MULTIPLE MARKER TEST (TRIPLE OR QUAD SCREEN)

Maternal serum screening has become an important, non-invasive, diagnostic tool to screen for several congenital and chromosomal abnormalities. The Triple Screen measures alpha-fetoprotein (AFP), human chorionic gonadotropin (HCG), and unconjugated estriol levels. If a fourth substance, Inhibin – A, is added then it is called a Quadruple Screen.

- All prenatal clients should have the Triple Screen test performed between 15-20 weeks gestation. The most ideal screening time is between 16-18 weeks gestation. Patient counseling must emphasize that this is a screening test that will identify high-risk pregnancy. If the patient declines testing, documentation must be noted in the medical record.
- The Multiple Marker specimen must be submitted to a clinical laboratory that has normative data specific to each week of gestational age and is able to provide interpretation that considers maternal age, weight, race, and relevant history such as maternal diabetes and family history of NTD. Imprecise information may lead to inaccurate test results.
- An abnormal Multiple Marker Test result is NOT diagnostic of a fetal anomaly but does warrant further evaluation.
  - DO NOT REPEAT THE TRIPLE SCREEN TEST IF YOU RECEIVE AN ABNORMAL RESULT.
  - Refer for ultrasound to determine an identifiable cause. Incorrect EDC, multiple gestation, or fetal death may be the cause of the abnormal result as well as congenital anomalies.
- If the ultrasound confirms the presence of a congenital anomaly, the patient should be referred immediately to a physician who provides care for high-risk obstetrical patients.
  - If the ultrasound fails to determine a cause of the abnormal Multiple Marker Test, the patient should be referred to an obstetrician for possible amniocentesis.

Reference: Available at http://www.acog.org/-/media/For-Patients/faq165.pdf?dmc=1&ts=20150512T0838463475

CYSTIC FIBROSION SCREENING

Cystic Fibrosis (CF) is a genetic disorder caused by changes in a pair of CF genes and is usually diagnosed in the first few years of life. Cystic Fibrosis causes problems with digestion and breathing but does not affect intelligence or appearance. Both parents must be carriers for the baby to develop CF. There is a 25% chance with each pregnancy that the child will have CF if both parents are carriers. Most patients are not familiar with CF and will need to learn about it. Written educational material or other formats should be used to educate patients and partners. Counseling, regarding CF carrier testing, is usually done by the primary obstetric care provider. However, in some circumstances referral to a medical geneticist may be helpful.

- CF screening should be offered to all prenatal patients, although non-Hispanic white and Ashkenazi Jewish populations are at a higher risk.
- Newborn screening panels that include CF screening do not replace maternal carrier screening.
- If she has been previously screened for CF, the results should be documented but the test should not be repeated.
- Appropriate screening does NOT include complete analysis of the CFTR gene by DNA sequencing or a newborn screening panel that includes CF screening.
- If the mom’s CF screening test shows that she is a carrier, then the father of the baby should be offered testing. This test may be performed by the LHD or he may be referred to a provider for testing, but the LHD does not have to pay for this test and it should not be coded to cost center 803. If he is tested at the LHD, he should sign a consent form. Education and interventions should be documented.
• The provider may offer the pt. additional testing during pregnancy, such as Chorionic villus sampling (generally done around the 11th week of pregnancy) and amniocentesis (generally done around the 16th week of pregnancy) to further determine if the baby has CF.
• Cystic Fibrosis is not a curable disease and there are no treatments available before the baby is born. However, there are treatments available after the baby is born. Couples can use the time prior to the birth to learn as much as possible about CF, current treatment options, and the experiences of families with CF children, or by talking to care providers.
• **Documentation of the consent process is extremely important.** A sample consent form in English and Spanish is available in the Forms Section.

References:

2. ACOG FAQ Guide available at [http://www.acog.org/Patients/FAQs/Cystic-Fibrosis-Prenatal-Screening-and-Diagnosis](http://www.acog.org/Patients/FAQs/Cystic-Fibrosis-Prenatal-Screening-and-Diagnosis)

**PERINATAL GROUP B STREPTOCOCCUS SCREENING**

The adherence to the most current CDC algorithm for GBS screening is estimated to prevent approximately 90% of newborn Group B Streptococcus infections. All prenatal clients will be screened for Group B Streptococcus between 35–37 weeks gestation. Clinicians should follow the most recent CDC/ACOG algorithms for management.

**Screening Method**

1. Swab the lower vagina (vaginal introitus), followed by the rectum (through the anal sphincter) using the same swab or two different swabs. Cervical, perianal, perirectal, perineal specimens are not acceptable. A speculum should not be used for culture collection.
2. Place the swab(s) into a nonnutritive transport medium. Group B streptococci isolates can remain viable in transport media at room temperature for 1 day without a risk of false-negative test results. Specimen requisitions should clearly indicate the specimens are for group B streptococci culture.
3. Laboratories performing these cultures should ensure clinicians have continuous access to results 24 hours per day/7 days per week.
4. If group B streptococcal bacteruria is detected any time during the pregnancy, it should be treated.


**HERPES SIMPLEX VIRUS (HSV)**

Couples should be educated about the natural history of genital HSV infection and should be advised that, if either partner is infected, they should abstain from sexual contact while lesions are present. To minimize the risk of transmission, use of condoms is recommended for asymptomatic HSV-infected individuals. Susceptible pregnant women should avoid sexual contact during the last eight weeks of pregnancy if their partners have active genital HSV infections.

Prior to delivery, women with a history of genital HSV should be asked about recent symptoms and should undergo careful examination of the perineum. **Cesarean delivery is indicated for all women with active (primary and recurrent) genital HSV lesions at the time of delivery.**

Reference: ACOG FAQ 054 available at [https://www.acog.org/Patients/FAQs/Genital-Herpes](https://www.acog.org/Patients/FAQs/Genital-Herpes)
GLUCOSE TOLERANCE TESTING GUIDELINES AND MANAGEMENT FOR GESTATIONAL DIABETES MELLITUS (GDM)

Purpose
Gestational diabetes mellitus (GDM) is a condition that begins during pregnancy due to carbohydrate intolerance. GDM is one of the most common medical complications that occur during pregnancy. Women with GDM are at an increased risk of gestational hypertension, preeclampsia, cesarean delivery and possibly other potential morbidities. Infants born to mothers with GDM are at an increased risk of macrosomia, neonatal hypoglycemia, hyperbilirubinemia, shoulder dystocia and cesarean section.

Screening

According to the ACOG guidelines, all pregnant women should be screened for GDM, either by the patient medical history, clinical risk factors or laboratory test results. Screening is generally performed at the 24-28 week prenatal visit, but early screening is recommended in women with risk factors.

Early screening for undiagnosed type 2 diabetes is also suggested in women with the following risk factors:

- A previous medical history of gestational diabetes mellitus
- A known impaired glucose metabolism
- Obesity (BMI > 30)

If GDM is not diagnosed, blood glucose testing should be repeated at the 24-28 weeks of gestation.

Testing Procedures

Diagnostic Testing Procedures

1. The Glucose Challenge Test (GCT) is the screening test that consists of a 50-gram (commercially prepared) oral glucose load followed by a plasma or serum glucose sample determination one hour later. The glucose load is best tolerated when it is chilled and citrus rather than cola flavored (the glucose should be taken orally within 5 minutes).
   - The patient does not need to be fasting for this test.
   - If the one hour test is abnormal (>140-179 mg/dl), a 100 gram diagnostic Oral Glucose Tolerance Test (OGTT) is performed. (Do not proceed with 3 hour OGTT if 1-hour 50-gram load venous blood glucose is >180 mg/dl—refer to physician.)
   - Schedule 3 hour OGTT within 7 days.

2. The Oral Glucose Tolerance Test (OGTT) is the diagnostic test for GDM.
   - It is recommended that the OGTT be performed in the morning after an overnight fast of at least 8 hours but no greater than 14 hours. At least 3 days of unrestricted diet (150 gram carbohydrate per day) and unrestricted activity (unless otherwise contraindicated) need to precede the test.
   - Women taking prescription medication should check with their health care provider for specific instructions.
   - Women need to remain seated and not smoke during the test.
   - A finger stick blood (capillary) sample along with a fasting venous (plasma) blood sample should be obtained prior to the administration of the commercially prepared glucose solution.
   - If the fasting finger stick blood level is greater than 126 mg/dl, do not administer oral glucose without consulting the patient’s provider. The patient’s provider should determine whether to proceed with the 3 hour OGTT.
   - If the fasting finger stick blood level is below 126 mg/dl proceed with the test. Venous blood samples are then collected at one, two, and three-hour intervals.
Diagnosis

- According to ACOG guidelines, diagnosis of GDM can be determined by the result of a 100 Gram, 3-hour oral glucose tolerance test.
- Either the plasma or serum glucose level established by Carpenter and Coustan or the plasma level designated by the National Diabetes Data Group is appropriate to use.
- A definitive diagnosis of GDM requires that two or more thresholds be met are exceeded.

Table 1. Diagnostic Criteria for the 100 gram, 3 hour Oral Glucose Tolerance Test (OGTT) for GDM

<table>
<thead>
<tr>
<th>Status</th>
<th>Carpenter and Coustan Conversion</th>
<th>National Diabetes Data Group Conversion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Plasma or Serum Glucose Level</td>
<td>Plasma Level</td>
</tr>
<tr>
<td>Fasting</td>
<td>95</td>
<td>105</td>
</tr>
<tr>
<td>1 Hour</td>
<td>180</td>
<td>190</td>
</tr>
<tr>
<td>2 Hours</td>
<td>155</td>
<td>165</td>
</tr>
<tr>
<td>3 Hours</td>
<td>140</td>
<td>145</td>
</tr>
</tbody>
</table>

- A positive diagnosis requires that two or more thresholds are met or exceeded.
- To make this test reliable, the patient must be fasting and administered a 100-gram commercially prepared solution.

Management of Diagnosed GDM

- Refer to physician for medical management and fetal surveillance.
- Refer to dietitian (RD/LD) or for Medical Nutrition Therapy.
- Counsel about GDM and the need for postpartum follow-up.
- Counsel about self-monitoring of blood glucose (SMBG) and daily fetal kick counts. (starting at 26–32 weeks gestation)

Home Blood Glucose Monitoring and Follow-up:

<table>
<thead>
<tr>
<th>CONTROLLED</th>
<th>UNCONTROLLED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting whole blood ≤ 95</td>
<td>Fasting whole blood &gt;95</td>
</tr>
<tr>
<td>Fasting plasma ≤105</td>
<td>Fasting plasma &gt; 105</td>
</tr>
<tr>
<td>1 hr. pp whole blood ≤140</td>
<td>1 hr. pp whole blood &gt;140</td>
</tr>
<tr>
<td>1 hr. pp plasma ≤155</td>
<td>1 hr. pp plasma &gt;155</td>
</tr>
<tr>
<td>2 hr. pp whole blood ≤120</td>
<td>2 hr. pp whole blood &gt;120</td>
</tr>
<tr>
<td>2 hr. pp plasma ≤130</td>
<td>2 hr. pp plasma &gt;130</td>
</tr>
<tr>
<td>Continue current therapy</td>
<td>Refer to physician</td>
</tr>
</tbody>
</table>

Note: Many blood glucose monitors now calibrate to plasma glucose. Values depend on the meter.
<table>
<thead>
<tr>
<th>GDM ASSESSMENT</th>
<th>APPROPRIATE SCREENING</th>
<th>RESULTS</th>
<th>MANAGEMENT</th>
</tr>
</thead>
</table>
| Abnormal BG at initial prenatal visit:  
- Fasting BG ≥ 126 mg/dl  
- Random (Casual) BG ≥ 200 mg/dl | Refer immediately for subsequent testing – do not do further testing | A fasting plasma glucose level ≥ 126 mg/dl or a random (casual) plasma glucose > 200 mg/dl meets the threshold for the diagnosis of diabetes, if confirmed on a subsequent day unless unequivocal symptoms of hyperglycemia are present. | As directed by a qualified physician |
| All pregnant women should be screened for GDM | Plasma glucose following a 1-hour 50 gm load prior to 20 weeks gestation | <139 mg/dl | Repeat at 24–28 weeks gestation |
| | | 140–179 mg/dl | Schedule 3hr OGTT within 7 days |
| | | ≥ 180 mg/dl | Refer to a physician |
| Repeat Screening at 24–28 weeks gestation | Perform 1-hour plasma glucose following a 50-gram load (See procedure) | <139 mg/dl | Further testing not needed |
| | | 140–179 mg/dl | Schedule for 3hr OGTT within 7 days (See procedure) |
| | | ≥180mg/dl | Refer to a physician |
| Postpartum screening for all women who had GDM  
Postpartum-screening: (With Hx of recent GDM) | Either a fasting plasma glucose, or a 2 hour OGTT performed at 6–12 weeks postpartum following delivery | Negative: <100mg/dl | Repeat q 3 years or more often depending on risk factors or if symptoms develop |
| | | Positive: ≥ 100mg/dl | Provide counseling & referral to physician & nutritionist |

References:
1. ACOG Gestational Diabetes FAQ177 available at: http://www.acog.org/Patients/FAQs/Gestational-Diabetes
## COUNSELING & REFERRAL FOR COMMON DISCOMFORTS IN PREGNANCY

<table>
<thead>
<tr>
<th>DISCOMFORT</th>
<th>POSSIBLE CAUSE</th>
<th>NURSE ACTION</th>
</tr>
</thead>
</table>
| Backaches/Low Back Pain   | • Possible sign of preterm labor  
                            • Possible symptom of a urinary tract infection  
                            • Normal lordosis of pregnancy caused by the enlarging uterus  
                            • Improper body mechanics  
                            • Normal relaxation of the pelvic joints | • Assess for symptoms of preterm labor/urinary tract infection  
                                                                                                                                                   • **Consult/refer to medical provider if preterm labor is suspected or symptoms of UTI**  
                                                                                                                                                   • Education: symptoms of preterm labor, proper body mechanics, prenatal exercises (pelvic tilt), avoid heels/ lifting, apply heat/ massage, firm mattress/proper rest, possible maternity “girdle” or “sling” for support. |
| Bleeding Gums             | • Possible sign of periodontal disease/gingivitis  
                            • Increased estrogen during pregnancy | • **Refer for dental evaluation if recurring**  
                                                                                                                                                   • Education: risk of preterm birth with untreated periodontal disease, proper oral hygiene with regular brushing, flossing, and rinsing with antiseptic mouth wash |
| Breast Tenderness         | • Caused by increase in estrogen, progestins, vascularity, and glandular components of the breasts. Usually decreases or subsides after first trimester. | • Education: wear a well-fitting support bra, avoid breast stimulation, use lanolin to nipple area if needed, use clear water on the nipples and avoid use of soap. |
| Constipation              | • Common side effect from iron therapy  
                            • Decreased motility of the gastro intestinal tract as a result of increase in progestin levels  
                            • Decreased physical activity  
                            • Inadequate roughage and fluids  
                            • Increased pressure of the uterus on the bowel | • Education: increase fluid intake and fiber in the diet (raw fruits, vegetables, whole grains), avoid laxatives (including mineral oil), increase foods with “laxative” effects such as prune juice, increase physical activity such as walking and establish regular bowel habits (following meal)  
                                                                                                                                                   • Medical provider may suggest stool softener |
| Edema                     | • Causes may include preeclampsia, protein deficiency, renal disease, or cardiac disease  
                            • Increased venous pressure in the legs from the gravid uterus  
                            • Increased capillary permeability  
                            • Sodium and water retention from hormonal influences  
                            • Increased dilatation of veins | • Assess signs of preeclampsia, if in the second or third trimester (including hypertension, proteinuria, rapid weight gain, generalized edema, brisk reflexes)  
                                                                                                                                                   • **Refer to provider if symptomatic of preeclampsia**  
                                                                                                                                                   • Refer to medical provider for symptoms of underlying disease  
                                                                                                                                                   • Education: avoid excess salt (chips, pickles, canned foods, sodas) but do not recommend a low salt diet, increase fluid intake (water, juices), elevation of the lower extremities, increase rest (preferable left lateral position) |
| Fainting (lightheaded, dizzy, vertigo) | • Common causes include anemia, hypoglycemia, hyperventilation, seizures, and dehydration.  
                            • Decreased venous return  
                            • Supine hypotension (Vena-Cava Syndrome)  
                            • Pooling of blood in the lower extremities  
                            • Eating disorders | • **Refer to provider if accompanied by headaches, visual disturbances, an increase frequency and as otherwise indicated**  
                                                                                                                                                   • Obtain blood pressure, hemoglobin, blood glucose as indicated  
                                                                                                                                                   • Assess diet for adequate calories and fluid intake  
                                                                                                                                                   • Education: lay in a left lateral position (avoid supine position), avoid sudden postural changes, eat small frequent meals to avoid hypoglycemia |
### Nasal stuffiness & Nosebleeds (epistaxis)
- Increase in hormones cause increase vascularity
- Increased dilation of capillaries in the skin and mucus membranes
- Most common in the 2nd trimester, return to normal following pregnancy
- **Refer to medical provider if heavy nosebleeds or infection; check BP**
- Education: avoid trauma such as hard blowing of the nose, avoid nasal sprays and decongestants, and may apply external gentle nasal pressure to stop the bleeding

<table>
<thead>
<tr>
<th>DISCOMFORT</th>
<th>POSSIBLE CAUSE</th>
<th>NURSE ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headaches</td>
<td>• May be a sign of preeclampsia in late second or third trimesters</td>
<td>• Assess for signs of preeclampsia if 2nd or 3rd trimester of pregnancy</td>
</tr>
<tr>
<td></td>
<td>• Other causes include hypoglycemia, migraines, dehydration, and illness</td>
<td>• Refer to medical provider if symptomatic</td>
</tr>
<tr>
<td></td>
<td>• Emotional tension/stress</td>
<td>• Education: importance of adequate rest/sleep, adequate diet/fluid intake,</td>
</tr>
<tr>
<td></td>
<td>• Nasal congestion from estrogen levels</td>
<td>avoid aspirin and ibuprofen products in pregnancy</td>
</tr>
<tr>
<td>Heartburn and</td>
<td>• Causes include vomiting, ulcers, hiatal hernia, gastric-esophageal reflux</td>
<td>• Refer to medical provider if underlying disease or persistent symptoms</td>
</tr>
<tr>
<td>Indigestion</td>
<td>disease (GERD)</td>
<td>• Education: eat small, frequent meals, eat slowly, avoid lying down after</td>
</tr>
<tr>
<td></td>
<td>• Fatty food intolerance</td>
<td>meals, avoid gas producing foods, sip on milk or herbal tea, avoid</td>
</tr>
<tr>
<td></td>
<td>• Stomach displacement and compression due to enlarging uterus</td>
<td>baking soda, eliminate greasy, spicy, fried foods from the diet, and</td>
</tr>
<tr>
<td></td>
<td>• Increase gastric reflux due to progesterone</td>
<td>clarify use of over the counter antacids (low sodium, high calcium).</td>
</tr>
<tr>
<td>Insomnia</td>
<td>• Contributing causes may include fetal movement*, heartburn, leg cramps,</td>
<td>• Consult/Refer to provider immediately if patient report decreased or no</td>
</tr>
<tr>
<td></td>
<td>shortness of breath, caffeine, or apprehension</td>
<td>fetal movement.</td>
</tr>
<tr>
<td></td>
<td>• Difficult positioning due to enlarged uterus</td>
<td>• Educate the patient regarding kick counts</td>
</tr>
<tr>
<td></td>
<td>• Urinary frequency (nocturia) is a common contributing factor</td>
<td>• Education: use pillows for support of back and between legs, avoid</td>
</tr>
<tr>
<td></td>
<td>• Inability to sleep usually occurs in the 3rd trimester</td>
<td>caffeine; increase activity; warm bath or shower, massage of back and neck,</td>
</tr>
<tr>
<td>Leg cramps/pain</td>
<td>• Thrombophlebitis and varicosities</td>
<td>and avoid long day-time napping.</td>
</tr>
<tr>
<td></td>
<td>• Calcium/phosphorous imbalance</td>
<td>• Assess for redness, warmth, edema, positive Homan’s sign, or severe pain</td>
</tr>
<tr>
<td></td>
<td>• Muscle strain/tatigue/ lack of exercise</td>
<td>• Refer to medical provider if symptomatic</td>
</tr>
<tr>
<td></td>
<td>• Blood vessel compression in legs</td>
<td>• Education: avoid sodas and processed foods (very high in phosphorous),</td>
</tr>
<tr>
<td></td>
<td>• Nerve compression in legs from the enlarging uterus</td>
<td>increase dietary calcium if needed; apply local heat; exercise</td>
</tr>
</tbody>
</table>

*Note: * Movement refers to kick counts.
<table>
<thead>
<tr>
<th>Skin changes</th>
<th>Refer to medical provider for rashes, allergic reaction, changes in moles, increased excoriation as indicated by patient’s history. Education: eliminate direct sunlight exposure and use sunscreen on exposed body parts.</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Striae (stretch marks), spider angiomas, chloasma (mask of pregnancy), linea nigra, darkening of aerola, increased hair and fingernail growth, redness of the palms of the hands and soles of the feet</td>
<td>- Caused by increased production of estrogen and increase in circulation</td>
</tr>
<tr>
<td>DISCOMFORT</td>
<td>POSSIBLE CAUSE</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Vaginal Discharge| - An increase in vaginal discharge over a short period of time may be a sign of impeding preterm labor  
- Malodorous or colored discharge with or without itching are symptoms indicative of an infection  
- Increase in estrogen levels during pregnancy results in an increase in cervical mucus production  
- Increase in odorless, thin-nucoid, clear-white vaginal discharge is normal in pregnancy                                                                                                                                  | - Consult/refer to medical provider if preterm labor is suspected  
- Refer to medical provider for complaint of itching, burning, malodor, bloody, or colored discharge  
- Education: daily personal hygiene, avoid douching or tampons, wear cotton panties, avoid feminine hygiene products, jeans, pantyhose and other tight fitting clothing                                                                                           |
| Nausea/Vomiting  | - Hyperemesis gravidarum - Extreme, excessive, and persistent vomiting in early pregnancy that may lead to dehydration and malnutrition.  
- May be increased with hydatiform mole and multiple gestations  
- Metabolic changes (possible reduction in vitamin B6 metabolism)  
- Changes in hormonal balance, increase in estrogen primarily  
- Decrease gastric motility  
- Gastroesophageal reflux  
- Increase in gastric secretions                                                                                                                                                                                                                           | - Assess for symptoms of dehydration (dry mouth, decrease in tear production, muscle cramps, nausea/vomiting, heart palpitations, lightheadedness, weakness, decreased urine output, and poor skin turgor. Refer to a medical provider if intractable vomiting, signs of dehydration, fever, or significant weight loss  
- **Refer to medical provider if intractable vomiting, signs of dehydration, fever or significant weight loss.**  
- **Refer for MNT is applicable,**  
- Education: Avoid overeating/eating on an empty stomach, fried, greasy, or spicy foods, cooking odors, smoking, and medications unless prescribed by the medical provider. Suggest small frequent high protein meals (6–8 per day) and drink fluids between meals instead of with meals. May also try dry toast, crackers, ginger ale, peppermints, and fresh fruit. |
| Palpitations      | - Increase in blood volume, cardiac output, and heart rate  
- Awareness of a rapid heartbeat more common in pregnancy  
- May be associated with cardiac disease                                                                                                                                                                                                                                   | **Refer to medical provider if signs of cardiac disease** (shortness of breath, irregular or weak pulse, hypertension, dilated neck veins, abnormal pulse pressure, edema, excess fatigue)  
- Education: avoid caffeine and encourage stress reduction                                                                                                           |
<table>
<thead>
<tr>
<th>DISCOMFORT</th>
<th>POSSIBLE CAUSE</th>
<th>NURSE ACTION</th>
</tr>
</thead>
</table>
| Pelvic Pressure | • Possible sign of impending premature labor or urinary tract infection (UTI)  
• Pressure of the enlarging uterus pull support ligaments  
• Relaxation of joints  
• Softening and separation of tissue and joints due to hormonal influence (separation of the symphysis pubis not uncommon)  
• Most common in the 3rd trimester once engagement of the presenting part has occurred | • **Report signs of preterm labor, limitation of locomotion, and/or severe or persistent discomfort to the medical provider**  
• Assess for symptoms of preterm labor  
• Assess for UTI  
• Education: rest in left lateral position with pillow support, frequent rest periods, and good body mechanics. Avoid prolonged standing/ sitting and lifting. |
| Shortness of breath | • May be caused by pulmonary cardiac disease  
• May be a sign of a pulmonary embolus  
• Tends to be on exertion (climbing stairs)  
• Increased if patient is anemic, obese, or has multiple fetuses  
• Expansion of diaphragm limited by the enlarging uterus  
• Most frequently seen in the late 3rd trimester | • **Refer to medical provider if symptoms increase in severity or are accompanied by excess fatigue, severe anemia, chest pain, palpitations, or other symptoms of pulmonary or cardiac disease.**  
• Education: importance of smoking cessation and avoid second hand smoke, avoid overeating, exertion and fatigue, utilize an extra pillow or elevate the head of the bed |
| Varicose Veins (Perineal Varicosities) | • May be present in the legs, vulva, and/or rectum; most common in 3rd trimester  
• Increase in blood volume adds pressure on the venous circulation  
• Stasis in lower extremities from the enlarging uterus  
• Heredity predisposition  
• Progestins cause relaxation of smooth muscles  
• Inactivity and poor muscle tone  
• Hemorrhoids may be caused by straining or heavy lifting | • **Report symptoms of thrombophlebitis, severe pain, or worsening symptoms to medical provider**  
• Education: left lateral rest periods, sitz baths for hemorrhoids, wear maternity well-fitting girdle/support elevate legs for varicosities, and elevate the foot of the bed (6 inches). Avoid standing or sitting for prolonged periods of time, restrictive clothing, avoid crossing legs at the knees, avoid constipation, straining, and heavy lifting |
CLINICAL PROTOCOLS

Rabies Pre-exposure Prophylaxis Table

Primary Course for Pre-exposure Rabies Vaccination

Post-Vaccination Serologic Testing

Pre-Exposure Booster Doses of Vaccine

Rabies Postexposure Prophylaxis
  Local Wound Treatment
  Human Rabies Immune Globulin Usage
  Vaccine Usage
  Postvaccination Serologic Testing
  Postexposure Prophylaxis Schedule
  Post-Exposure Prophylaxis Protocol for People Exposed to Animals
  Interruptions in Vaccination Schedule

Notes & References
Table 1. Rabies pre-exposure prophylaxis guide — United States, 2008

![https://www.cdc.gov/mmwr/PDF/rr/rr5703.pdf](http://www.cdc.gov/mmwr/PDF/rr/rr5703.pdf)

<table>
<thead>
<tr>
<th>Risk category</th>
<th>Nature of risk</th>
<th>Typical populations</th>
<th>Pre-exposure recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous</td>
<td>Virus present continuously, often in high concentrations. Specific exposures likely to go unrecognized. Bite, nonbite, or aerosol exposure.</td>
<td>Rabies research laboratory workers; rabies biologics production workers.</td>
<td>Primary course. Serologic testing every 6 months; booster vaccination if antibody titer is below acceptable level.*</td>
</tr>
<tr>
<td>Frequent</td>
<td>Exposure usually episodic with source recognized, but exposure also might be unrecognized. Bite, nonbite, or aerosol exposure.</td>
<td>Rabies diagnostic laboratory workers, cavers, veterinarians and staff, and animal-control and wildlife workers in areas where rabies is enzootic. All persons who frequently handle bats.</td>
<td>Primary course. Serologic testing every 2 years; booster vaccination if antibody titer is below acceptable level.*</td>
</tr>
<tr>
<td>Infrequent (greater than population at large)</td>
<td>Exposure nearly always episodic with source recognized. Bite or nonbite exposure.</td>
<td>Veterinarians and animal-control staff working with terrestrial animals in areas where rabies is uncommon to rare. Veterinary students. Travelers visiting areas where rabies is enzootic and immediate access to appropriate medical care including biologics is limited.</td>
<td>Primary course. No serologic testing or booster vaccination.</td>
</tr>
<tr>
<td>Rare (population at large)</td>
<td>Exposure always episodic with source recognized. Bite or nonbite exposure.</td>
<td>U.S. population at large, including persons in areas where rabies is epizootic.</td>
<td>No vaccination necessary.</td>
</tr>
</tbody>
</table>

*Minimum acceptable antibody level is complete virus neutralization at a 1:5 serum dilution by the Rapid Fluorescent Focus Inhibition Test. A booster dose should be administered if the titer falls below this level.*
Primary Course for Pre-exposure Rabies Vaccination

Two rabies vaccines are currently available in the United States, i.e., human diploid cell vaccine (HDCV) and purified chick embryo cell vaccine (PCECV). For immune-competent persons, a primary course is a series of three 1-mL doses of HDCV or PCECV, given intramuscularly (IM). The initial dose is given on designated day 0. Additional doses of HDCV or PCECV are given on day 7 and day 21 or 28 after the first vaccination. Rabies vaccine should always be given IM in the deltoid for adults and older children. The anterolateral thigh is an acceptable alternate site for small children. HDCV or PCECV should never be administered in the gluteal area since administration in this area results in lower neutralizing antibody titers. Rabies vaccine preparations for intra-dermal (ID) administration are no longer available in the United States. (1)

<table>
<thead>
<tr>
<th>Type of vaccination</th>
<th>Route</th>
<th>Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>Intramuscular</td>
<td>Human diploid cell vaccine (HDCV) or purified chick embryo cell vaccine (PCECV); 1.0 mL (deltoid area), one each on days 0, *7, and 21 or 28</td>
</tr>
<tr>
<td>Booster†</td>
<td>Intramuscular</td>
<td>HDCV or PCECV; 1.0 mL (deltoid area), day 0 only</td>
</tr>
</tbody>
</table>

*Day 0 is the day the first dose of vaccine is administered.

†Persons in the continuous-risk category should have a serum sample tested for rabies virus neutralizing antibody every 6 months, and persons in the frequent-risk category should be tested every 2 years. An intramuscular booster dose of vaccine should be administered if the serum titer falls to maintain a value of at least complete neutralization at a 1:5 serum dilution by Rapid Fluorescent Focus Inhibition Test.
Post-Vaccination Serologic Testing

Healthy persons who were tested 2–4 weeks after completion of pre-exposure rabies prophylaxis in accordance with ACIP guidelines have demonstrated an adequate antibody response to rabies. Therefore, no testing of patients completing pre-exposure prophylaxis is necessary to document seroconversion unless the person is immunosuppressed.

Preferably, persons who are immunosuppressed by disease or medications should postpone pre-exposure vaccinations and consider avoiding activities for which rabies pre-exposure prophylaxis is indicated. When that is not possible, immunosuppressed persons who are at risk for exposure to rabies should be vaccinated and their virus neutralizing antibody titers checked. In these cases, failures to seroconvert after the third dose of rabies vaccine should be managed in consultation with the State Public Health Veterinarian, or DPH physicians. For adequate seroconversion, specimens collected 1–2 weeks after pre-exposure prophylaxis should completely neutralize challenge virus at a 1:5 serum dilution by the Rapid Fluorescent Focus Inhibition Test (RFFIT) (1).

Pre-Exposure Booster Doses of Vaccine (Table 1 and Table 2)

Persons who work with rabies virus in research laboratories or vaccine production facilities (continuous risk category [Table 1]) are at the highest risk for inapparent exposures. Such persons should have a serum sample tested for rabies virus neutralizing antibody every 6 months. An IM booster dose (Table 2) of vaccine should be administered if the serum titer falls to maintain a serum titer corresponding to a value of at least complete neutralization at a 1:5 serum dilution by the RFFIT.

The frequent-risk category includes other laboratory workers (e.g., those performing rabies diagnostic testing), cavers, veterinarians and staff, and animal control and wildlife officers in areas where animal rabies is enzootic. The frequent-risk category also includes persons who frequently handle bats, regardless of location in the United States or throughout the world, because of the existence of lyssaviruses on all continents except Antarctica. Persons in the frequent-risk group should have a serum sample tested for rabies virus neutralizing antibody every 2 years. If the titer is less than complete neutralization at a 1:5 serum dilution by the RFFIT, the person also should receive a single booster dose of vaccine.

Veterinarians, veterinary students, and terrestrial animal-control and wildlife officers working in areas where rabies is uncommon to rare (infrequent exposure group) and certain at-risk international travelers who have completed a full pre-exposure vaccination series with licensed vaccines and according to ACIP schedule do not require routine serologic verification of detectable antibody titers or routine pre-exposure booster doses of vaccine. If they are exposed to rabies in the future, they are considered immunologically primed against rabies and simply require postexposure prophylaxis for a person previously vaccinated (i.e., days 0 and 3 vaccination) (1).

Both the CDC and the Kentucky Department for Public Health recommend that the Rapid Fluorescent Focus Inhibition Test (RFFIT) be used for the determination of rabies antibody titers in humans. Local Health Departments should call the State Public Health Veterinarian or DPH physicians for consultation BEFORE ordering laboratory tests other than RFFIT for the determination of rabies antibody titers.

References:
RABIES POSTEXPOSURE PROPHYLAXIS

The decision to administer rabies postexposure prophylaxis (PEP) is based on several factors related to the potential exposure to rabies virus. These factors include the type of exposure (i.e. bite or nonbite), the species of animal involved, if the bite was provoked, and the epidemiology of rabies in a specific geographic area. An enclosed algorithm serves as a guide to indications for PEP. The environmentalist in your health department is usually quite familiar with these factors and the circumstances involving a potential exposure, and should be regarded as a local resource for determining if PEP is indicated. Ultimately, the decision to administer PEP is between the patient and their physician. **The local health department must have a physician’s order (phone order is acceptable) to administer PEP.** Administering PEP is not difficult.

Rabies is an incurable disease. Postexposure prophylaxis is a rabies prevention strategy, not a rabies treatment. Prevention strategies for rabies consist of three steps:

1. Immediate and thorough washing of the exposed site/wound,
2. Administration of human rabies immune globulin for immediate passive immunity, and
3. Administration of multiple doses of rabies vaccine for active immunity.

Local Wound Treatment

The immediate and thorough washing of bite wounds, scratches, and mucous membranes exposed to rabies virus with soap and water has been shown to markedly decrease the likelihood of rabies. If available, a virucidal agent (e.g., povidine-iodine solution) should be used to irrigate the wounds. Tetanus prophylaxis should be administered by protocol if indicated. Measures to control bacterial infection and indications for surgical intervention (suturing) are decisions for the physician.

Human Rabies Immune Globulin Usage

Human Rabies Immune Globulin (HRIG) is administered only once (at the beginning of rabies postexposure prophylaxis) to provide immediate antibodies until the patient responds to rabies vaccine by actively producing antibodies. Previously vaccinated individuals do not receive HRIG. If HRIG is not given at the same time vaccination is begun, it can be given through the seventh day after the administration of the first dose of vaccine. HRIG is not given beyond the seventh day since an antibody response to the vaccine is presumed to have occurred. The dose of HRIG is 20 IU/kg (approximately 0.06 mL/lb of HRIG containing 150 IU/mL). The current recommendation of the Advisory Committee on Immunization Practices (ACIP) is for the entire dose to be infiltrated around and into the wound(s) if anatomically feasible. If none or only part of the HRIG is used for infiltration, the remaining volume should be administered at an anatomical site (intramuscular [IM]) distant from vaccine administration. HRIG should never be administered in the same syringe or into the same anatomic site as rabies vaccine.

Vaccine Usage

Unvaccinated Persons
For unvaccinated persons, the combination of RIG and vaccine is recommended for both bite and nonbite exposures, regardless of the time interval between exposure and initiation of PEP. If PEP has been initiated and appropriate laboratory diagnostic testing (i.e., the direct fluorescent antibody test) indicates that the animal that caused the exposure was not rabid, PEP may be discontinued.
Two rabies vaccines are currently available in the United States, purified chick embryo cell vaccine (PCECV) and the human diploid cell vaccine (HDCV). For immune-competent persons, a regimen of four 1-mL doses of PCECV or HDCV is given intramuscularly. The first dose is given as soon as it is determined that PEP is indicated. This initial dose is given on designated day 0. HRIG is usually administered at the same time as described above. Additional doses of PCECV or HDCV are given on day 3, day 7 and day 14 after the first vaccination. The vaccine should always be given IM in the deltoid for adults and older children. The anterolateral thigh is an acceptable alternate site for small children. PCECV or HDCV should never be administered in the gluteal area since administration in this area results in lower neutralizing antibody titers. All immunosuppressed individuals such as, but not limited to, organ transplant patients, asplenic individuals, treated individuals with any autoimmune disorder, HIV positive individuals should receive five postexposure doses on day 0, day 3, day 7, day 14 or 21 and day 28.

**Previously Vaccinated Persons**

Previously vaccinated persons are those with a history of preexposure vaccination with HDCV, PCECV, or rabies vaccine adsorbed (RVA); prior PEP with HDCV, PCECV or RVA, or previous vaccination with any other type of rabies vaccine and a documented history of antibody response to prior vaccination. Previously vaccinated persons should receive two vaccine doses, (1-mL of PCECV or HDCV administered IM in the deltoid on days 0 and 3 only). Administration of HRIG is unnecessary, and HRIG should not be administered to previously vaccinated persons to avoid possible inhibition of the relative strength or rapidity of an expected anamnestic response. Local wound care remains an important part of rabies PEP for any previously vaccinated persons.

**Postvaccination Serologic Testing**

Because the antibody response after the recommended postexposure vaccination regimen with PCECV or HDCV has been satisfactory, routine postvaccination serologic testing is not recommended for healthy persons to document seroconversion. Serologic testing is only indicated in unusual circumstances, as when the patient is known to be immunosuppressed. When titers are obtained, serum specimens collected 1--2 weeks after prophylaxis (after last dose of vaccine) should completely neutralize challenge virus at least at a 1:5 serum dilution by the rapid fluorescent focus inhibition test (RFFIT).

### Rabies Postexposure Prophylaxis Schedule, Kentucky Health Departments

<table>
<thead>
<tr>
<th>Patient status</th>
<th>Treatment</th>
<th>Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not previously vaccinated and Immunocompetent</td>
<td>Local wound cleansing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>All PEP should begin with immediate thorough cleansing of all wounds with soap and water. If available, a virucidal agent (e.g., povidine-iodine solution) should be used to irrigate the wounds.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HRIG</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Administer 20 IU/kg body weight.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If anatomically feasible, the full dose should be infiltrated around and into the wound(s) and any remaining volume should be administered at an anatomical site (intramuscular [IM]) distant from vaccine administration. HRIG should not be administered in the same syringe or into the same anatomical site as the first vaccine dose. Because HRIG may partially suppress active production of rabies virus antibody, no more than the recommended dose should be given.</td>
<td></td>
</tr>
<tr>
<td>Previously vaccinated\textsuperscript{3} and Immunocompetent</td>
<td>Vaccine</td>
<td>PCECV or HDCV 1-mL, IM (deltoid area\textsuperscript{2}), on days 0, 3, 7 and 14.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Local wound cleansing</td>
<td>All postexposure treatment should begin with immediate thorough cleansing of all wounds with soap and water. If available, a virucidal agent (e.g., povidine-iodine solution) should be used to irrigate the wounds.</td>
<td></td>
</tr>
<tr>
<td>HRIG</td>
<td>HRIG should not be administered.</td>
<td></td>
</tr>
<tr>
<td>Vaccine</td>
<td>PCECV or HDCV 1-mL, IM (deltoid area\textsuperscript{2}), on days 0 and 3</td>
<td></td>
</tr>
<tr>
<td>Immunosuppressed regardless of vaccination status</td>
<td>Local wound cleansing</td>
<td>All postexposure treatment should begin with immediate thorough cleansing of all wounds with soap and water. If available, a virucidal agent (e.g., povidine-iodine solution) should be used to irrigate the wounds</td>
</tr>
<tr>
<td>HRIG</td>
<td>Administer 20 IU/kg body weight. If anatomically feasible, the full dose should be infiltrated around and into the wound(s) and any remaining volume should be administered at an anatomical site (intramuscular [IM]) distant from vaccine administration. HRIG should not be administered in the same syringe or into the same anatomical site as the first vaccine dose. Because HRIG may partially suppress active production of rabies virus antibody, no more than the recommended dose should be given.</td>
<td></td>
</tr>
<tr>
<td>Vaccine</td>
<td>PCECV or HDCV 1.0 mL, IM (deltoid area\textsuperscript{2}), on days 0, 3, 7, 14 - 21, and 28.</td>
<td></td>
</tr>
</tbody>
</table>

\textsuperscript{1}These regimens are applicable for all age groups, including children and pregnant women.

\textsuperscript{2}The deltoid area is the only acceptable site of vaccination for adults and older children. For younger children, the outer aspect of the thigh may be used. Vaccine should never be administered in the gluteal area.

\textsuperscript{3}Any person with a history of preexposure vaccination with HDCV, PCECV, or rabies virus adsorbed (RVA); prior PEP with HDCV, PCECV or RVA, or previous vaccination with any other type of rabies vaccine and a documented history of antibody response to prior vaccination.

For questions about PEP, call the Division of Epidemiology and Health Planning (502) 564-3418.
Rabies Post-Exposure Prophylaxis (PEP) Protocol for People Exposed to Animals

Did the person have contact with the saliva or brain tissue of a mammal via open wound or mucous membrane, or was

Yes

Was the exposure to a wild animal, such as a bat, fox, raccoon, or skunk?

No PEP

Yes

Was the animal a rodent, such as a squirrel, hamster, or the animal a dog cat, or ferret?

No

Was the animal captured - or can it be located - for 10-day observation?

No

No PEP

Yes

Did the animal exhibit abnormal behavior or die within 10-day

No

No PEP

Yes

Administer PEP7,8

PEP may be considered

Yes

Was the animal brain available for rabies testing at the state

No

No PEP

Yes

Was the direct fluorescent antibody test positive?

No PEP
# Rabies PEP

<table>
<thead>
<tr>
<th>Schedule Type</th>
<th>Doses</th>
<th>Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated</td>
<td>0, 3, 7, 14, 28</td>
<td>0, 3, 7, 14, 28</td>
</tr>
<tr>
<td>Previously vaccinated</td>
<td>0, 3</td>
<td>0, 3</td>
</tr>
</tbody>
</table>

What to do when the vaccine schedule is interrupted or is off schedule:

1. The series does not need to be reinitiated because of minor interruptions of the vaccine schedule-just pick up at the point it was discontinued, maintaining the proper intervals between doses specified in the schedule.

2. **Example:** if the day 7 vaccination was given on the 10th day, the next shot would be given on day 17 instead of day 14, maintaining the 7 day interval between the 3rd and 4th shot of the series.

3. If major deviations occur, and for all immunosuppressed individuals, test antibody titers 2 weeks after completing the series (a rapid fluorescent focus inhibition test that demonstrates complete virus neutralization at a serum dilution of 1:5 is considered to be indicative of protection) is recommended.


4. Consultation with the State Public Health Veterinarian is available during work and after hours for unusual cases and situations that are unusual or if the provider has questions on how to proceed.  
   **Mobile:** 502-682-4048
NOTES
1. Rabies risk assessment requires balancing a number of criteria: the species of animal and the endemcity of rabies for that species in Kentucky, the observed health and behavior of the animal, and the circumstances of the bite.
2. This algorithm only addresses rabies post-exposure prophylaxis. Other treatment such as wound care, antibiotics, and tetanus immunization may be indicated.
3. In addition to obvious bites or mucous membrane exposures, the CDC suggests that PEP be considered in cases where there is a reasonable probability that contact with a bat may have occurred (i.e. a sleeping person awakens to find a bat in the same room, an adult witnesses a bat in a room with a previously unattended child, mentally disabled person, or intoxicated individual) and rabies cannot be ruled out by testing of the bat. PEP would not be warranted for other household members.
4. Barring unusual circumstances, rodents and rabbits are not considered at-risk species. In questionable or unusual circumstances involving rodent, rabbits, and livestock bites, consult the local/state health department. Rabies is predominantly a disease of carnivorous animals (animals that eat other animals) while canines eaters like the opossum who eat dead or decaying flesh are seldom affected. Consultation with the state health department is strongly recommended for opossum human bites on rabies Post Exposure Prophylaxis.
5. Provoked exposures may include attempting to feed an animal, entering an animal’s territory, petting or playing with an animal, handling an animal, attempting to break up a fight between animals, having contact with an injured animal, and walking, running, or riding a bicycle past an animal. Unprovoked exposures are rare and typically require an animal to cross neutral space and attack. The physician should attempt to get the patient to describe the scenario in order to establish the true nature or the circumstances surrounding the biting incident – DO NOT simply ask if the bite was provoked or unprovoked.
6. The severity and location of a wound (severe wounds or obvious wounds near the head and neck should be given highest priority), and the expected interval between the time of the bite and receipt of rabies test results should be considered when making a decision to begin PEP while awaiting test results.
7. Unless the person previously received rabies immunoprophylaxis, PEP consists of four (4) doses of vaccine (1.0 mL each administered IM in the deltoid region) on days 0, 3, 7 and 14 and one (1) dose of human rabies immune globulin (HRIG) administered on day 0, infiltrated into and around the bite wound as much as anatomically feasible, with the remainder administered IM at an anatomical site distant from vaccine administration. HRIG should not be administered in the same syringe or at the same site as vaccine. HRIG dosage is based on the weight of the patient, 20 IU/kg, and should not be given in more than the recommended dose, as it may suppress active production of antibody. A previously vaccinated person needs an abbreviated PEP schedule, specifically day 0 and day 3. Immunocompromised individuals should receive the 5 series of immunizations on days 0, 3, 7, 14-21 and 28 in addition to HRIG on day 0. Contact the health department for the schedule, if needed.
8. If the biting animal is captured and tests negative for rabies after PEP has begun, PEP may be discontinued.

Modified from: Kent County Health Department. Determining the need for rabies post-exposure prophylaxis (PEP) with human rabies immune globulin (RIG) and rabies vaccine; Ohio Department of Health. Rabies Post-Exposure Treatment (PET) Algorithm, December 2000.
Reference: Centers for Disease Control and Prevention. Use of a Reduced (4-Dose) Vaccine Schedule for Postexposure Prophylaxis to Prevent Human Rabies, 2010: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2010; 59(RR-2)
Reportable Diseases

Table of Contents

CLINICAL PROTOCOLS

Reportable Disease Reporting Deadlines
REPORT IMMEDIATELY by TELEPHONE to the Local Health Department or the KY Department for Public Health:

- Unexpected pattern of cases, suspected cases or deaths which may indicate a newly recognized infectious agent
- An outbreak, epidemic, related public health hazard or act of bioterrorism, such as SMALLPOX
- Outbreaks or Unusual Public Health Occurrences

**Kentucky Department for Public Health in Frankfort**

**Telephone 502-564-3418 or 1-888-9REPORT (973-7678)**

**FAX 502-696-3803**

### REPORT WITHIN 24 HOURS

<table>
<thead>
<tr>
<th>Disease</th>
<th>Disease</th>
<th>Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthrax</td>
<td>Hansen's disease</td>
<td>Rubella syndrome, congenital</td>
</tr>
<tr>
<td>Arboviral Disease*</td>
<td>Hantavirus infection</td>
<td>Salmonellosis</td>
</tr>
<tr>
<td>Neuroinvasive</td>
<td>Hepatitis A</td>
<td>Shigellosis</td>
</tr>
<tr>
<td>Non-Neuroinvasive Botulism</td>
<td>Listeriosis</td>
<td>Syphilis, primary, secondary,</td>
</tr>
<tr>
<td></td>
<td>Measles</td>
<td>early latent or congenital</td>
</tr>
<tr>
<td>Brucellosis</td>
<td>Meningococcal infections</td>
<td>Tetanus</td>
</tr>
<tr>
<td>Campylobacteriosis</td>
<td>Pertussis</td>
<td>Tularemia</td>
</tr>
<tr>
<td>Cholera</td>
<td>Plague</td>
<td>Typhoid Fever</td>
</tr>
<tr>
<td>Cryptosporidiosis</td>
<td>Poliomyelitis</td>
<td><em>Vibrio parahaemolyticus</em></td>
</tr>
<tr>
<td>Diptheria</td>
<td>Q Fever</td>
<td><em>Vibrio vulnificus</em></td>
</tr>
<tr>
<td><em>Escherichia coli (E. coli)</em> 0157:H7</td>
<td>Rabies, animal</td>
<td>Yellow Fever</td>
</tr>
<tr>
<td><em>E. coli</em> shiga toxin positive (STEC)</td>
<td>Rabies, human</td>
<td></td>
</tr>
<tr>
<td><em>Haemophilus influenza</em> invasive disease</td>
<td>Rubella</td>
<td></td>
</tr>
</tbody>
</table>

### REPORT WITHIN ONE (1) BUSINESS DAY

<table>
<thead>
<tr>
<th>Disease</th>
<th>Disease</th>
<th>Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal conditions known to be communicable to man</td>
<td>Hepatitis B infection in a pregnant woman or a child born in or after 1992</td>
<td>Streptococcal disease invasive, Group A</td>
</tr>
<tr>
<td>Foodborne outbreak / intoxication</td>
<td>Mumps</td>
<td>Toxic Shock Syndrome</td>
</tr>
<tr>
<td>Hepatitis B, acute</td>
<td></td>
<td>Tuberculosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Waterborne out break</td>
</tr>
</tbody>
</table>

### REPORT WITHIN FIVE (5) BUSINESS DAYS

- **AIDS**
- **HIV**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Disease</th>
<th>Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chancroid</td>
<td>Syphilis, other than primary, secondary, early latent or congenital</td>
<td>Toxoplasmosis</td>
</tr>
<tr>
<td><em>Chlamydia trachomatis</em> infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ehrlichiosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gonorrhea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Granuloma inguinale</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis C, acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Histoplasmosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rocky Mountain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spotted Fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Streptococcus pneumoniae</em>, drug-resistant invasive disease</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
REPORT WITHIN (3) MONTHS FOLLOWING DIAGNOSIS:
Asbestosis, Coal Worker’s Pneumoconiosis, and Silicosis

Human Immunodeficiency Virus/AIDS surveillance: See “Report within five (5) business days” above

All cases of HIV infections/AIDS are reportable to a separate surveillance system in accordance with KRS 211.180(1)b. To report a HIV/AIDS case call 866-510-0008.

* Includes California group, Eastern Equine, St. Louis, Venezuelan Equine Western Equine, and West Nile Viruses

Laboratory Surveillance: Influenza virus isolates are to be reported weekly by laboratories.

902 KAR 02:065 requires long term care facilities to report an outbreak (2 or more cases) of influenza-like illnesses (ILI) within 24 hours to the local health department or the KDPH.

Note: Animal bites shall be reported to local health departments within twelve (12) hours in accordance with KRS 258:065.
# STD

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Expedited Partner Therapy................................................................................................................ 

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  - Syphilis ........................................................................................................................................ 
  - Gonococcal Infections ................................................................................................................ 
  - Chlamydial Infections ................................................................................................................ 
  - Mucopurulent Cervicitis (MPC) ............................................................................................... 
  - Nongonococcal Urethritis (NGU) ........................................................................................... 
  - Epididymitis ............................................................................................................................... 
  - Pelvic Inflammatory Disease (PID) .......................................................................................... 
  - Bacterial Vaginosis (BV) .......................................................................................................... 
  - Trichomoniasis .......................................................................................................................... 
  - Candidiasis ................................................................................................................................. 
  - Human Papillomavirus (HPV) ...................................................................................................

STD Drugs in Pregnancy .....................................................................................................................

### CASE MANAGEMENT

STD Offices by Area Developmental Districts .................................................................................. 

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July 2019
# STD MATRIX

<table>
<thead>
<tr>
<th>REASON FOR VISIT</th>
<th>STD VISIT (Primary reason for visit is due to symptoms, exposure, partner problem, positive test and/or high risk behavior)</th>
<th>STD RE-VISIT (Requirements of an STD Visit)</th>
</tr>
</thead>
</table>
| Males and Females | PRIMARY REASON:  
- Positive Test  
- Symptoms – (for STD symptom and duration)  
- Symptomatic Partner  
- Exposure (list STD)  
- STD test only  
- HIV test only  
- Referral (list agency)  
*For all other clinical visits (i.e. Family planning, Adult/Child Prevention, Cancer, etc.), lab testing for STD screening does not require an STD physical exam unless STD symptoms are reported.* | • Positive Test  
• Symptoms – (list symptom and duration)  
• Results  
• Follow-up appointment  
• Other |
| MEDICAL HISTORY | • Significant illnesses; hospitalizations; chronic or acute medical conditions  
• Allergies  
• Current prescription medication and/or antibiotics w/in the last month  
• HX of STD/HIV (list condition, date, and place of RX) | • Identify any changes to the medical history obtained during the prior visit including allergies, prescriptions and/or antibiotics |
| SEXUAL & REPRODUCTIVE HISTORY | • Sex with males, females or both  
• Number of partners w/in 12 mos  
• Number of partners w/in 60 days  
• Number of new partners w/in 60 days  
• Date of last sexual exposure (LSE)  
• Anatomical sites exposed during sexual activity  
<table>
<thead>
<tr>
<th>Exposed Sites</th>
<th>≤ 60 days</th>
<th>≤ 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vagina</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mouth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Penis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
• Frequency of condom usage  
• FEMALES: Last menstrual period, obstetrical history, and gynecological conditions, and current contraceptive use. | • Sexual exposure since last visit  
• Identify any changes to the sexual & reproductive history obtained during the prior visit. |
| RISK ASSESSMENT | Suggested Questions to Ask During The Sexual History | • Identify any changes since last visit |
• When was the last time you had sex?
<table>
<thead>
<tr>
<th>STD VISIT</th>
<th>STD RE-VISIT</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>(Primary reason for visit is due to symptoms, exposure, partner problem, positive test and/or high risk behavior)</em></td>
<td><em>(Requirements of an STD Visit)</em></td>
</tr>
<tr>
<td><strong>Males and Females</strong></td>
<td><strong>Males and Females</strong></td>
</tr>
<tr>
<td>- How many partners have you had sex with in the last 12 months?</td>
<td>- Repeat physical exam per medical/sexual history and risk assessment</td>
</tr>
<tr>
<td>- How many new partners have you had sex with in the last 2 months?</td>
<td></td>
</tr>
<tr>
<td>- When is the last time you had sex with a man? Woman? Both?</td>
<td></td>
</tr>
<tr>
<td>- At what age did you become sexually active?</td>
<td></td>
</tr>
<tr>
<td>- What are you doing to prevent pregnancy?</td>
<td></td>
</tr>
<tr>
<td>- Did you use a barrier the last time you had sex?</td>
<td></td>
</tr>
<tr>
<td>- How often do you use a barrier when you have sex?</td>
<td></td>
</tr>
<tr>
<td>- When is the last time you engaged in oral, anal, or vaginal intercourse?</td>
<td></td>
</tr>
<tr>
<td>- Are you the insertive partner, the receptive partner, or both?</td>
<td></td>
</tr>
<tr>
<td>- Was the sexual encounter consensual or nonconsensual?</td>
<td></td>
</tr>
<tr>
<td>- Have you ever been paid for sex (exchanged sex for drugs or exchanged sex for money)?</td>
<td></td>
</tr>
<tr>
<td>- Have you ever been a resident in a correctional facility?</td>
<td></td>
</tr>
<tr>
<td>- Do you have a history of sexually transmitted diseases?</td>
<td></td>
</tr>
<tr>
<td>- Has your judgment ever been impaired by the use of alcohol or drugs?</td>
<td></td>
</tr>
<tr>
<td>- STD/HIV exposure</td>
<td></td>
</tr>
<tr>
<td>- Substance abuse including IV drug use and alcohol</td>
<td></td>
</tr>
<tr>
<td>- Multiple partners</td>
<td></td>
</tr>
<tr>
<td>- Anonymous partners</td>
<td></td>
</tr>
<tr>
<td>- Sex for money or drugs</td>
<td></td>
</tr>
<tr>
<td>- Abuse or domestic violence</td>
<td></td>
</tr>
<tr>
<td><strong>PHYSICAL EXAM</strong></td>
<td></td>
</tr>
<tr>
<td>- Oral examination.</td>
<td></td>
</tr>
<tr>
<td>- Skin inspection over entire body, especially the lower abdomen, inguinal areas, thighs, hands, palms, and forearms.</td>
<td></td>
</tr>
<tr>
<td>- Inspection of the pubic hair for lice and nits.</td>
<td></td>
</tr>
<tr>
<td>- Inspect external genitalia, perineum, and anus.</td>
<td></td>
</tr>
<tr>
<td>- Palpate for lymphadenopathy, especially the inguinal and femoral regions.</td>
<td></td>
</tr>
<tr>
<td><strong>EMALES:</strong> The examination for STDs should not be deferred for menses unless bleeding is extremely heavy. Urine specimen can be collected for CT/GC testing.</td>
<td></td>
</tr>
<tr>
<td>pregnant patient should be examined and tested in the same manner as the non-pregnant patient with the exception of the bimanual pelvic exam. If a pregnant patient is experiencing vaginal bleeding she should be immediately referred to her obstetrician or certified nurse midwife.</td>
<td></td>
</tr>
<tr>
<td>- Examine the vagina and the cervix, using the appropriate speculum. It is highly recommended that a specimen be obtained from the vaginal vault for a wet mount. Obtain an endocervical specimen for gonorrhea and Chlamydia utilizing an APTIMA test kit. A urine specimen should be obtained from females without a cervix.</td>
<td></td>
</tr>
<tr>
<td>STD VISIT</td>
<td>STD RE-VISIT</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td><strong>(Primary reason for visit is due to symptoms, exposure, partner problem, positive test and/or high risk behavior)</strong></td>
<td><strong>Requirements of an STD Visit</strong></td>
</tr>
<tr>
<td><strong>Males and Females</strong></td>
<td><strong>Males and Females</strong></td>
</tr>
<tr>
<td>• Obtain specimens for gonorrhea from other exposure sites as indicated i.e. throat, rectum</td>
<td></td>
</tr>
<tr>
<td>• Perform a Bimanual pelvic examination. A bimanual exam is to be performed on all females presenting for STD evaluation with the exception of pregnancy and hysterectomy.</td>
<td></td>
</tr>
<tr>
<td>• Recommend women complaining of rectal symptoms to have an anoscopy exam at their primary care provider or an appropriate specialist.</td>
<td></td>
</tr>
<tr>
<td><strong>MALES:</strong></td>
<td></td>
</tr>
<tr>
<td>• Inspect scrotum and palpate scrotal contents; inspect rectal area (perineum &amp; anus) if patient has had male-male sex.</td>
<td></td>
</tr>
<tr>
<td>• Inspect and palpate penis, retract foreskin, and inspect urethra. Using APTIMA Test Kits, obtain intraurethral specimens for gonorrhea and Chlamydia testing and Gram staining if available. If patient is asymptomatic and has not urinated for one hour, may obtain first-catch urine specimen for gonorrhea and Chlamydia.</td>
<td></td>
</tr>
<tr>
<td>• Obtain specimens for gonorrhea from other exposure sites as indicated, i.e. throat, rectum. Recommend men complaining of rectal symptoms to have an anoscopy exam at their primary care provider or an appropriate specialist.</td>
<td></td>
</tr>
<tr>
<td><strong>LABORATORY</strong></td>
<td>Repeat labs per medical/sexual history and risk assessment.</td>
</tr>
<tr>
<td>Note:</td>
<td>(<strong>Note:</strong> Testing for Chlamydia less than 3 weeks from date of treatment may result in a positive result which may represent nonviable Chlamydia remnants from an earlier infection)</td>
</tr>
<tr>
<td>Outline laboratory tests shall be obtained at each STD visit. An STD visit is defined as a visit in which the patient presents with new symptoms, new exposure, partner problem, positive test and/or high risk behavior.</td>
<td></td>
</tr>
<tr>
<td>Obtain blood specimens from all patients for Syphilis IgG (if using the Kentucky Division of Laboratory Services) or RPR (Rapid Plasma Reagin) at each visit except for those patients who have had a documented non-reactive Syphilis test within the past 30 days. Patients presenting with symptoms suggestive of syphilis or who are epidemiologically related to another person with syphilis should have a syphilis test regardless of documentation of testing within the last 30 days. For patients presenting with lesion(s) suggestive of syphilis, a confirmatory test should be requested if using a non-state laboratory. Confirmatory tests for syphilis are IGG, TPHA and FTA.</td>
<td></td>
</tr>
<tr>
<td>• Obtain specimen for Chlamydia (CT/GC APTIMA Test)</td>
<td></td>
</tr>
<tr>
<td>• Except in pregnant women, a test of cure is not recommended for persons treated with the recommended or alternative regimens, unless therapeutic compliance is in question symptoms persist, or re-infection is suspected. Testing in less than 3 weeks after completion of therapy could yield a false positive result due to the presence of dead CT organisms.</td>
<td></td>
</tr>
<tr>
<td>• Obtain specimen for Gonorrhea (CT/GC APTIMA Test)</td>
<td></td>
</tr>
</tbody>
</table>
### STD VISIT

(Primary reason for visit is due to symptoms, exposure, partner problem, positive test and/or high risk behavior)

<table>
<thead>
<tr>
<th>Males and Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Test of cure is not recommended routinely for patients with uncomplicated gonorrhea who have been treated with the recommended regimens. Patients with persistent symptoms or whose symptoms recur shortly after treatment should be reevaluated by culture; positive isolates should undergo antimicrobial susceptibility testing.</td>
</tr>
<tr>
<td>• Obtain blood or oral specimens for HIV testing from all patients seeking STD services except for those patients who have a documented negative HIV test within the past 90 days or if the patient declines.</td>
</tr>
<tr>
<td>• Obtain blood specimens for HCV testing from all patients seeking STD services. Please refer to HCV Matrix 1 - Collection and Handling Guidance and HCV Matrix 2 – Screening and Referral Guidance.</td>
</tr>
</tbody>
</table>

#### at Testing (Dependent upon availability at the LHD)

Stat RPRs for syphilis, if available, should be ordered on patients with ANY of the following:
- Genital lesion(s)
- Rash suggestive of syphilis
- Epidemiological link to another person with syphilis
- History of lesions or lymphadenopathy since last negative serologic test for syphilis (STS).

If stat RPR is not available and the patient has a lesion(s), obtain a blood specimen for Syphilis IGGE (if using the Division of Laboratory Services). If using a lab that does not use reverse syphilis testing, order a VDRL or RPR plus request confirmatory testing such as IGG, TPPA, or FTA. (A negative VDRL or RPR with clinical symptoms suggestive of primary syphilis such as a lesion(s) does not rule out syphilis). Repeat screening for primary disease may require additional testing at 2-4 weeks but should not impede empiric treatment if symptoms are highly suggestive of syphilis. For specimens submitted to Kentucky’s Division of Laboratory Services, reflexive confirmatory testing will follow the current CDC Guidelines (VDRL and TPPA as indicated for positive results).

Gram stain for gonorrhea, if available, should be ordered on male patients who present with ANY of the following:
- Penile Discharge
- Dysuria

### STD RE-VISIT

Requirements of an STD Visit

<table>
<thead>
<tr>
<th>Males and Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>• As assessed for individual patient needs.</td>
</tr>
</tbody>
</table>

### PROVIDE

<table>
<thead>
<tr>
<th>Males and Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Treatment as indicated in this guide or CDC Treatment Guidelines.</td>
</tr>
<tr>
<td>• Recommendation/Referral for other health care needs or to a higher level provider if needed.</td>
</tr>
<tr>
<td>• Recommendation/Referral for social services (as needed)</td>
</tr>
<tr>
<td>• Linkage for partner services (contact STD regional area to initiate partner services if patient is diagnosed with syphilis and/or HIV.</td>
</tr>
<tr>
<td>STD VISIT</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>(Primary reason for visit is due to symptoms, exposure, partner problem, positive test and/or high risk behavior)</td>
</tr>
<tr>
<td>Males and Females</td>
</tr>
<tr>
<td>• Follow up appointment (as needed)</td>
</tr>
<tr>
<td>• Condoms</td>
</tr>
</tbody>
</table>

Priority consideration in regards to patient flow should be given to patients who are known to be infected with an STD or is an epidemiological link to an individual known to be infected.

**Counseling messages should include:**
- Take medication as directed.
- Abstain from sex until the patient and patient’s sex partners have completed treatment. Abstinence should be continued until 7 days after a single-dose regimen or after completion of a multi-dose regimen.
- Return for all follow-up appointments.
- How to obtain test results.
- Safe sex, risk reduction messages.
- Pregnancy prevention.
- Provide partner services to individuals diagnosed with Chlamydia, gonorrhea, NGU or MPC.

Educational materials can be located at: [http://www.cdc.gov/std/products/default.htm](http://www.cdc.gov/std/products/default.htm)

**REQUIREMENTS FOR STD EXAMINATIONS**

- Assure that patients with positive Chlamydia and/or gonorrhea tests return for treatment within seven (7) days of receipt of laboratory report. The STD Program goal is to provide treatment to 85% of infected patients within 14 days of specimen collection and to 90% within 30 days of specimen collection.
- Provide face-to-face counseling/interviewing to public health clinic patients diagnosed with Chlamydia, gonorrhea, NGU or Mucopurulent Cervicitis. Interviews should be achieved in a timely manner, with the goal of obtaining an average of at least one contact elicited per case interviewed. This service should be available to privately diagnosed and treated patients upon request of their physician. Although infected patients are under no legal obligation to participate in partner services, every effort should be made to motivate the patient to engage in partner services to ensure that exposed partners are identified, notified and provided adequate exam and treatment services.
- Assure that contacts to syphilis, HIV, Chlamydia, gonorrhea, NGU, Mucopurulent Cervicitis named in interviews with infected patients are referred for medical evaluation in a timely manner.
- Assure that DIS priority referrals are “fast tracked” within the LHD STD clinic.
REQUIREMENTS FOR STD EXAMINATIONS

- Assure reporting of suspected sexual abuse to the Department for Community-Based Services.
- Provide all patients with counseling and/or printed materials, and motivate patients to:
  - Increase patients’ awareness of signs and symptoms of STDs and prompt patient to seek medical care immediately should evidence of symptoms occur.
  - Increase the number of sexual partners referred for evaluation by STD patients.
  - Increase patients’ rate of compliance with prescribed medication regimens.
  - Increase the practice of preventive behaviors in the patient population (e.g. use of condoms, selection of partners, etc.).
- Request area DIS for epidemiologic follow-up for 100% of suspected or diagnosed cases of priority STD (early syphilis and HIV infection).

Guidance for Delivering Expedited Partner Therapy

**Goal:**
To reduce the risk of re-infection among persons treated for gonorrhea and chlamydia, prevent disease complications, and reduce transmission to un-infected persons.

**Objective:**
To implement expedited partner therapy (EPT) to the sex partners of persons with gonorrhea and chlamydia without an intervening medical evaluation or professional prevention counseling.

**Background:**
Most health care providers advise their patients with STDs to notify their sex partners. The CDC estimates the proportion of partners who seek evaluation and treatment in response to patient referral ranges from 29% to 59%. In addition, because of limited staff and resources, partners of patients diagnosed with gonorrhea or chlamydia are less likely to be contacted and treated by public health personnel. In Kentucky, health departments rarely actively pursue partners of index patients with gonorrhea or chlamydia.

The ideal approach for the partner(s) of a patient diagnosed with any STD is to be evaluated, examined, tested, counseled, and treated by a medical provider. However, this approach is not always feasible. EPT is the clinical practice of treating partners of patients diagnosed with gonorrhea or chlamydia without an intervening medical evaluation or professional prevention counseling. The usual implementation of EPT is where patients deliver medications or prescriptions to their sexual partner(s). (However, if their sex partner accompanies a patient diagnosed with gonorrhea and/or chlamydia to their appointment, the provider should ensure the partner is examined, tested, and treated during that visit.) Other potential means to achieve EPT include prescriptive arrangements
with cooperating pharmacies, retrieval of medication by partners at public health clinics, or delivery of medication to partners in non-clinical settings by public health workers.

Several studies have shown that EPT is an effective option for treating gonorrheal and chlamydial infections in the sex partners of heterosexual patients, can prevent re-infection of an index patient, and slow/stop the transmission of disease to other uninfected partners. EPT also saves money by reducing more advanced disease, and it allows clinicians to treat more infected persons.

**Practical Issues in Providing EPT**

**Special Populations**

1) Adolescents should be given high priority in partner management. This age group has the highest rates of infection of all age groups. 2) Full STD exams are preferred in men who have sex with men (MSM) because of the likely high prevalence of co-morbidities, including HIV infection and other STDs. 3) Preventing re-infection in pregnant women is a high priority. If the partner is pregnant, every effort should be made to contact her for referral to pregnancy services and/or prenatal care. Rescreening pregnant patients for CT in 3-4 weeks after treatment should be emphasized.

**Missed Opportunities**

Potential pitfalls of using EPT include: 1) inability to diagnose and treat co-infection that would be detected by personal evaluation of the partner(s), 2) missing complications of infection (e.g., PID, pregnancy, testicular pain, abdominal pain, fever, etc.), 3) lack of risk reduction counseling, 4) inability to evaluate the risk of sexual abuse.

**Cost of Providing EPT**

Local Health Department STD clinics should provide partners with medications supplied to them by the Kentucky STD Prevention Program. STD clinics may not charge for partner medications supplied by the Kentucky STD Prevention Program. The clinic may provide a written prescription for the index patient to take to his or her partner(s) to fill at the clinic or DIS may also deliver medications to partners under certain circumstances. The prescription will be written in the partner(s)’s name.

**Selecting Appropriate Patients for EPT**

Appropriate patients are heterosexual and have a clinical or presumptive diagnosis of chlamydia or gonorrhea infection.

The partners of the following patients are candidates for EPT:

- Women with PID (treat for GC and CT)
- Women with GC and/or CT diagnosed by lab testing
- Men with laboratory diagnosis of Chlamydia and/or gonorrhea or clinical diagnosis of NGU for female partners only
- Women with mucopurulent cervicitis (MPC) (treat for CT)
Guidance for Delivering Expedited Partner Therapy

Exclusions from EPT:

- Partners with symptoms – especially fever, pelvic, testicular, groin, or abdominal pain. These partners need a clinical evaluation.
- MSM because of the additional risk of syphilis or HIV infection. These partners need a clinical evaluation and HIV/syphilis testing.

**Partner Treatment**

Gonorrhea: cefixime 400mg **AND** azithromycin 1gm

Chlamydia: azithromycin 1gm

Partners in the 60 days prior to diagnosis should be treated with the same medication(s). Partners of partners are not candidates for EPT.

**Partner Information**

Written partner informational materials are printed in the partner’s language and given to the patient to deliver to each partner. A referral for partner evaluation is included. Key partner counseling messages include:

- Partners should seek a complete STD evaluation as soon as possible.
- Partners should read the informational material very carefully before taking the medication.
- Partners who have allergies to antibiotics or who have serious health problems should not take the medication and should see a health care provider.
- Partners who have symptoms of a more serious infection (e.g., pelvic pain in women, testicular pain in men, or fever in men or women) should not take EPT and should seek care as soon as possible.
- Partners who are or who could be pregnant should seek care as soon as possible.
- Patients and partners should abstain from sex for at least seven days after treatment and for seven days after all partners have been treated, in order to reduce the risk of recurrent infection.
- Partners should re-test three months after treatment.

**Documentation**

The names of partners receiving EPT are written in the index patient’s chart. Sexual partners do not require a medical chart in order to be provided EPT.

Additional note in the index patient’s chart documents the following information:

- The number of partners who are being provided with EPT
- The medication and dose being provided
Guidance for Delivering Expedited Partner Therapy

- Whether the partner(s) are pregnant
- Or known to be allergic to antibiotics.

A log is kept to document the following information:

- Index patient’s name
- Date of birth
- Date medication(s) given
- Name of medication and strength
- Number of doses given
- Lot number and expiration date
# Protocols for Treatment of Common Sexually Transmitted Diseases

## Syphilis

(see 2015 CDC guidelines for follow-up recommendations and management of congenital syphilis)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Symptoms</th>
<th>Tests</th>
<th>Recommended Treatment</th>
<th>Alternatives</th>
<th>Partner Services</th>
<th>Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary (1st)</strong>,</td>
<td>Indurated chancre usually painless</td>
<td>(For specimens submitted to the Kentucky Division of Laboratory Services)</td>
<td><strong>Benzathine Penicillin</strong> G 2.4 million units (MU) IM</td>
<td>(For penicillin allergic)</td>
<td>Contact STD Supervisor within your regional area within 24 hours to initiate partner services for index patient.</td>
<td>Complete EPID 200 and fax to State STD Program within 24 hours.</td>
</tr>
<tr>
<td><strong>Secondary (2nd)</strong></td>
<td>Rash - bilateral macular, papular, follicular, papulosquamous or pustular lesions.</td>
<td>VDRL or TPPA (For specimens submitted to labs not using reverse syphilis testing)</td>
<td>Symptomatic men &amp; women shall be treated empirically on their initial visit.</td>
<td>DOXYCYCLINE 100 mg orally 2 times a day for 14 days</td>
<td>All Sex partners exposed to any stage of syphilis in the previous 90 days should be examined, tested and preventively treated for syphilis on their initial visit. Partners shall be screened for gonorrhea, Chlamydia and HIV. Sexual partners beyond 90 days shall be examined and screened for syphilis, HIV, gonorrhea, and Chlamydia.</td>
<td></td>
</tr>
<tr>
<td><strong>EARLY LATENT</strong> (&lt;1 year)</td>
<td>Alopecia, Condylomata lata, Mucous Patches</td>
<td><strong>CEFTIRAXONE</strong> 1 g daily IV or IM for 10-14 days. (please see footnote below)</td>
<td><strong>Alopecia, Condylomata lata, Mucous Patches</strong></td>
<td><strong>(please see footnote below) This recommendation is based on limited studies. Therefore, the optimal dose and duration of ceftriaxone therapy have not been defined.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Adults</strong></td>
<td></td>
<td>VDRL/RPR And confirmatory test if needed such as: TPPA, FTA, or MHA Stat RPR and Dark Field is desired if primary or secondary SX are present</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Children</strong></td>
<td>Same as Adult</td>
<td>Same as Adult Plus</td>
<td>Infants and children who are allergic to penicillin should be desensitized</td>
<td>Contact STD Supervisor within your regional area ≥ 12 years of age.</td>
<td></td>
<td>Same as Adult Plus Report suspected cases</td>
</tr>
<tr>
<td><strong>Primary, Secondary or Early Latent</strong></td>
<td>Same as Adult</td>
<td>Same as Adult Plus</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

### Footnotes:

1. **CEFTIRAXONE**

   - This recommendation is based on limited studies. Therefore, the optimal dose and duration of ceftriaxone therapy have not been defined.
<table>
<thead>
<tr>
<th>CONDITION</th>
<th>SYMPTOMS</th>
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<th>RECOMMENDED TREATMENT</th>
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<th>REPORTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>SYPHILIS (see 2015 CDC guidelines for follow-up recommendations and management of congenital syphilis)</td>
<td>(aged ≥ 1 month)</td>
<td>See CDC Treatment Guidelines for the management of congenital syphilis</td>
<td>CSF Examination</td>
<td>should be managed by the child's physician. LHDs shall assure adequate RX.</td>
<td>and then treated with penicillin</td>
<td>of sexual abuse to the Dept of Community Based Services</td>
</tr>
</tbody>
</table>
## Protocols for Treatment of Common Sexually Transmitted Diseases

### Syphilis

<table>
<thead>
<tr>
<th>Condition</th>
<th>Symptoms</th>
<th>Tests</th>
<th>Recommended Treatment</th>
<th>Alternatives</th>
<th>Partner Services</th>
<th>Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LATE LATENT (&gt;1 YEAR) OR LATENT OF UNKNOWN DURATION</strong></td>
<td>None</td>
<td>(For specimens submitted to the Kentucky Division of Laboratory Services) Syphilis IGGE with reflex to VDRL or TPPA (For specimens submitted to labs not using reverse syphilis testing) VDRL/RPR (And confirmatory test if needed such as TPPA, FTA, or MHA) See CDC Treatment Guidelines to determine if CSF exam is needed</td>
<td>Benzathine penicillin G 2.4 million units IM for 3 doses, 1 week apart (total: 7.2 million units)</td>
<td>(For penicillin allergic non-pregnant adult patients) DOXYCYCLINE 100 mg orally 2 times a day for 28 days (for adults only)</td>
<td>Contact STD Supervisor within your regional area.</td>
<td>Complete EPID 200 and fax to State STD Program.</td>
</tr>
</tbody>
</table>

**Adults**

**Children**

| Late Latent or Latent of Unknown Duration | Same as Adult | Same as Adult Plus | Benzathine penicillin G 50,000 units/kg IM up to the adult dose of 2.4 million units, Infants and children who are allergic to penicillin should be desensitized | Same as Adult Plus | Report suspected cases | |
# Protocols for Treatment of Common Sexually Transmitted Diseases

**Syphilis** (see 2015 CDC guidelines for follow-up recommendations and management of congenital syphilis)

<table>
<thead>
<tr>
<th>Condition</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Syphilis (aged ≥1 month)</td>
<td>CSF Examination</td>
<td>administered for three doses at 1 week intervals (total 150,000 units/kg up to the adult total dose of 7.2 million units)</td>
<td>and then treated with penicillin</td>
<td>Complete EPID 200 and fax to State STD Program.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurosyphilis</td>
<td>Neurologic or ophthalmic abnormalities</td>
<td>CSF Examination</td>
<td>* Aqueous crystalline penicillin G 18-24 million units per day, administered as 3-4 million units IV every 4 hours or continuous infusion, for 10-14 days</td>
<td>Procaine penicillin 2.4 million units IM once daily for 10-14 days plus probenecid 500 mg orally 4 times a day for 10-14 days</td>
<td>Contact STD Supervisor within your regional area.</td>
<td></td>
</tr>
<tr>
<td>Syphilis with a co-infection of HIV</td>
<td>SEE ABOVE</td>
<td>SEE ABOVE</td>
<td>* For 1\textsuperscript{st}, 2\textsuperscript{nd} and early latent syphilis: Treat as above. *Additional doses of Benzathine penicillin G in early syphilis do not enhance efficacy, regardless of HIV status.</td>
<td>The use of any alternative therapy in HIV infected persons has not been well studied; therefore the use of doxycycline</td>
<td>Contact STD Supervisor within your regional area if index patient is co-infected w/HIV to initiate partner services.</td>
<td>Notify HIV/AIDS surveillance if newly diagnosed HIV case.</td>
</tr>
</tbody>
</table>

*Generally, RX for STDs found in a pre-pubertal child should be managed by the child's physician. LHDs shall assure adequate RX.*
### PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES

<table>
<thead>
<tr>
<th>CONDITION</th>
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<th>REPORTING</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SYphilis</strong> (see 2015 CDC guidelines for follow-up recommendations and management of congenital syphilis)</td>
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<tr>
<td><strong>SYphilis AND PREGNANCY</strong></td>
<td>SEE ABOVE</td>
<td>SEE ABOVE</td>
<td>Penicillin is the only recommended treatment for syphilis during pregnancy. Women who are allergic should be desensitized and then treated with penicillin. Dosages are the same as in non-pregnant patients for each stage of syphilis.2</td>
<td>N/A</td>
<td>Contact STD Supervisor within your regional area within 24 hours of laboratory receipt.</td>
<td>Complete EPID 200 and fax to State STD Program within 24 hours. Indicate pregnancy status on EPID 200.</td>
</tr>
</tbody>
</table>

Centers for Disease Control and Prevention. MMWR 2015; Vol. 64/No.3: Syphilis (Pages 34-48)
### Gonococcal Infections

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>SYMPTOMS</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>GC - ADULTS</strong></td>
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<tr>
<td>Cervix, Urethra, Rectum</td>
<td>Females- Often asymptomatic.</td>
<td>APTIMA CT/GC COMBO 2 (NAAT) TEST</td>
<td>Ceftriaxone (^1) 250 mg IM in a single dose <strong>PLUS</strong></td>
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<td></td>
<td>Cervical: Cervical discharge. Also-Increased vaginal discharge, bleeding between periods and dysuria.</td>
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<td>Azithromycin 1 gm orally in a single dose</td>
<td>Cefixime 400 mg orally in a single dose <strong>PLUS</strong></td>
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<tr>
<td></td>
<td>Males- May be asymptomatic.</td>
<td>DLS offers this molecular test for rectal and pharyngeal specimens.</td>
<td>Azithromycin 1 gm orally in a single dose</td>
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<tr>
<td></td>
<td>Males &amp; Females- Urethra: Discharge (white, yellow or green), Dysuria. Rectal: Pain, itching discharge,</td>
<td>Male: Gram stain of urethral discharge (if test is available at LHD).</td>
<td>Ceftriaxone and Azithromycin should be administered together on the same day, preferably simultaneously.</td>
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<td></td>
<td>Sex partners exposed during the previous 60 days should be examined, tested and preventively treated for gonorrhea and Chlamydia on their initial visit. They shall also be screened for Chlamydia, syphilis and HIV.</td>
<td>Complete EPID 200 and fax or mail to State STD Program within 14 days.</td>
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<td></td>
<td>EPID 200's that do not contain treatment at time of initial report shall be updated with treatment information and sent to state STD office 7 days after RX administration</td>
<td>85% of patients' diagnosed w/GC should be treated within 14 days from the date of lab collection and 90% within 30 days from the</td>
</tr>
</tbody>
</table>

**Special Considerations**

**Azithromycin allergy:**
Doxycycline 100 mg orally BID for 7 days may be used as the second antimicrobial.

**Cephalosporin or IgE-mediated penicillin allergy:**
Consult an infectious disease specialist.

**Potential options:**
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>GONOCOCCAL INFECTIONS</strong></td>
<td>bleeding; may be asymptomatic.</td>
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<td></td>
<td>Gemifloxacin 320 mg orally in a single dose PLUS Azithromycin 2 gm orally in a single dose OR Gentamicin 240 mg IM PLUS Azithromycin 2 gm orally in a single dose</td>
<td>date of lab collection.</td>
<td></td>
</tr>
<tr>
<td>CONDITION</td>
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<tr>
<td><strong>GONOCOCCAL INFECTIONS</strong></td>
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</tr>
<tr>
<td><strong>GC – PHARYNX</strong></td>
<td>Sore throat, pharyngeal exudate, enlarged cervical lymph nodes; often asymptomatic.</td>
<td>APTIMA CT/GC COMBO 2 (NAAT) TEST DLS offers this molecular test for rectal and pharyngeal specimens. DLS does not perform GC cultures</td>
<td>• Ceftriaxone¹ 250 mg IM in a single dose <strong>PLUS</strong> • Azithromycin 1 gm orally in a single dose</td>
<td>Cephalosporin or IgE-mediated penicillin allergy: Consult an infectious disease specialist (Individuals receiving alternative regimens for pharyngeal GC shall have a test of cure (NAAT) 14 days after completion of therapy)</td>
<td>SEE ABOVE</td>
<td>SEE ABOVE</td>
</tr>
<tr>
<td><strong>GC in CHILDREN</strong></td>
<td>SEE GC SX IN ADULTS</td>
<td>DLS lab does not perform GC cultures.</td>
<td>• Ceftriaxone¹ 25-50 mg/kg IV or IM in a single dose, not to exceed 125 mg IM</td>
<td>N/A</td>
<td>SEE ABOVE if &gt;12 years of age.</td>
<td>Complete EPID 200 and fax or mail to State STD Program within 14 days. Report suspected cases of sexual abuse to the Dept of Community Based Services</td>
</tr>
<tr>
<td>(=&lt;45KG or &lt;100 lbs) Uncomplicated Vulvovaginitis, Cervicitis, Urethritis, Pharyngitis, or Proctitis</td>
<td>Generally, RX for STDs found in a pre-pubertal child should be managed</td>
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</tbody>
</table>
### Gonococcal Infections

**GC in CHILDREN**

(>45KG)

- Generally, RX for STDs found in a pre-pubertal child should be managed by the child's physician. LHDs shall assure adequate RX.

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</tr>
</thead>
<tbody>
<tr>
<td>SEE GC SX IN ADULTS</td>
<td>DLS lab does not perform GC cultures. Because of the legal implications of a diagnosis of <em>N. gonorrhoeae</em> infection in a child, culture is the preferred method. NAATs, however, can be used for vaginal or urine specimens from girls (only).</td>
<td>Same regimen as recommended for adults</td>
<td>Same regimen as recommended for adults</td>
<td>SEE ABOVE if ≥12 years of age.</td>
<td>Complete EPID 200 and fax or mail to State STD Program within 14 days.</td>
<td>Report suspected cases of sexual abuse to the Dept of Community Based Services</td>
</tr>
</tbody>
</table>
## Gonococcal Infections

<table>
<thead>
<tr>
<th>Condition</th>
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<th>Partner Services</th>
<th>Reporting</th>
</tr>
</thead>
</table>
| GC - PREGNANCY     | SEE GC SX IN ADULTS | SEE GC TESTS IN ADULTS | - Ceftriaxone 1 250 mg IM once *PLUS*  
   - Azithromycin 1 gm orally in a single dose | When cephalosporin allergy or other considerations preclude treatment with the recommended regimen, consultation with an infectious-disease specialist is recommended. | Sex partners exposed during the previous 60 days should be examined, tested and preventively treated for gonorrhea and Chlamydia on their initial visit. They shall also be screened for Chlamydia, syphilis and HIV. | Complete EPID 200 and fax or mail to State STD Program within 14 days.  
   Indicate pregnancy status on EPID 200 form. |

Centers for Disease Control and Prevention. MMWR 2015; Vol. 64/No. 3: Gonococcal Infections (Pages 60-68)
<table>
<thead>
<tr>
<th>PROTOCOLS FOR TREATMENT OF COMMON SEXUALLY TRANSMITTED DISEASES (continued)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CONDITION</strong></td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td><strong>CHLAMYDIAL INFECTIONS</strong></td>
</tr>
</tbody>
</table>
| **CT - ADULT** | Men- Urethral discharge or dysuria; often asymptomatic. | MALE & FEMALE APTIMA CT/GC COMBO 2 (NAAT) TEST | • Azithromycin 1 g orally single dose  
 OR  
 • Doxycycline 100 mg orally 2 times a day for 7 days  
 Symptomatic men and women, presenting for an STD visit, shall be treated empirically for both CT and GC on their initial visit. | • Erythromycin base 500 mg orally 4 times a day for 7 days  
 OR  
 • Erythromycin ethylsuccinate 800 mg orally 4 times a day for 7 days  
 OR  
 • Ofloxacin$^4$ 300 mg orally 2 times a day for 7 days  
 OR  
 • Levofloxacin$^4$ 500 mg orally once a day for 7 days | Sex partners exposed during the previous 60 days should be examined, tested and preventively treated for Chlamydia on their initial visit. They shall also be screened for gonorrhea, syphilis and HIV. | Complete EPID 200 and fax or mail to State STD Program within 14 days.  
 • EPID 200’s that do not contain treatment at time of initial report shall be updated with treatment information and sent to state STD office 7 days after RX administration  
 85% and 90% of patients DX w/CT should be treated within 14 and 30 days, respectively, from the date of lab collection. |
| | Women- Vaginal/cervical discharge, dysuria; often asymptomatic. | DLS offers this molecular test for rectal and pharyngeal specimens.  
 Retest men and women who have been treated for Chlamydia whenever they seek medical care within 3–12 months following treatment. | | | | |
| **CT in CHILDREN** (<45 KG or <100 lbs) | SEE CT SX IN ADULTS ABOVE | MALE & FEMALE APTIMA CT/GC COMBO 2 (NAAT) TEST | • Erythromycin base or ethylsuccinate 50 mg/kg/day orally divided into four doses daily for 14 days$^6$ | N/A | N/A | Complete EPID 200 and fax or mail to State STD Program within 14 days.  
 PLUS |
<table>
<thead>
<tr>
<th>CONDITION</th>
<th>SYMPTOMS</th>
</tr>
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<tbody>
<tr>
<td>CHLAMYDIAL INFECTIONS</td>
<td></td>
</tr>
<tr>
<td>child's physician. LHDs shall assure adequate RX.</td>
<td></td>
</tr>
<tr>
<td>possibility of false-positive test results.</td>
<td></td>
</tr>
<tr>
<td>(DLS lab does not perform CT culture)</td>
<td></td>
</tr>
<tr>
<td>Report suspected cases of sexual abuse to the Dept of Community Based Services</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CT in CHILDREN</th>
<th>SEE CT SX IN ADULTS ABOVE</th>
<th>SEE CT IN CHILDREN &quot;TESTS&quot; ABOVE</th>
<th>Azithromycin 1 g orally single dose</th>
<th>N/A</th>
<th>N/A</th>
<th>See Above</th>
</tr>
</thead>
<tbody>
<tr>
<td>(≥45 KG and &lt;8 years of age)</td>
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<tr>
<td>Generally, RX for STDs found in a pre-pubertal child should be managed by the child's physician. LHDs shall assure adequate RX.</td>
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<tr>
<th>CT in CHILDREN</th>
<th>SEE CT SX IN ADULTS ABOVE</th>
<th>SEE CT IN CHILDREN &quot;TESTS&quot; ABOVE</th>
<th>Azithromycin 1 g orally single dose</th>
<th>Doxycycline 100 mg orally 2 times a day for 7 days</th>
<th>SEE ABOVE if ≥ 12 years of age.</th>
<th>See Above</th>
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</thead>
<tbody>
<tr>
<td>( ≥ 8 years)</td>
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</table>

<table>
<thead>
<tr>
<th>CT IN PREGNANCY</th>
<th>SEE ABOVE</th>
<th>SEE ABOVE</th>
<th>Azithromycin 1 g orally single dose</th>
<th>Amoxicillin 500 mg orally 3 times a day for 7 days</th>
<th>Sex partners exposed during the previous 60 days should be examined, tested and</th>
<th>Complete EPID 200 and fax or mail to State STD Program within 14 days.</th>
</tr>
</thead>
</table>
### CHLAMYDIAL INFECTIONS

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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 weeks after completion of therapy is recommended for all pregnant women to ensure therapeutic cure.</td>
<td></td>
<td>• Erythromycin base 500 mg orally 4 times a day for 7 days <strong>OR</strong>&lt;br&gt;• Erythromycin 250 mg orally 4 times a day for 14 days <strong>OR</strong>&lt;br&gt;• Erythromycin ethylsuccinate 800 mg orally 4 times a day for 7 days <strong>OR</strong>&lt;br&gt;• Erythromycin ethylsuccinate 400 mg 4 times a day for 14 days</td>
<td>preventively treated for Chlamydia on their initial visit. They shall also be screened for gonorrhea, syphilis and HIV.</td>
<td>Indicate pregnancy status on EPID 200 form.</td>
<td></td>
</tr>
</tbody>
</table>

Centers for Disease Control and Prevention. MMWR 2015; Vol. 64/No. 3: Chlamydial Infections (Pages 55-59)
<table>
<thead>
<tr>
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</thead>
</table>
| MPC  Mucopurulent Cervicitis | 1. Endocervical discharge which may appear green or yellow when viewed on a white cotton tipped swab.  
2. Easily induced cervical bleeding (friability, i.e. bleeding when the first swab is placed in the endocervix). | APTIMA CT/GC COMBO 2(NAAT) TEST | • Azithromycin 1 g orally single dose <br> **OR** <br> • Doxycycline 100 mg orally 2 times a day for 7 days | • Azithromycin 1 gm orally in a single dose* <br> **OR** <br> • Erythromycin 500 mg orally 4 times a day for 7 days | Sex partners exposed during the previous 60 days should be examined and tested for gonorrhea and chlamydia on their initial visit. They shall also be screened for syphilis and HIV. | MPC is not a reportable condition. However if the Chlamydia or gonorrhea test is positive, complete the EPID 200 form and report to state STD program within 14 days. |

Symptomatic women presenting for an STD visit, shall receive empirical treatment for both CT and GC during their initial visit.

*Consider concurrent treatment for gonococcal infection if prevalence of gonorrhea is high in the patient population under assessment.

Symptomatic sex partners should be empirically treated on their initial visit.

Asymptomatic sex partners should be preventively treated on their initial visit if the original patient’s lab result is pending or positive.
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>MPC Mucopurulent Cervicitis</td>
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</tr>
<tr>
<td>MPC in PREGNANCY</td>
<td>SEE ABOVE</td>
<td>SEE ABOVE</td>
<td>• Azithromycin 1 g orally single dose OR • Amoxicillin 500 mg orally 3 times a day for 7 days</td>
<td>• Azithromycin 1 gm orally in a single dose * OR • Erythromycin 500 mg orally 4 times a day for 7 days</td>
<td>SEE ABOVE</td>
<td>SEE ABOVE</td>
</tr>
</tbody>
</table>

*Consider concurrent treatment for gonococcal infection if prevalence of gonorrhea is high in the patient population under assessment.

Centers for Disease Control and Prevention. MMWR 2015; Vol. 64/No. 3: Cervicitis (Pages 53-55)
<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>NGU</strong> Nongonococcal Urethritis</td>
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<tr>
<td><strong>NON-GONOCOCCAL URETHRITIS (NGU)</strong></td>
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<tr>
<td>Men</td>
<td>Urethral Discharge (Often early a.m.) And Dysuria. Discharge can be mucopurulent, purulent or clear. NGU is a clinical assessment based on symptoms. It is best supported by one type of lab. Such as a gram stain with five (5) or more PMNs per oil immersion field with no evidence of gonorrhea. Submit APTIMA CT/GC COMBO (NAATS) test</td>
<td></td>
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<td></td>
<td>Symptomatic men shall receive empirical treatment for both CT and GC during their initial visit. • Azithromycin 1 g orally single dose OR • Doxycycline 100 mg orally 2 times a day for 7 days</td>
<td></td>
<td>Erythromycin base 500 mg orally 4 times a day for 7 days OR Erythromycin ethylsuccinate 800 mg orally 4 times a day for 7 days OR Ofloxacin 300 mg orally 2 times a day for 7 days OR Levofoxacin 500 mg orally once a day for 7 days</td>
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<td></td>
<td>All persons sexually exposed within the previous 60 days should be tested and preventively treated for chlamydia and gonorrhea on their initial visit. Partners shall be screened for CT, GC, syphilis and HIV.</td>
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<td>Empiric treatment for partners with a drug regimen effective against chlamydia is recommended for women exposed to NGU regardless of whether a specific etiology is identified in the original patient. Empiric partner treatment for gonorrhea may be omitted if ruled out by Gram Stain or NAATS testing in the original patient.</td>
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<td></td>
<td>NGU is not a reportable condition. However if the Chlamydia or gonorrhea test is positive, complete the EPID 200 form and report to state STD program within 14 days.</td>
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</tbody>
</table>
Centers for Disease Control and Prevention. MMWR 2015; Vol. 64/No. 3: Nongonococcal Urethritis (Pages 52-53).
<table>
<thead>
<tr>
<th>CONDITION</th>
<th>SYMPTOMS</th>
<th>TESTS</th>
<th>RECOMMENDED TREATMENT</th>
<th>ALTERNATIVES</th>
<th>PARTNER SERVICES</th>
<th>REPORTING</th>
</tr>
</thead>
</table>
| EPIDIDYMITIS | Epididymitis\(^9\) | 1. Acute pain (present for less than 7 days) and swelling in area of epididymis (may also involve testes). 2. Tender swelling, infrequently accompanied by redness, usually unilateral noted in the posterior aspect of the scrotum. 3. Accompanying urethral discharge or dysuria. | Submit CT/GC APTIMA test. | • Ceftriaxone\(^1\) 250 mg IM single dose **PLUS**  
• Doxycycline 100 mg orally 2 times a day for 10 days **CONSULT PHYSICIAN OR REFER IF:**  
• Any patient with No. 1 and No. 2 listed under symptoms who is 40 yrs of age or older.  
• History of symptoms present for longer than 30 days.  
• Consider testicular torsion in adolescent without pyuria/white cells on urethral smear with acute onset pain.  
*Note: This is a surgical emergency.* | Ceftriaxone 250 mg IM in a single dose **PLUS**  
• Ofloxacin\(^3\) 300 mg orally twice daily for 10 days **OR**  
• Levofloxacin\(^4\) 500 mg orally once a day for 10 days  
For acute epididymitis most likely caused by sexually-transmitted chlamydia and gonorrhea and enteric organisms (men who practice insertive anal sex) | All persons sexually exposed within the previous 60 days should be tested and preventively treated for Chlamydia and gonorrhea on their initial visit. Partners shall be screened for CT, GC, syphilis and HIV. | Epididymitis is not a reportable condition. However, if the Chlamydia or gonorrhea test is positive, complete the EPID 200 form and report to state STD program within 14 days. |

Centers for Disease Control and Prevention. MMWR 2015; Vol. 64/No. 3: Epididymitis (Pages 82-84).
## Protocols for Treatment of Common Sexually Transmitted Diseases (continued)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Symptoms</th>
<th>Tests</th>
<th>Recommended Treatment</th>
<th>Alternatives</th>
<th>Partner Services</th>
<th>Reporting</th>
</tr>
</thead>
</table>
| **Pelvic Inflammatory Disease (PID)**  
(outpatient management)           | 1. Low abdominal pain or painful intercourse by patient’s history.        | Submit CT/GC APTIMA test.     | **• Ceftriaxone 250 mg IM once**                                                      | **• Cefoxitin 2 g IM once plus probenecid 1 g orally once**                  |                   |                                                |
<p>|                                  | 2. Low abdominal tenderness on bimanual exam.                             |                               | <strong>PLUS</strong>                                                                             | <strong>OR</strong>                                                                       |                   |                                                |
|                                  | 3. Adnexal tenderness or adnexal mass.                                    |                               | <strong>• Doxycycline 100 mg orally 2 times a day for 14 days</strong>                            | <strong>• Other third generation cephalosporin</strong>                                   |                   |                                                |
|                                  | 4. Cervical motion tenderness or pain.                                    | Perform stat pregnancy test   | <strong>• Erythromycin 500 mg 4 x daily for 14 days is appropriate for pregnant women</strong>    | <strong>PLUS</strong>                                                                     |                   |                                                |
|                                  | 5. Fever and chills                                                       | (Although PID is uncommon in  | <strong>• Assessment is made by identifying symptoms No. 3 or No. 4 or both.</strong>             | <strong>• Doxycycline 100 mg orally 2 times a day for 14 days</strong>                    |                   |                                                |
|                                  | 6. Nausea and vomiting.                                                   |                               | <strong>• If symptoms No. 3, 4, 5, 6 and/or abdominal rebound tenderness is identified, treat and refer to E.R.</strong> |                                                                          |                   |                                                |
|                                  |                                                                          |                               | Women w/PID should be re-evaluated in 3-4 days and 10-14 days after initial visit to re-assess symptoms and RX tolerance. Consult with an upper level provider. If worse, direct the patient to a hospital of her choice. |                                                                          |                   |                                                |
|                                  |                                                                          |                               |                                                                                     |                                                                              |                   | <strong>Sexual contacts within the previous 60 days should be evaluated and treated for GC and CT during their initial visit. Partners shall also be screened for syphilis and HIV.</strong> | PID, alone, is not a reportable condition. However, if the Chlamydia or gonorrhea test is positive, complete EPID 200 form and report to state STD program within 14 days. Mark “PID” box as well as the appropriate CT and/or GC box. |</p>
<table>
<thead>
<tr>
<th>CONDITION</th>
<th>SYMPTOMS</th>
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<th>RECOMMENDED TREATMENT</th>
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<th>REPORTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>BV  Bacterial Vaginosis</td>
<td>Mild to moderate amount of homogeneous chalky white or grey-green discharge; patient may complain of odor.</td>
<td>Note character of vaginal discharge 2. Ensure normal appearance of cervix with speculum exam 3. Collect discharge from lateral wall of vagina 4. Determine vaginal pH 5. Perform microscopic exam of discharge with 10% KOH</td>
<td>Metronidazole(^{11}) 500 mg orally 2 times a day for 7 days. OR Metronidazole gel 0.75% intravaginally once a day for 5 days. OR Clindamycin cream(^{12}) 2% intravaginally at bedtime for 7 days Assessment is made by identifying 3 out of the 4 symptoms listed.</td>
<td>Tinidazole 2 g orally once daily for 2 days OR Tinidazole 1 g orally once daily for 5 days OR Clindamycin 300 mg orally 2 times a day for 7 days OR Clindamycin ovules 100 g intravaginally at bedtime for 3 days</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>BV(^{11}) AND PREGNANCY</td>
<td>SEE ABOVE</td>
<td>SEE ABOVE</td>
<td>Metronidazole(^{11}) 500 mg orally 2 times a day for 7 days BV in pregnancy has been associated with preterm delivery. Metronidazole can be given during pregnancy, but avoid repeated dosing. Consult and/or direct patient to an upper level provider if BV is suspected.</td>
<td>Metronidazole(^{11}) 250 mg orally 3 times a day for 7 days OR Clindamycin 300 mg orally 2 times a day for 7 days</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Centers for Disease Control and Prevention. MMWR 2015; Vol. 64/No.3: Bacterial Vaginosis (Pages 69-72).
<table>
<thead>
<tr>
<th>CONDITION</th>
<th>SYMPTOMS</th>
<th>TESTS</th>
<th>RECOMMENDED TREATMENT</th>
<th>ALTERNATIVES</th>
<th>PARTNER SERVICES</th>
<th>REPORTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trichomoniasis</td>
<td></td>
<td></td>
<td>• Metronidazole&lt;sup&gt;11&lt;/sup&gt; 2 g orally single dose</td>
<td>• Metronidazole&lt;sup&gt;11&lt;/sup&gt; 500 mg orally 2 times a day for 7 days</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Femaales</td>
<td>1. Frothy grey or yellow-green vaginal discharge</td>
<td></td>
<td><strong>OR</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Pruritus/Itching</td>
<td></td>
<td>• Tinidazole&lt;sup&gt;13&lt;/sup&gt; 2 g orally single dose (not recommended in pregnancy)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>3. Cervical petechiae (&quot;strawberry-cervix&quot;)</td>
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<tr>
<td></td>
<td></td>
<td><strong>SEE ABOVE</strong></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Usual mode of assessment is made by observation of motile trichomonas in saline wet mount.</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Consult and/or direct patient to an upper level provider if Trichomoniasis is suspected.</td>
<td></td>
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</tr>
</tbody>
</table>

Centers for Disease Control and Prevention. MMWR 2015; Vol. 64/No. 3: Trichomoniasis (Pages 72-75).
### Protocols for Treatment of Common Sexually Transmitted Diseases (Continued)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Symptoms</th>
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<th>Recommended Treatment</th>
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<th>Partner Services</th>
<th>Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Candidiasis</strong></td>
<td>1. Thick white discharge of a cottage cheese consistency</td>
<td>SEE ABOVE</td>
<td>• Terconazole 0.4% vaginal cream, 5 g intravaginally daily for 7 days</td>
<td>• Butoconazole cream 2% (single dose bioadhesive product), 5 g intravaginally</td>
<td></td>
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<tr>
<td></td>
<td>2. Itching and burning of the labia and vulva</td>
<td></td>
<td>OR</td>
<td>in a single application</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td></td>
<td>3. Painful intercourse</td>
<td></td>
<td>• Clotrimazole vaginal cream 1% (over the counter) – 5 g intravaginally for 7-14 days</td>
<td>• Fluconazole 150 mg PO for 1 dose (contraindicated in pregnancy)</td>
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<td></td>
<td>4. Burning during urination</td>
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<td>OR</td>
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<td></td>
<td>5. Pelvic exam reveals cheese discharge in labial folds and at vaginal opening with patches adhering to vaginal wall and cervix</td>
<td></td>
<td>• Clotrimazole vaginal cream 2% (over the counter) – 5 g intravaginally for 3 days</td>
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<td></td>
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<td></td>
<td>• Assessment is made by observing budding yeast cells or pseudo hyphae on 10% KOH exam, wet mount or Gram stain</td>
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<td>OR</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Clinical presentation and symptoms</td>
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<td></td>
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<td></td>
<td>Consult and/or direct patient to a higher level provider if candida is suspected</td>
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</tbody>
</table>
(If pH is abnormally high (≥4.5) consider concurrent BV or Trichomoniasis)
<table>
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<tr>
<th>CONDITION</th>
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</tr>
</thead>
<tbody>
<tr>
<td>HPV (Genital Warts)</td>
<td>1. Pedunculated, elongated, raised fleshy lesions of the genitalia; pink to red in color. Large lesions appear in cauliflower-like masses or clusters 2. Usually painless, unless there is irritation from friction or secondary infection</td>
<td>Screening women or men with an HPV test, outside of the recommendations for cervical cancer screening, is not recommended. Assessment of genital warts is made by visual inspection. HPV may be confirmed by biopsy, but needed only under certain circumstances (diagnosis is uncertain, lesions do not respond to standard therapy; lesions worsen during therapy, warts are pigmented, indurated, bleeding, etc.)</td>
<td>EXTERNAL GENITAL WARTS</td>
<td>EXTERNAL GENITAL WARTS</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**PROVIDER – APPLIED**

- Cryotherapy with liquid nitrogen or cryoprobe. Repeat application every 1-2 weeks. *OR*
- Trichloroacetic acid (TCA) or bichloroacetic acid (BCA) 80%-90%. Apply small amount only to warts. Allow to dry. Repeat weekly if necessary

Consult and/or direct the patient to a higher level provider for evaluation and treatment of suspected HPV lesions

**PATIENT-APPLIED**

- Podofilox 0.5% solution or gel<sup>14</sup>. Apply 2 times a day for 3 days, followed by 4 days of no therapy. This cycle can be repeated as necessary for up to 4 times. Total wart area should not exceed 10 cm<sup>2</sup> and total volume applied daily not to exceed 0.5 mL. (Contraindicated in pregnancy). *OR*
- Imiquimod 5% cream<sup>14</sup>. Apply once daily at bedtime 3 times a week for up to 16 weeks. Wash treatment area with soap and water 6-10 hours after application (Not for use in pregnancy)

*OR*
- Sinecatechina 15% ointment (Not for use in pregnancy)
<table>
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<tr>
<th>CONDITION</th>
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<th>ALTERNATIVES</th>
<th>PARTNER SERVICES</th>
<th>REPORTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV (Genital Warts) and Pregnancy</td>
<td>SEE ABOVE</td>
<td>SEE ABOVE</td>
<td>EXTERNAL GENITAL WARTS</td>
<td>EXTERNAL GENITAL WARTS</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Genital warts can proliferate and become friable during pregnancy. Although removal of warts during pregnancy can be considered, resolution might be incomplete or poor until pregnancy is complete.</td>
<td>PROVIDER – APPLIED Cryotherapy with liquid nitrogen or cryoprobe. Repeat application every 1-2 weeks. <strong>OR</strong> Trichloroacetic acid (TCA) or dichloroacetic acid (BCA) 80% -90%. Apply small amount only to warts. Allow to dry.</td>
<td>Consult and or direct patient to a higher level provider for evaluation and treatment of suspected HPV lesions</td>
<td>(Imiquimod, podophyllin, Sinecatechins and Podofilox should not be used during pregnancy.)</td>
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<tr>
<td>HPV types 6 and 11 rarely can cause respiratory papillomatosis in infants and children.</td>
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</tbody>
</table>

Centers for Disease Control and Prevention. MMWR 2015; Vol. 64/No. 3: Human Papillomavirus Infections (Pages 84-90).
1 Some patients who are allergic to penicillin may also be allergic to ceftriaxone or other cephalosporin regimens. Doxycycline is the preferred syphilis treatment if allergic to PCN. There are limited clinical studies for ceftriaxone for the treatment of syphilis. If neither penicillin nor doxycycline can be administered for the treatment of syphilis desensitization may be necessary. Close follow-up of persons receiving any alternative therapies is essential. Tetracycline/doxycycline is contraindicated in pregnancy; erythromycin is not recommended for the treatment of syphilis in pregnancy because it does not reliably cure an infected fetus; data insufficient to recommend azithromycin or ceftriaxone. Cefixime tablets are currently not available through the state STD Program, and spectinomycin is not currently available in the US. In most situations Quinolones should not be used for the treatment of gonorrhea. If a quinolone is the only alternative regimen available for gonorrhea, a test of cure is required. A test of cure can be performed using the APTIMA CT/GC COMBO 2 (NAAT) TEST 3 weeks after completion of therapy. Unreliable to treat pharyngeal infections. Patients who have suspected or known pharyngeal infection should have a pharyngeal culture 3-5 days after treatment to verify eradication of infection. The efficacy of treating neonatal Chlamydial conjunctivitis and pneumonia is about 80%. A second course of therapy may be required. An association between oral erythromycin and infantile hypertrophic pyloric stenosis (IHPS) has been reported in infants aged less than 6 weeks treated with this drug. Data on other macrolides (azithromycin, clarithromycin) for the treatment of neonatal Chlamydial infection are limited. The results of one study involving a limited number of patients suggest that a short course of azithromycin 20 mg/kg/day, 1 dose daily for 3 days may be effective for Chlamydial conjunctivitis. Infections with M. genitalium may respond better to azithromycin. If this dose cannot be tolerated, then erythromycin base 250 mg orally or erythromycin ethylsuccinate 400 mg orally 4 times a day for 14 days can be used. The recommended regimen of ceftriaxone and doxycycline is for epididymitis most likely caused by GC or CT infection. The alternative regimen of ofloxacin or levofloxacin is recommended if the epididymitis is most likely caused by enteric organisms, or for patients allergic to cephalosporins and/or tetracycline. Metronidazole will also treat bacterial vaginosis, frequently associated with PID. Whether the management of immunodeficient HIV-infected women with PID requires more aggressive intervention has not been determined. Multiple studies and meta-analyses have not demonstrated a consistent association between metronidazole use during pregnancy and teratogenic or mutagenic effects in newborns. Screening for, and oral treatment of, BV in pregnant women at high risk for premature delivery is recommended by some experts and should occur at the first prenatal visit. Intravaginal clindamycin treatment for low risk women should be used only during the first half of pregnancy. Clindamycin cream is oil-based and may weaken latex condoms and diaphragms for 5 days after use. Safety during pregnancy not established.
## STD Drugs in Pregnancy

<table>
<thead>
<tr>
<th>DRUG</th>
<th>Use in Pregnancy</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acyclovir</td>
<td>OK</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Genital HSV (Page 24).</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>OK</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Chlamydial Infections-Pregnancy (Page 47).</td>
</tr>
<tr>
<td>Azithromycin</td>
<td>OK</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Chlamydial Infections-Pregnancy (Page 47).</td>
</tr>
<tr>
<td>Cefixime</td>
<td>OK</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Uncomplicated Gonococcal Infections-Pregnancy (Page 51-52).</td>
</tr>
<tr>
<td>Cefoxitin</td>
<td>OK</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Uncomplicated Gonococcal Infections-Pregnancy (Page 51-52).</td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>OK</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Uncomplicated Gonococcal Infections-Pregnancy (Page 51-52).</td>
</tr>
<tr>
<td>Clindamycin</td>
<td>OK; do not use cream in pregnancy</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Bacterial Vaginosis (Page 58).</td>
</tr>
<tr>
<td>Clotrimazole*</td>
<td>OK</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Vulvovaginal Candidiasis (Page 61).</td>
</tr>
<tr>
<td>Doxycycline</td>
<td>Contraindicated</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Granuloma Inguinale (Page 25), LGV (Page 26), Syphilis (Page 35), Chlamydia (Page 47).</td>
</tr>
<tr>
<td>Erythromycin+</td>
<td>OK</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Chlamydial Infections-Pregnancy (Page 47).</td>
</tr>
<tr>
<td>Famciclovir</td>
<td>No data; avoid</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Genital HSV (Page 24).</td>
</tr>
<tr>
<td>Fluconazole</td>
<td>Avoid</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Vulvovaginal Candidiasis-Pregnancy (Page 63).</td>
</tr>
<tr>
<td>Imiquimod</td>
<td>Contraindicated</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Genital Warts-Pregnancy (Page 74).</td>
</tr>
<tr>
<td>Lindane</td>
<td>Contraindicated</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Pediculosis Pubis-Pregnancy (Page 89).</td>
</tr>
<tr>
<td>DRUG</td>
<td>Use in Pregnancy</td>
<td>References</td>
</tr>
<tr>
<td>-----------------------------</td>
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<td>--------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>OK</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Bacterial Vaginosis-Pregnancy (Page 59), Trichomoniasis-Pregnancy (Page 60).</td>
</tr>
<tr>
<td>Ofloxacin</td>
<td>Contraindicated</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Chlamydia - Pregnancy (Page 47).</td>
</tr>
<tr>
<td>Penicillin G</td>
<td>OK</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Syphilis and Syphilis During Pregnancy (Pages 29, 35).</td>
</tr>
<tr>
<td>Permethrin</td>
<td>OK</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12; Pediculosis Pubis (Page 89).</td>
</tr>
<tr>
<td>Podophyllin</td>
<td>Contraindicated</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Genital Warts-Pregnancy (Page 74).</td>
</tr>
<tr>
<td>Podofilox</td>
<td>Contraindicated</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Genital Warts-Pregnancy (Page 74).</td>
</tr>
<tr>
<td>Pyrethrins</td>
<td>OK</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12; Pediculosis Pubis-Pregnancy (Page 88).</td>
</tr>
<tr>
<td>Sinecatechins</td>
<td>Contraindicated</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Genital Warts-Pregnancy (Page 74).</td>
</tr>
<tr>
<td>Trimethoprim-sulfamethoxazole</td>
<td>Avoid</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Granuloma Inguinale (Page 25).</td>
</tr>
<tr>
<td>Valacyclovir</td>
<td>No data; avoid</td>
<td>Centers for Disease Control and Prevention. MMWR 2010; Vol. 59/No. RR-12: Genital HSV (Page 24).</td>
</tr>
</tbody>
</table>

* Includes other topical imidazole drugs
+ Except erythromycin estolate (Ilosone), this is contraindicated.

Medications available from the State STD Program for the treatment of STDs:

- Amoxicillin (500 mg tablets)
- Benzathine Penicillin G (Bicillin LA)
- Azithromycin (500 mg tablets)
- Doxycycline Hyclate (100 mg tablets)
- Ceftriaxone (Rocephin) 250 mg
**STD Offices by Area Developmental Districts (ADD)**

<table>
<thead>
<tr>
<th>ADD</th>
<th>STD Office</th>
<th>Telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 &amp; 3</td>
<td>Western Kentucky, Bowling Green, KY</td>
<td>(270) 781-2490, ext. 218</td>
</tr>
<tr>
<td>2</td>
<td>Western Kentucky, Pennyrile Health District</td>
<td>(270) 365-6571, option 8</td>
</tr>
<tr>
<td>4</td>
<td>Warren County Health Dept., Bowling Green, KY</td>
<td>(270) 781-2490, ext. 219</td>
</tr>
<tr>
<td>5–6</td>
<td>Specialty Clinic, Louisville, KY</td>
<td>(502) 574-6697</td>
</tr>
<tr>
<td>7</td>
<td>Northern Kentucky Independent District Health Dept., Florence, KY</td>
<td>(859) 363-2075</td>
</tr>
<tr>
<td>8–15</td>
<td>Fayette County Health Dept., Lexington, KY</td>
<td>(859) 288-2461</td>
</tr>
<tr>
<td>State Office</td>
<td>Kentucky Public Health Department – STD Program</td>
<td>(502) 564-4804, ext. 4300 or ext. 4301</td>
</tr>
</tbody>
</table>

Regional STD Programs should be contacted to initiate partner services for early syphilis and/or HIV cases.

**Downloads & Resources:**

2015 STD Treatment Guidelines

2015 STD TX Guide App

Download the 2015 STD Treatment Guide app for Apple and Android devices. The free app is an easy-to-use reference that combines information from the STD Treatment Guidelines as well as MMWR update, and features a streamlined interface so providers can access treatment and diagnostic information. Open iTunes on your device to download.
# Tuberculosis (TB)

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- GeneXpert MTB/RIF Assay Testing Protocol  
- Managing Laboratory Data  
- Guidelines for Follow-up Notification  
- Classifying the Tuberculin Skin Test Reaction  
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### CASE MANAGEMENT

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- Treatment Algorithm for Culture Negative TB  
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- KY VDOT Video Directly Observed Therapy  
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  - Drug Regimens for Culture-Positive Pulmonary TB  
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  - Pyridoxine (Vitamin B6) Supplementation  
  - Dosage Chart  
  - Drug-Drug Interactions Involving the Rifamycins  
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  - Potential Regimens for Management of Drug-Resistant Pulmonary TB  
- Criteria for Determining When A Patient Is Noninfectious  
- Management of Treatment Interruptions  
- Risk Factors for MTB Infection (LTBI)  
- Directly Observed Preventive Therapy (DOPT)  
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- Determining the Infectious Period for a Patient with Active TB Disease  

# Tuberculosis (TB)

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- Initial Assessment of Contacts
- Window-Period Prophylaxis
- Evaluation, Treatment and Follow-up of TB Contacts
- References & WHO TB Incidence Link
# TUBERCULOSIS MATRIX

<table>
<thead>
<tr>
<th>Condition</th>
<th>Assessment</th>
<th>Education</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification 0</td>
<td>Patient TB Risk Assessment (TB-4) with targeting testing of persons in at-risk groups</td>
<td>Complete patient TB Risk Assessment (TB-4) prior to tuberculin skin test (TST) or blood assay for Mycobacterium tuberculosis (BAMT) for all classifications. TSTs are preferred for children aged less than five years.</td>
<td>Educate on signs and symptoms of active TB disease, risk factors for Latent TB Infection (LTBI), and risk factors for rapid progression from LTBI to active TB disease.</td>
</tr>
<tr>
<td>No TB Exposure</td>
<td>Persons at Increased Risk for Mycobacterium tuberculosis Infection</td>
<td>Tuberculin skin test (TST) with Purified Protein Derivative (PPD) using the Mantoux method (use Tubersol antigen) The TST must be given and read by a nurse per 902 KAR 20:016</td>
<td>See procedure for TST in this reference. Review CDC TST Video, 2006</td>
</tr>
<tr>
<td>Not Infected</td>
<td>• Close contacts of a person known or suspected to have active TB disease</td>
<td>Two-step TST: • If first step TST is positive, consider the person infected. • If first step TST is negative, give the second step TST 1–3 weeks later. • If second step TST is positive, consider person infected. • If second step TST is negative, consider person uninfected. BAMT reported as positive, consider person infected.</td>
<td>Some groups may need annual TB Risk Assessments (TB-4). Some groups, e.g. HCWs may need annual TSTs or BAMTs in addition to annual TB Risk Assessments (TB-4).</td>
</tr>
<tr>
<td></td>
<td>• Foreign-born persons, including children who have immigrated within the last 5 years from areas where TB is prevalent**</td>
<td></td>
<td>All testing activities should be accompanied by a plan for follow-up care.</td>
</tr>
<tr>
<td></td>
<td>• Persons who visits areas with a high TB prevalence, especially if visits are frequent or prolonged</td>
<td></td>
<td>Patients should return in 48–72 hours for TST reading, interpretation, and recording by nurse.</td>
</tr>
<tr>
<td></td>
<td>• Residents and employees of high-risk congregate settings</td>
<td></td>
<td>Anergy Suspects</td>
</tr>
<tr>
<td></td>
<td>• Health care workers (HCWs) who serve high-risk clients</td>
<td></td>
<td>Do not rule out TB diagnosis based on negative skin test result; consider anergy if immunosuppressed; also see other diseases/conditions that can cause suppression of delayed-type hypersensitivity (DTH) response.</td>
</tr>
<tr>
<td></td>
<td>• Medically underserved, low income populations, homeless</td>
<td></td>
<td>Delayed type hypersensitivity (DTH) antigen tests are not recommended for administration at LHDs.</td>
</tr>
<tr>
<td></td>
<td>• High-risk racial or ethnic minority populations</td>
<td></td>
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<tr>
<td></td>
<td>• Persons who abuse drugs or alcohol</td>
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</tr>
<tr>
<td></td>
<td>• Infants, children, and adolescents exposed to adults at high-risk for latent TB infection or active TB disease</td>
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<td></td>
</tr>
</tbody>
</table>

* See Core Curriculum on Tuberculosis (2013) for TB Classification System. ** See tables with international TB incidence and prevalence rates in this reference for more information.

**MMWR, 2016 Clinical Practice Guidelines for Diagnosis of Tuberculosis in Adults and Children.**

1. Each LHD shall have a designated employee responsible for Tuberculosis (TB) services in their county. This person must attend periodic TB updates or keep updated by having the latest educational and scientific materials for the prevention and control of TB from CDC/ATS/ALA, the Southeastern National Tuberculosis Center, and other National Tuberculosis Centers.
2. The physician or clinician knowledgeable in the field of mycobacterial diseases shall provide patient care. They shall agree to update themselves through professional meetings, consultations, and review of journal articles. This must be a component of any LHD contract for TB clinician services.

*This current classification system of tuberculosis (TB) is based on the pathogenesis of TB. A person with a classification of 3 or 5 should be receiving drug treatment for TB and should be reported to the LHD.*
<table>
<thead>
<tr>
<th>Condition</th>
<th>Assessment</th>
<th>Education</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification 0 (Continued)</td>
<td><strong>Groups that should be TB Tested (Continued)</strong></td>
<td>Develop a policy that the LHD will repeat TSTs given by other health care providers not trained by the LHD unless their skill is known and trusted by the LHD.</td>
<td></td>
</tr>
<tr>
<td>No TB Exposure Not Infected</td>
<td><strong>Persons at higher risk for developing active TB disease once infected</strong></td>
<td>LHDs DO NOT need a similar policy for repeating BAMTs.</td>
<td></td>
</tr>
<tr>
<td>*Targeted Testing for low risk individuals is no longer recommended (2016 LTBI Guidelines; pg. e4)</td>
<td></td>
<td>TSTs administered by LHDs can be read by staff in other LHDs and do not usually need to be repeated.</td>
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<tr>
<td></td>
<td>• Persons with HIV infection</td>
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<tr>
<td></td>
<td>• Persons who are receiving immunosuppressive therapy such as tumor necrosis factor-alpha (TNF-α) antagonists, systemic corticosteroids equivalent to ≥15 mg of prednisone per day, or immune suppressive drug therapy following organ transplantation</td>
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</tr>
<tr>
<td></td>
<td>• Silicosis</td>
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<tr>
<td></td>
<td>• Diabetes mellitus</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>• Chronic renal disease</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>• Certain hematologic disorders (leukemias and lymphomas)</td>
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<td></td>
<td>• Cancer of the head, neck, or lung</td>
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<tr>
<td></td>
<td>• Gastrectomy or jejunooileal bypass</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• People receiving immunosuppressive therapy for rheumatoid arthritis or Crohn’s disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Low body weight (BMI &lt; 19)</td>
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</tr>
</tbody>
</table>
**TUBERCULOSIS MATRIX**
(Continued)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Assessment</th>
<th>Treatment</th>
<th>Education</th>
<th>Follow-up</th>
</tr>
</thead>
</table>
| Classification 1 | **Identify** contacts within 3 workdays of suspect/case report, using prioritization and the Concentric Circle Approach (p. 41). | Infants and Children <5 years of age, who are high priority contacts and who have a negative TST or negative BAMT, should be started on window period prophylaxis, with therapy administered by Directly Observed Preventive Therapy (DOPT) until retested in 8-10 weeks. | Discuss:  
- How TB is transmitted  
- LTBI versus active TB disease  
- Importance and significance of repeat skin test in 8-10 weeks  
- Treatment of active TB disease or LTBI  
- Importance of taking medicine on a regular basis if indicated | If TST or BAMT is negative, must return 8–10 weeks after contact has been broken, for repeat TST or BAMT.  
To avoid difficulty with test interpretation in a contact investigation, the follow-up TB test method for a particular contact, whether TST or BAMT, should preferably be the same test method used for the first TB test. Use of the same test method for repeat testing will minimize the number of conversions that occur because of test differences. |
| TB Exposure (contact), no evidence of infection | Administer **TST or draw blood for BAMT and Examine** high-risk contacts within 7 workdays of identification (See pages 37 and 46) | If repeat TST or BAMT is positive, continue medicines by DOPT (see classification 2) | | |
|  | Give TST or draw blood for BAMT for medium and low-risk contacts based on findings from the Concentric Circle Approach (See pages 41 and 46) | If repeat TST or BAMT is negative, stop medicine unless contact with infectious case has not or cannot be broken. | | |
|  | Do the following:  
1. Patient TB Risk Assessment (TB-4)  
2. Medical History (TB H&P 13 or TB 20 follow up form)  
3. TST or BAMT (unless there is previously documented positive reaction)  
4. Chest x-ray, at the same time those who:  
   - Have TB symptoms  
   - Are HIV infected or have other immunosuppressed conditions  
   - Are < 4 years of age  
   Posterior–Anterior (PA) chest x-ray is the standard view used to detect abnormalities  
   PA and lateral view should be done on those < 5 years of age  
   If symptomatic, see sputum collection recommendations in this reference and in online forms. | Contacts with immunocompromising conditions (e.g. HIV-infected) that have a negative TST or negative BAMT should be started on window prophylaxis therapy by DOPT until retested in 8-10 weeks. If the repeat TST or BAMT remains negative, and an evaluation for active TB disease is negative, a full course of treatment for LTBI should still be completed. | Steps for patient producing a sputum specimen at home:  
- Clean & thoroughly rinse mouth with water  
- Breathe deeply 3 times (a tickling sensation at end of breath)  
- After 3rd breath, cough hard & try to bring up sputum from deep in lungs  
- Expectorate sputum into a sterile container collecting at least one teaspoonful  
- Perform this in a properly ventilated room, booth, or outdoors  
Provide patient information for an informed consent. | |

*Self-Study Modules on Tuberculosis, Contact Investigation for Tuberculosis, CDC Core Curriculum on Tuberculosis (2013)*

MMWR,

2016 Clinical Practice Guidelines for Diagnosis of Tuberculosis in Adults and Children.
<table>
<thead>
<tr>
<th>Condition</th>
<th>Assessment</th>
<th>Treatment</th>
<th>Education</th>
<th>Follow-up</th>
</tr>
</thead>
</table>
| **Classification 2**  
Infection **without** active TB disease  
- Positive TST (mm induration) or positive BAMT  
- Negative bacteriological studies (if done)  
- No clinical bacteriological or radiographic evidence of active TB disease. |  
- Candidates for treatment of LTBI  
  - See TST reaction classification or guidelines for BAMTs, this reference  
  - **Careful assessment to rule out active TB disease is necessary before treatment for LTBI is started**  
  - Immediately get a chest x-ray for patients with symptoms AND a positive TST or positive BAMT  
  - Others should be given a chest x-ray as soon as possible. When TB disease is ruled out, treat for LTBI if indicated.  
  - If chest x-ray abnormal, obtain sputum’s, and consider as a suspect case  
  - Determine history of prior treatment for LTBI or active TB disease  
  - Determine if there are any medical conditions that are contraindications to treatment or would increase risk of adverse reactions  
  - Provide HIV counseling, testing, and referral. If HIV test is refused, reoffer HIV testing monthly while on LTBI treatment.  
  - Baseline hepatic measurements recommended for:  
    - Patients whose initial evaluation suggests a liver disorder or regular use of alcohol  
    - Patient with HIV infection  
    - Pregnant women and those in immediate post-partum period (3 months, especially Black and Hispanic women)  
    - Patients with history of chronic liver disease (e.g., hepatitis B or hepatitis C) |  
- See LTBI regimens in this reference  
  - The following groups are considered to be high-risk individuals when it comes to being adherent to taking their medications. If found to have LTBI, these groups must be placed on Directly Observed Preventive Therapy (DOPT):  
    - Children and adolescents  
    - Contacts to a case with active TB disease  
    - Homeless individuals  
    - Persons who abuse substances  
    - Persons with a history of treatment non-adherence  
    - Immunocompromised patients, especially HIV-infected  
  - Obtain signed DOPT consent TB-15b  
  - For any other persons, DOPT should be used if LTBI treatment is ordered twice weekly (See pages 39 - 43). Call the Kentucky TB Program to discuss twice-weekly treatment of LTBI. |  
- Establish rapport with patient and emphasize:  
  - Benefits of treatment  
  - Importance of adherence to treatment regimen  
  - Possible adverse side effects of medicine(s)  
  - When to stop medication and call the local health department (LHD)  
  - HIV testing with pre- and post-test counseling  
  - Directly Observed Preventive Therapy (DOPT) for LTBI is recommended for any at risk adults who cannot or will not reliably self-administer drugs |  

**ATTENTION:** Medical providers should consult pages 39-43 of this reference about medications to treat LTBI in children and adolescents, doses, and intervals for administration by DOPT, unless medically contraindicated.  
Call the KY TB Program to discuss treatment of LTBI in children and adolescents.

*Centers for Disease Control and Prevention, Core Curriculum on Tuberculosis (2013)*  
*2016 Clinical Practice Guidelines for Diagnosis of Tuberculosis in Adults and Children.*
### Classification 3
TB disease, clinically active

**Tuberculosis Case Definition:**

**Positive Lab Test**
Mycobacterium tuberculosis culture
* M. tuberculosis complex demonstrated in Nucleic Acid Amplification (NAA) test or PCR test

- or -

**Clinical Case:**
- Positive TST or positive BAMT
- Abnormal changing chest x-ray or clinical evidence of disease
- Placed on 2 or more antibacterial antibiotic drugs
- **Completed** diagnostic evaluation to include a patient TB risk assessment (TB-4)

| See Contact Investigation and the Concentric Circle approach in this reference |
| Should be seen by local health department (LHD) physician as soon as possible if LHD is supplying TB medications |
| **Case Management** |
| - Assignment of responsibility |
| - Systematic regular review |
| - Plans to address barriers to adherence |
| - Provide HIV counseling, testing, and referral. If HIV test is refused, reoffer HIV testing monthly while on treatment for active TB disease. |

**Adherence**
- Non adherence is a major problem in TB control
- Use case management and directly observed therapy (DOT) to ensure patients complete treatment. If more than 3 doses are missed, contact KY DPH TB staff.
- Initially order AST, ALT, Bilirubin, Alkaline phosphatase, serum creatinine, and platelets for adults. Visual acuity and color vision as baseline if on EMB, question vision status monthly
- Obtain baseline weight and monitor weights monthly

Determine the Patient’s clinical condition:
- Immediately if not hospitalized
- Within 3 days of notification if hospitalized (best to visit in hospital)
- Basic physical exam done within 7 days of notification

**Basic Principles of Treatment: Kentucky endorses Regimen 1 initially (The 4 drug TB antibiotic therapy; pg. 19)**
- Provide safest, most effective therapy in shortest time
- Multiple drugs to which the organisms are susceptible
- **Never** add single drug to failing regimen
- Ensure adherence to therapy
- DOT is the standard of care for all cases of active TB disease

Management of HIV related active TB disease is complex; care should be provided by a consultant expert in both HIV and TB
- Obtain signed DOT consent TB-15a

**Pregnant Women**
- 9 month regimen - RIF, INH, and EMB
- SM is contraindicated
- In HIV-positive pregnant women, consult an expert. (SNTC Hotline 1-800-4TB-INFO) Notify the State TB Program about the prescribed regimen.

**Infants**
- Treat as soon as tuberculosis is suspected.
- See regimens in this reference for treatment of adults, children, and those with extrapulmonary tuberculosis

**Tuberculosis caused by Drug Resistant Organisms**
- Treatment should be done by, or in close consultation, with an expert in the management of these difficult situations

Vitamin B6 10–25mg for those with certain conditions (e.g. HIV infection)

**Instruct patient about:**
- Active TB disease and how it is spread
- Importance of taking medications on a regular basis
- Medication side effects and instructions to immediately report adverse reactions
- Proper times and way to collect/mail sputum specimens
- The taking of other medications and the potential risks of drug interactions
- Importance of good nutrition
- Tobacco cessation and nicotine replacement therapy

See Kentucky TB Control Law KRS 215

Patients shall be placed in isolation until deemed noninfectious (See criteria pg 36)

Confinement and/or restriction of activities must be addressed (TB Control Law, KRS 215.540)

KRS 215.531 states drug susceptibility test on initial TB isolates from patient with active TB disease must be ordered by the physician

Ensure that all initial positive TB cultures from independent labs have drug susceptibility studies ordered by private physicians

- Monitor for Adverse Reactions
- See Recommendations for Sputum Collection
- Chest x-rays **initially**, at 2 months after starting therapy, and at 0 to 60 days after completion of therapy. Clinical cases **also need** chest x-ray after 2 months of multiple drug therapy
- All efforts to follow-up must be documented in the patient’s chart
- A home visit must be done
- Consult with DPH if the patient’s status changes while on treatment

Directly Observed Therapy (DOT)
- Health Department health care worker must watch patient swallow each dose of medication
- DOT shall be the Kentucky standard of care for all cases of active TB disease
- DOT must be used with all intermittent regimens
- DOT can lead to reductions in relapse and acquired drug resistance
- Use DOT with other measures to promote adherence
- Court ordered DOT may be necessary
- See DOT in this reference
- For Video DOT protocols, see page 19 TB isolate from all specimens with a positive TB culture shall be sent to the Kentucky Department of Laboratory Services (DLS) for drug susceptibility and genotyping tests. LHD TB staff shall contact hospital labs, independent labs, or national reference labs to coordinate shipment of TB isolate to DLS.

902 KAR 2:020

*Centers for Disease Control and Prevention, Core Curriculum on Tuberculosis (2013)*
### TUBERCULOSIS MATRIX
(Continued)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Assessment</th>
<th>Treatment</th>
<th>Education</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification 4</td>
<td>TB no longer clinically active</td>
<td></td>
<td>Teach patient signs and symptoms of possible recurrence of active TB disease</td>
<td></td>
</tr>
<tr>
<td>Classification 5</td>
<td>TB suspected. Diagnosis pending. Should not have this classification for more than three (3) months</td>
<td>If NAA test on sputum is positive, treatment should begin with a 4-drug regimen until TB is ruled out</td>
<td>Teach patient signs and symptoms of possible recurrence of active TB disease.</td>
<td>As indicated</td>
</tr>
</tbody>
</table>

Results of a positive Nucleic Acid Amplification (NAA) test, e.g. Gen-Probe, on a sputum sample can help determine active TB disease with *Mycobacterium tuberculosis* (MTB)

*Centers for Disease Control and Prevention, Core Curriculum on Tuberculosis (2013)*
## Recommendations for Sputum Collection

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Frequency</th>
<th>Number of Specimens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline for TB suspects</td>
<td>Initial</td>
<td>3 samples that are collected 8 – 24 hours apart. Recommend at least one sample collection be observed by health care worker. <strong>Obtain sputum samples BEFORE initiating tuberculosis therapy.</strong></td>
</tr>
<tr>
<td>Monitoring for smear and culture conversion (AFB Smear positive Culture positive)</td>
<td><strong>Every 2 weeks</strong> after 2 weeks of therapy have been completed, until 3 consecutive AFB smears are negative.</td>
<td>1 sample – Recommend collection be observed by health care worker</td>
</tr>
<tr>
<td></td>
<td></td>
<td>After 2 months of uninterrupted therapy.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Note:</strong> 3 negative smears are required per 902 KAR 20:200 and 902 KAR 20:016</td>
</tr>
<tr>
<td>Monitoring during treatment for culture conversion (AFB Smear negative Culture positive)</td>
<td><strong>Every 2 weeks</strong> until 2 consecutive specimens are negative on culture.</td>
<td>3 samples on consecutive days. Recommend at least one be observed by health care worker</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Patients who have positive cultures after 4 months of treatment should be treated as treatment failures (MMWR, June 20, 2003)</td>
</tr>
<tr>
<td>Monitoring after culture conversion to negative (or a clinical case)</td>
<td><strong>Monthly</strong> until treatment is completed. Patient may not be able to produce sputum at this point</td>
<td>1 sample. Recommend collection be observed by health care worker</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Frequency of collections may be increased if there is a recurrence of symptoms or treatment interruption. Patients with MDR-TB or HIV infection and TB may require additional sputum testing to monitor their clinical course</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Send specimens to the state lab and instruct private hospitals and physicians to use the state lab</td>
</tr>
</tbody>
</table>

**Obtain three (3) consecutive sputum samples for any patient who has evidence of worsening clinical signs / symptoms of active TB disease (i.e. new cough, hemoptysis, fever, sweats, or worsening chest x-ray findings)**

**Source:**  
*MMWR 2009; 58(01):7-10  
**SNTC Clinical Consultation – July 2010*
GeneXpert MTB/RIF Assay TESTING PROTOCOL

Intended Use

The GeneXpert MTB/RIF Assay is intended for use with sputum specimens from patients for whom there is clinical suspicion of tuberculosis (TB). This test is intended as an aid in the diagnosis of pulmonary tuberculosis when used in conjunction with clinical and other laboratory findings. The GeneXpert MTB/RIF Assay must also be used in conjunction with mycobacterial culture to address the risk of false negative results and to recover the organisms for further characterization and drug susceptibility testing.

Sample Criteria

Sputum samples (raw sputum or concentrated sediments prepared from induced or expectorated sputum) from a patient with first time positive acid-fast bacilli (AFB) sputum-smear results will be tested with the GeneXpert MTB/RIF assay. Exceptions to this protocol include:

- grossly bloody specimens,
- non-sputum specimens (e.g., blood, CSF, gastric aspirate, stool, tissue, urine, etc.) except for specimens obtained by BAL,
- patients that have been treated for M. tuberculosis complex within the last year,
- patients that have been on anti-tuberculosis treatment or have been on therapy more than 3 days prior to collection of the specimen.

Sample Storage

- Sputum specimens may be stored for a maximum of 3 days at room temperature (maximum temperature not to exceed 35°C or 95°F) or up to 10 days at refrigerated (2-8°C) temperature from collection.
- Sputum sediment may be stored up to 7 days from collection at refrigerator (2-8°C) temperature.

Testing

Testing will be performed within 24 hours from the time a positive AFB sputum-smear result is reported. Please contact the DLS TB lab at 502-564-4446 x 4422 or 4423 as soon as possible if a sample is anticipated to arrive to the DLS in the mid to late afternoon. This advance notification will help the TB staff in their planning on whether to perform the test beyond the standard operating hours of 8 AM until 4:30 PM (Eastern Time Zone) and to prepare necessary reagents/supplies for GeneXpert MTB/RIF assay testing.
Specimens from patients with negative AFB sputum-smear results are not routinely tested by the GeneXpert MTB/RIF assay. Medical providers should contact the State TB program for consultation concerning testing of patients with negative AFB sputum-smear results and with signs and symptoms of active TB disease. The State TB program will discuss criteria and provide guidance on a case-to-case basis with the submitter and will gladly provide consultation on any suspected TB case. Only smear negative specimens approved through the state TB Program will be tested. If approved, three early morning or induced sputum specimens may be sent to DLS. The sensitivity of the GeneXpert MTB/RIF assay for detection of *M. tuberculosis* from AFB-smear negative specimens is 76.1%.

**State TB Program contacts: 502-564-4276**

**Limitations**

- GeneXpert MTB/RIF Assay is not a test of cure and should not be performed on patients who have received more than 3 days of treatment. Previously treated patients must be off anti-tuberculosis therapy for at least 1 year for valid testing.
- A negative test does not exclude the possibility of isolating MTB-complex from the sputum sample. The GeneXpert MTB/RIF Assay must be used in conjunction with mycobacterial culture to address the risk of false negative results and to recover the organism for further characterization and susceptibility testing.
- A positive test does not necessarily indicate the presence of viable organisms.
- The GeneXpert MTB/RIF Assay does not differentiate between the species of the MTB-complex (e.g., *Mycobacterium tuberculosis*, *M. africanum*, *M. bovis*, *M. bovis* BCG, *M. canetti*, *M. caprae*, *M. microti*, or *M. pinnipedii*)
- **Because the detection of MTB-complex is dependent on the number of organisms present in the sample, accurate results are dependent on proper specimen collection, handling, and storage. Erroneous test results might occur from improper specimen collection**
- The performance of the GeneXpert MTB/RIF Assay has not been evaluated with samples from pediatric patients.
- The test is FDA approved only for sputum specimens (induced or non-induced). Testing on other respiratory specimens (e.g., BAL) will be reported with a disclaimer. No other specimens will be tested by this method.
INTERFERING SUBSTANCES

Potential inhibitory effects of substances that may be present in samples processed with the GeneXpert MTB/RIF Assay include, but are not limited to, blood, pus, mammalian cells, and hemoglobin. Interference may be observed in the presence of Lidocaine (>20% v/v), mucin (>1.5% w/v), Ethambutol (>5 μg/mL), Guaifenesin (>2.5 mg/mL), Phenylephrine (>25% v/v), or tea tree oil (>0.008% v/v).

Note: Please call the TB Lab for any questions or guidance on entering any TB testing request orders in the DLS Psyche Outreach LIMS System. Please include thorough patient clinical history and administration of any current and past drug treatment for tuberculosis. When entering orders for patient specimens in Outreach it is important to search for previous orders on that particular patient. If the patient has previous orders, select that patient to bring up all the patient demographics on file and proceed with edit clinical order. This links the patient data that is crucial for patient history, surveillance, and tracking patient results. This information is helpful for the state TB program and for the DLS lab to better serve the patient and submitter in public health’s goals of expedited treatment, TB control, and in the national and global efforts to eliminate TB.

Sources:
- http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6241a1.htm?s_cid=mm6241a1_e
- 2019
Managing Laboratory Data

- The LHD shall ensure that all culture positive pulmonary and extrapulmonary Mycobacterium tuberculosis isolates from outside laboratories are sent to the State Public Health Laboratory for drug susceptibility and genotype testing. Per the amendments to the Kentucky regulation, “902 KAR 2:020, Reportable disease surveillance,” [http://www.lrc.ky.gov/kar/902/002/020.htm](http://www.lrc.ky.gov/kar/902/002/020.htm), “A medical or national reference laboratory shall submit clinical isolates or, if not available, the direct specimen from” tuberculosis cases to the Division of Laboratory Services (i.e., the State Public Health Laboratory). The amended regulation became effective on February 26, 2015.

- The LHD shall ensure that copies of sputum positive TB culture results, positive TB culture results from any other body site, and positive results for Nucleic Acid Amplification tests (e.g., MTD positive results and PCR positive results) from outside laboratories are sent to the State TB Prevention and Control Program. Copies should be sent to the Kentucky TB Program within one (1) business day of being received by LHD TB Coordinators.

- It is the responsibility of the LHD to ensure that drug susceptibility testing is performed on initial culture positive pulmonary and extrapulmonary TB isolates. Send a copy of the laboratory report about drug susceptibility testing to the State TB Prevention and Control Program. Outside laboratories that report culture positive pulmonary and extrapulmonary TB isolates may need an additional physician order to perform drug susceptibility testing.

- It is recommended that all sputum samples be sent to the State Public Health Lab for testing.
GUIDELINES FOR FOLLOW-UP NOTIFICATION

For active TB cases, suspects, contacts to cases, and individuals receiving directly observed preventive therapy, LHDs shall make at least three attempts to notify patients / parents of missed appointments, abnormal laboratory or radiology tests as follows:

1. Initial contact may be made by telephone if the number is available.

2. The second contact should be a regular mailed letter with directions for the patient to contact the LHD for follow-up.

3. The third contact should be a certified or registered letter with directions for the patient to contact the LHD for follow-up. The letter receipt shall be retained or scanned in the patient’s medical record.

4. If the patient cannot be contacted by the above measures, a face-to-face visit shall be attempted.

5. If after three of the above measures are made with no response, the LHD should document in the medical record that the patient is lost to follow-up care and notify the KY TB Program for additional guidance.
## CLASSIFYING THE TUBERCULIN SKIN TEST REACTION

<table>
<thead>
<tr>
<th>≥ 5 mm is classified as positive in:</th>
<th>≥ 10 mm is classified as positive in:</th>
<th>≥ 15 mm is classified as positive in:</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-positive persons</td>
<td>People who have come to the U.S. within the last 5 years from areas of the world where TB is common *</td>
<td>Persons with no known risk factors for TB</td>
</tr>
<tr>
<td>Recent contacts of a case with active TB disease</td>
<td>Injection drug users</td>
<td>Targeted skin testing programs should only be conducted among high-risk groups</td>
</tr>
<tr>
<td>People who have previously had active TB disease</td>
<td>People who live or work in high-risk congregate settings</td>
<td></td>
</tr>
<tr>
<td>Persons with fibrotic changes on chest radiograph consistent with old healed TB</td>
<td>Mycobacteriology laboratory personnel</td>
<td></td>
</tr>
<tr>
<td>Patients with organ transplants and other immunosuppressed patients (including patients taking a prolonged course of oral or intravenous corticosteroids or tumor necrosis factor alpha (TNF-alpha) antagonists)</td>
<td>Children younger than 4 years</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Infants, children, and adolescents exposed to adults in high-risk categories**</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Persons with clinical conditions that place them at high-risk for TB (silicosis, diabetes mellitus, severe kidney disease, certain types of cancer, and certain intestinal conditions)</td>
<td></td>
</tr>
</tbody>
</table>

A tuberculin skin test conversion is defined as an increase of ≥ 10 mm of induration within a 2-year period, regardless of age.  
*See tables with international TB incidence and prevalence rates in this reference for more information.*  
**According to Red Book, 2018, ≥ 10 mm induration is considered positive for children with increased exposure to adults who are HIV-infected, homeless, users of illicit drugs, residents of nursing homes, incarcerated or migrant farm workers, p. 830.
TUBERCULIN SKIN TEST (TST) RECOMMENDATIONS FOR INFANTS, CHILDREN, AND ADOLESCENTS

Children for whom immediate TST or IGRA is indicated:
- Contacts of people with confirmed or suspected contagious [active] tuberculosis [disease] (contact investigation)
- Children with radiographic or clinical findings suggesting [active] tuberculosis disease
- Children immigrating from countries with endemic infection (e.g., Asia, Middle East, Africa, Latin America, countries of the former Soviet Union) including international adoptees
- Children with travel histories to countries with endemic infection and substantial contact with indigenous persons from such countries

Children who should have annual TST or IGRA:
- Children infected with HIV infection (TST only)
- Incarcerated adolescents

Children at increased risk of progression of LTBI to tuberculosis disease: Children with other medical conditions, including diabetes mellitus, chronic renal failure, malnutrition, and congenital or acquired immunodeficiency’s deserve special consideration. Without recent exposure, these people are not at increased risk of acquiring tuberculosis infection. Underlying immune deficiencies associated with these conditions theoretically would enhance the possibility for progression to severe disease. Initial histories of potential exposure to tuberculosis should be included for all of these patients. If these histories or local epidemiologic factors suggest a possibility of exposure, immediate and periodic TST or IGRA should be considered. An initial TST or IGRA should be performed before initiation of immunosuppressive therapy, including prolonged steroid administration, use of tumor necrosis factor-alpha antagonists, or other immunosuppressive therapy in any child requiring these treatments.”

A TST can be administered to individuals of any age who are at increased risk for acquiring LTBI or active TB disease, even to newborn infants (See Congenital Tuberculosis in the 2018 edition of the Red Book, p. 830.).

IGRA indicates interferon-gamma release assay; HIV indicates human immunodeficiency virus; LTBI, latent tuberculosis infection.

1 Bacille Calmette-Guérin immunization is not a contraindication to a TST.
2 Beginning as early as 3 months of age.
3 If the child is well, the TST or IGRA should be delayed for up to 10 weeks after return.

Reference: Red Book 2018
INDICATIONS FOR TWO-STEP TUBERCULIN SKIN TESTS (TSTs)

<table>
<thead>
<tr>
<th>Situation</th>
<th>Recommended testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>No previous TST result</td>
<td>Two-step baseline TSTs</td>
</tr>
<tr>
<td>Previous negative TST result (documented or not)</td>
<td>Two-step baseline TSTs</td>
</tr>
<tr>
<td>&gt;12 months before new employment</td>
<td>Single TST needed for baseline testing; this test will be the second-step</td>
</tr>
<tr>
<td>Previous documented negative TST result ≤12 months before new employment</td>
<td>Single TST; two-step testing is not necessary</td>
</tr>
<tr>
<td>≥2 previous documented negative TSTs but most recent TST &gt;12 months before new employment</td>
<td>No TST</td>
</tr>
<tr>
<td>Previous documented positive TST result</td>
<td>Two-step baseline TST(s)</td>
</tr>
<tr>
<td>Previous undocumented positive TST result*</td>
<td>Two-step baseline TST(s)</td>
</tr>
<tr>
<td>Previous BCG† vaccination</td>
<td>See Supplement, Use of QFT-G** for Diagnosing M. tuberculous Infections in Health-Care Workers (HCWs)</td>
</tr>
<tr>
<td>Programs that use serial BAMT,§ including QFT¶ (or the previous version QFT)</td>
<td></td>
</tr>
</tbody>
</table>

* For newly hired health care workers and others who will be tested on a routine basis (e.g., residents or staff of correctional or long-term care facilities), a previous TST is not a contraindication to a subsequent TST, unless the test was associated with severe ulceration or anaphylactic shock, which are substantially rare adverse events. If the previous positive TST result is not documented, administer two-step TSTs or offer BAMT. SOURCES: Aventis Pasteur. Tuberculin purified protein derivative (Mantoux) Tubersol® diagnostic antigen. Toronto, Ontario, Canada: Aventis Pasteur; 2001. Parkdale Pharmaceuticals APLISOL (Tuberculin purified protein derivative, diluted [stabilized solution]). Diagnostic antigen for intradermal injection only. Rochester, MI: Parkdale Pharmaceuticals, 2002. Froeschle JE, Ruben FL, Bloh AM. Immediate hypersensitivity reactions after use of tuberculin skin testing. Clin Infect Dis 2002;34:EL2–3.
† Bacille Calmette-Guérin.
§ Blood assay for Mycobacterium tuberculosis.
¶ QuantiFERON®-TB test.
** QuantiFERON®-TB Gold test.

* MMWR Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care settings, 2005, p 29.
I. MANAGEMENT OF TUBERCULOSIS DISEASE

## BOX 2. Risk factors for progression of infection to active tuberculosis

Persons at increased risk* for progression of infection to active tuberculosis include

- persons with human immunodeficiency virus (HIV) infection;†
- infants and children aged <5 years;†
- persons who are receiving immunosuppressive therapy such as tumor necrosis factor--alpha (TNF-α) antagonists, systemic corticosteroids equivalent to ≥15 mg of prednisone per day, or immune suppressive drug therapy following organ transplantation;†
- persons who were recently infected with *M. tuberculosis* (within the past 2 years);
- persons with a history of untreated or inadequately treated active tuberculosis, including persons with fibrotic changes on chest radiograph consistent with prior active tuberculosis;
- persons with silicosis, diabetes mellitus, chronic renal failure, leukemia, lymphoma, or cancer of the head, neck, or lung;
- persons who have had a gastrectomy or jejunoleal bypass;
- persons who weigh <90% of their ideal body weight;
- cigarette smokers and persons who abuse drugs or alcohol; and
- populations defined locally as having an increased incidence of active tuberculosis, possibly including medically underserved or low-income populations

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**Source:** Based on [https://academic.oup.com/cid/article/64/2/e1/2629583](https://academic.oup.com/cid/article/64/2/e1/2629583)

**2016 Clinical Practice Guidelines for Diagnosis of Tuberculosis in Adults and Children.**

* Persons with these characteristics have an increased risk for progression of infection to active tuberculosis compared with persons without these characteristics.

† Indicates persons at increased risk for a poor outcome (e.g., meningitis, disseminated disease, or death) if active tuberculosis occurs.
Treatment Algorithm for Culture-Positive Tuberculosis

FIGURE 1. Treatment algorithm for tuberculosis.

Patients in whom tuberculosis is proved or strongly suspected should have treatment initiated with isoniazid, rifampin, pyrazinamide, and ethambutol for the initial 2 months. A repeat smear and culture should be performed when 2 months of treatment has been completed. If cavities were seen on the initial chest radiograph or the acid-fast smear is positive at completion of 2 months of treatment, the continuation phase of treatment should consist of isoniazid and rifampin daily or twice weekly for 4 months to complete a total of 6 months of treatment. If cavitation was present on the initial chest radiograph and the culture at the time of completion of 2 months of therapy is positive, the continuation phase should be lengthened to 7 months (total of 9 months of treatment). If the patient has HIV infection and the CD4+ cell count is <100/µl, the continuation phase should consist of daily or three times weekly isoniazid and rifampin. In HIV-uninfected patients having no cavitation on chest radiograph and negative acid-fast smears at completion of 2 months of treatment, the continuation phase may consist of either once weekly isoniazid and rifapentine, or daily or twice weekly isoniazid and rifampin, to complete a total of 6 months (bottom). Patients receiving isoniazid and rifapentine, and whose 2-month cultures are positive, should have treatment extended by an additional 3 months (total of 9 months).

*EMB may be discontinued when results of drug susceptibility testing indicate no drug resistance.
†PZA may be discontinued after it has been taken for 2 months (56 doses).
‡RPT should not be used in HIV-infected patients with tuberculosis or in patients with extrapulmonary tuberculosis.
§Therapy should be extended to 9 months if 2-month culture is positive.

CXR = chest radiograph; EMB = ethambutol; INH = isoniazid; PZA = pyrazinamide; RIF = rifampin; RPT = rifapentine.

http://cid.oxfordjournals.org/content/63/7/e147
The decision to begin treatment for a patient with sputum smears that are negative depends on the degree of suspicion that the patient has tuberculosis. The considerations in choosing among the treatment options are discussed in text. If the clinical suspicion is high (bottom), then multidrug therapy should be initiated before acid-fast smear and culture results are known. If the diagnosis is confirmed by a positive culture, treatment can be continued to complete a standard course of therapy (see Figure 1). If initial cultures remain negative and treatment has consisted of multiple drugs for 2 months, then there are two options depending on repeat evaluation at 2 months (bottom): 1) if the patient demonstrates symptomatic or radiographic improvement without another apparent diagnosis, then a diagnosis of culture-negative tuberculosis can be inferred. Treatment should be continued with isoniazid and rifampin alone for an additional 2 months; 2) if the patient demonstrates neither symptomatic nor radiographic improvement, then prior tuberculosis is unlikely and treatment is complete once treatment including at least 2 months of rifampin and pyrazinamide has been administered. In low-suspicion patients not initially receiving treatment (top), if cultures remain negative, the patient has no symptoms, and the chest radiograph is unchanged at 2–3 months, there are three treatment options: these are 1) isoniazid for 9 months, 2) rifampin with or without isoniazid for 4 months, or 3) rifampin and pyrazinamide for 2 months. CXR = chest X-ray; EMB = ethambutol; INH = isoniazid; PZA = pyrazinamide; Rif = rifampin; Sx = signs/symptoms. (It should be noted that the Rif/PZA 2-month regimen should be used only for patients who are not likely to complete a longer course of treatment and can be monitored closely.)

http://cid.oxfordjournals.org/content/63/7/e1.47
DIRECTLY OBSERVED THERAPY (DOT)

DOT is a method of ensuring patients’ adherence to therapy. LHD staff must recognize DOT as the Kentucky standard of care. All active TB disease, whether pulmonary or extrapulmonary, shall be treated by DOT. The DOT method must be conveyed with confidence to patients. Always respect the patient’s confidentiality.

The Centers for Disease Control and Prevention (CDC) and the American Thoracic Society (ATS) recommends that all TB patients be considered for DOT because of the difficulty in predicting who will adhere to the treatment regimen.

The following persons must be placed on DOT for treatment of tuberculosis:

- All patients being treated for suspected pulmonary or extrapulmonary TB.
- All patients diagnosed with culture positive pulmonary and or extrapulmonary TB.
- All patients diagnosed as a “clinical case” of pulmonary TB or extrapulmonary TB because of negative TB cultures but who had chest x-ray and / or clinical improvement on antiTB therapy.

DOT means that a specially trained health department health care professional, not related to the patient, watches the patient swallow each dose of TB medication. DOT is never to be delegated to a family member. Kentucky’s TB Control Program does not consider nor count the dosage as DOT if a family observes the patient taking the medication. Such actions could result in prolonged treatment and be considered noncompliance with the DOT agreement.

Be aware of techniques a patient may use to avoid swallowing the medication such as hiding the pills in the mouth, spitting the pills into the fluid used to take them with, or vomiting the pills after leaving the treatment site.

DOT reduces the frequency of treatment failures, of acquiring drug resistance, and in suffering relapse of the disease. Intermittent DOT reduces the total number of doses a patient must take and the number of encounters with LHD personnel. If the patient cannot go to a LHD, LHD staff can arrange another site that is safe, convenient, and agreeable to both patient and staff.

Besides being cost effective, DOT has many other benefits. DOT is a patient-focused service that also provides the health care worker with a better understanding of the patient’s needs, thus placing the worker in position to assist with needed health or social services, and making the appropriate referrals. DOT provides an effective opportunity for education, not only of the patient but also of the patient’s support system. DOT is also advantageous to the community because a patient on DOT becomes noninfectious much more quickly. This reduces the time that a patient is able to spread the disease in the community.
KY V-DOT
Video Directly Observed Therapy

Directly observed therapy (DOT) for tuberculosis increases patient adherence. This increased adherence both reduces the risk of disease recurrence and prevents the development of resistant *Mycobacterium tuberculosis* strains.

Once the patient has completed eight (8) weeks of medication by DOT (initial phase), video DOT is an option. Video DOT is an option in place of at home/office DOT that local health departments can offer to patients.

During Video DOT, the local health department determines a supply of pre-packaged medication doses that will be given to the patient at each clinic visit. The local health department personnel will arrange a set time for the remote video call with the patient. During the video call, the patient will be expected to display the medications onscreen*. The health worker will then witness the patient swallowing the medication.

All patients participating must agree to the requirements of the Video DOT program and sign a consent form.

*See TB Program teaching sheet TB-14a for Video DOT protocols and consent form TB-14b.

Exclusion Criteria for Video DOT

- Patient in isolation.
- Patient with side effects requiring graduated doses.
- Illegal activities occurring in the home.
- Video DOT must be accomplished within 15 minutes.
- Lack of stable environment or lack of telephone at patient location.
- Less than 90% compliance with therapy during the initial eight (8) weeks of standard DOT.
- Less than 90% compliance with the treatment regimen or scheduled Video DOT appointments
- Inability to maintain effective communication via the video call either due to patient disability or language barriers.
- Inability of the patient to demonstrate effective use of the equipment.
- MDR TB
DRUG REGIMENS FOR MICROBIOLOGICALLY CONFIRMED PULMONARY TUBERCULOSIS CAUSED BY DRUG-SUSCEPTIBLE ORGANISMS

Preferred Regimen from 2016 Treatment Guidelines:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Intensive Phase</th>
<th>Continuation Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Interval and Dose&lt;sup&gt;b&lt;/sup&gt; (Minimum Duration)</td>
<td>Interval and Dose&lt;sup&gt;b&lt;/sup&gt;,&lt;sup&gt;c&lt;/sup&gt; (Minimum Duration)</td>
</tr>
<tr>
<td>INH</td>
<td>7 d/wk for 56 doses (8 wk), or</td>
<td>INH 7 d/wk for 126 doses (18 wk), or</td>
</tr>
<tr>
<td>RIF</td>
<td>5 d/wk for 40 doses (8 wk)</td>
<td>RIF 5 d/wk for 90 doses (18 wk)</td>
</tr>
<tr>
<td>PZA</td>
<td>EMB</td>
<td></td>
</tr>
</tbody>
</table>

Preferred Alternative Regimen from 2016 Treatment Guidelines:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Intensive Phase</th>
<th>Continuation Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Interval and Dose&lt;sup&gt;b&lt;/sup&gt; (Minimum Duration)</td>
<td>Interval and Dose&lt;sup&gt;b&lt;/sup&gt;,&lt;sup&gt;c&lt;/sup&gt; (Minimum Duration)</td>
</tr>
<tr>
<td>INH</td>
<td>7 d/wk for 56 doses (8 wk), or</td>
<td>INH 3 times weekly for 54 doses (18 wk)</td>
</tr>
<tr>
<td>RIF</td>
<td>5 d/wk for 40 doses (8 wk)</td>
<td>RIF</td>
</tr>
<tr>
<td>PZA</td>
<td>EMB</td>
<td></td>
</tr>
</tbody>
</table>

DRUG REGIMENS FOR MICROBIOLOGICALLY CONFIRMED
PULMONARY TUBERCULOSIS CAUSED BY DRUG-SUSCEPTIBLE
ORGANISMS (Continued) Footnotes for 2016 Treatment Regimens:

Abbreviations: DOT, directly observed therapy; EMB, ethambutol; HIV, human immunodeficiency virus; INH, isoniazid; PZA, pyrazinamide; RIF, rifampin.

* Other combinations may be appropriate in certain circumstances; additional details are provided in the section “Recommended Treatment Regimens.”

When DOT is used, drugs may be given 5 days per week and the necessary number of doses adjusted accordingly. Although there are no studies that compare 5 with 7 daily doses, extensive experience indicates this would be an effective practice. DOT should be used when drugs are administered <7 days per week.

Based on expert opinion, patients with cavitary on initial chest radiograph and positive cultures at completion of 2 months of therapy should receive a 7-month (31-week) continuation phase.

Pyridoxine (vitamin B6), 25-50 mg/day, is given with INH to all persons at risk of neuropathy (eg, pregnant women, breastfeeding infants; persons with HIV; patients with diabetes, alcoholism, malnutrition, or chronic renal failure; or patients with advanced age). For patients with peripheral neuropathy, experts recommend increasing pyridoxine dose to 100 mg/day.

Alternative Regimen from 2003 Treatment Guidelines

<table>
<thead>
<tr>
<th>Initial phase</th>
<th>Continuation phase</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drugs</strong></td>
<td><strong>Interval and doses† (minimal duration)</strong></td>
</tr>
<tr>
<td>INH</td>
<td>Seven days per week for 56 doses (8 wk) or 5 d/wk for 40 doses (8 wk)</td>
</tr>
<tr>
<td>RIF</td>
<td></td>
</tr>
<tr>
<td>PZA</td>
<td></td>
</tr>
<tr>
<td>EMB</td>
<td></td>
</tr>
</tbody>
</table>

Definition of abbreviations: EMB = Ethambutol; INH = isoniazid; PZA = pyrazinamide; RIF = rifampin; RPT = rifapentine.

*Please note 2018 Red book: Rifampin Dosing: Standard Treatment 2018 15-20 mg/kg/day Infant, Toddlers, TB management (any age) 2018 20-30 mg/kg/day

### DOSES\(^a\) OF ANTI-TUBERCULOSIS DRUGS FOR ADULTS AND CHILDREN\(^b\)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First-line drugs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isoniazid</td>
<td>Tablets (50 mg, 100 mg, 300 mg); elixir (50 mg/5 mL); aqueous solution (100 mg/mL) for intravenous or intramuscular injection. Note: Pyridoxine (vitamin B6), 25–50 mg/day, is given with INH to all persons at risk of neuropathy (eg, pregnant women; breastfeeding infants; persons with HIV; patients with diabetes, alcoholism, malnutrition, or chronic renal failure; or patients with advanced age). For patients with peripheral neuropathy, experts recommend increasing pyridoxine dose to 100 mg/d.</td>
<td>Adults</td>
<td>5 mg/kg (typically 300 mg)</td>
<td>15 mg/kg (typically 900 mg)</td>
<td>15 mg/kg (typically 900 mg)</td>
<td>15 mg/kg (typically 900 mg)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Children</td>
<td>10–15 mg/kg</td>
<td>20–30 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rifampin</td>
<td>Capsule (150 mg, 300 mg). Powder may be suspended for oral administration. Aqueous solution for intravenous injection.</td>
<td>Adults</td>
<td>10 mg/kg (typically 600 mg)</td>
<td>...</td>
<td>10 mg/kg (typically 600 mg)</td>
<td>10 mg/kg (typically 600 mg)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Children</td>
<td>10–20 mg/kg</td>
<td>...</td>
<td>10–20 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Rifabutin</td>
<td>Capsule (150 mg)</td>
<td>Adults</td>
<td>5 mg/kg (typically 300 mg)</td>
<td>...</td>
<td>Not recommended</td>
<td>Not recommended</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Children</td>
<td>...</td>
<td>...</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td>Rifapentine</td>
<td>Tablet (150 mg film coated)</td>
<td>Adults</td>
<td>10–20 mg/kg</td>
<td>...</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Children</td>
<td>Active tuberculosis; for children ≥12 yr of age, same dosing as for adults, administered once weekly. Rifapentine is not FDA-approved for treatment of active tuberculosis in children &lt;12 yr of age.</td>
<td></td>
<td>...</td>
<td></td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td>Tablet (500 mg scored)</td>
<td>Adults</td>
<td>See Table 10</td>
<td>...</td>
<td>See Table 10</td>
<td>See Table 10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Children</td>
<td>35 (30–40) mg/kg</td>
<td>...</td>
<td>50 mg/kg</td>
<td>...</td>
</tr>
<tr>
<td>Ethambutol</td>
<td>Tablet (100 mg; 400 mg)</td>
<td>Adults</td>
<td>See Table 11</td>
<td>...</td>
<td>See Table 11</td>
<td>See Table 11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Children</td>
<td>20 (15–25) mg/kg</td>
<td>...</td>
<td>50 mg/kg</td>
<td>...</td>
</tr>
</tbody>
</table>

*Please note 2018 Red Book standard dosing for Rifampin Dosing 15 – 20 mg/kg/day Infants, Toddlers, and TB management (any age) 20-30 mg/kg/day*  
# Doses of Antituberculosis Drugs for Adults and Children (Continued)

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<tr>
<td>Cycloserine</td>
<td>Capsule (250 mg)</td>
<td>Adults&lt;sup&gt;b&lt;/sup&gt;</td>
<td>10–15 mg/kg total (usually 250–500 mg once or twice daily)</td>
<td>There are inadequate data to support intermittent administration.</td>
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<td>Children</td>
<td>15–20 mg/kg total (divided 1–2 times daily)</td>
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<td>Ethionamide</td>
<td>Tablet (250 mg)</td>
<td>Adults&lt;sup&gt;b&lt;/sup&gt;</td>
<td>15–20 mg/kg total (usually 250–500 mg once or twice daily)</td>
<td>There are inadequate data to support intermittent administration.</td>
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<td>Children</td>
<td>15–20 mg/kg total (divided 1–2 times daily)</td>
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<td>Streptomycin</td>
<td>Aqueous solution (1 g vials) for IM or IV administration.</td>
<td>Adults</td>
<td>15 mg/kg daily. Some clinicians prefer 25 mg/kg 3 times weekly. Patients with decreased renal function may require the 15 mg/kg dose to be given only 3 times weekly to allow for drug clearance.</td>
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<tr>
<td></td>
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<td>Children</td>
<td>15–20 mg/kg [427]</td>
<td>25–30 mg/kg&lt;sup&gt;1&lt;/sup&gt;</td>
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<td>Amikacin/kanamycin</td>
<td>Aqueous solution (500 mg and 1 g vials) for IM or IV administration.</td>
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<td>15 mg/kg daily. Some clinicians prefer 25 mg/kg 3 times weekly. Patients with decreased renal function, including older patients, may require the 15 mg/kg dose to be given only 3 times weekly to allow for drug clearance.</td>
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<tr>
<td></td>
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<td>Children</td>
<td>15–20 mg/kg [427]</td>
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<td>Capreomycin</td>
<td>Aqueous solution (1 g vials) for IM or IV administration.</td>
<td>Adults</td>
<td>15 mg/kg daily. Some clinicians prefer 25 mg/kg 3 times weekly. Patients with decreased renal function, including older patients, may require the 15 mg/kg dose to be given only 3 times weekly to allow for drug clearance.</td>
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<td>Children</td>
<td>15–20 mg/kg [427]</td>
<td>25–30 mg/kg&lt;sup&gt;1&lt;/sup&gt;</td>
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<tr>
<td>Para-aminosalicylic acid</td>
<td>Granules (4 g packets) can be mixed in and ingested with soft food (granules should not be chewed). Tablets (500 mg) are still available in some countries, but not in the United States. A solution for IV administration is available in Europe.</td>
<td>Adults</td>
<td>8–12 g total (usually 4000 mg 2–3 times daily)</td>
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<td>Children</td>
<td>200–300 mg/kg total (usually divided 100 mg/kg given 2 to 3 times daily)</td>
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DOSES\textsuperscript{a} OF ANTITUBERCULOSIS DRUGS FOR ADULTS AND CHILDREN\textsuperscript{b} (Continued)

http://cid.oxfordjournals.org/content/63/7/e1-47

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<td>Levofloxacin</td>
<td>Tablets (250 mg, 500 mg, 750 mg); aqueous solution (500 mg vials) for IV injection.</td>
<td>Adults</td>
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<td>Children</td>
<td>The optimal dose is not known, but clinical data suggest 15–20 mg/kg \textsuperscript{[427]}</td>
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<td>Moxifloxacin</td>
<td>Tablets (400 mg); aqueous solution (400 mg/250 mL) for IV injection</td>
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<td>400 mg daily</td>
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<td>Children</td>
<td>The optimal dose is not known. Some experts use 10 mg/kg daily dosing, though lack of formulations makes such titration challenging. Aiming for serum concentrations of 3–5 μM/L 2 h postdose is proposed by experts as a reasonable target.</td>
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Abbreviations: FDA, US Food and Drug Administration; HIV, human immunodeficiency virus; IM, intramuscular; INH, isoniazid; IV, intravenous.

\textsuperscript{a} Dosing based on actual weight is acceptable in patients who are not obese. For obese patients (>20% above ideal body weight (IBW)), dosing based on IBW may be preferred for initial doses. Some clinicians prefer a modified IBW (IBW + 0.40 × (actual weight – IBW)) as is done for initial aminoglycoside doses. Because tuberculosis drug dosing for obese patients has not been established, therapeutic drug monitoring may be considered for such patients.

\textsuperscript{b} For purposes of this document, adult dosing begins at age 15 years or at a weight of >40 kg in younger children. The optimal doses for thrice-weekly therapy in children and adolescents have not been established. Some experts use in adolescents the same doses as recommended for adults, and for younger children the same doses as recommended for twice-weekly therapy.

\textsuperscript{1} Higher doses of rifampin, currently as high as 35 mg/kg, are being studied in clinical trials.

\textsuperscript{1} Rifabutin dose may need to be adjusted when there is concomitant use of protease inhibitors or nonnucleoside reverse transcriptase inhibitors.

\textsuperscript{1} TBTC Study 22 used rifapentine (RPT) dosage of 10 mg/kg in the continuation phase of treatment for active disease \textsuperscript{9}. However, RIFAQUIN and PREVENT TB safely used higher dosages of RPT, administered once weekly \textsuperscript{164, 210}. Daily doses of 1200 mg RPT are being studied in clinical trials for active tuberculosis disease.

\textsuperscript{1} As an approach to avoiding ethambutol (EMB) ocular toxicity, some clinicians use a 3-drug regimen (INH, rifampin, and pyrazinamide) in the initial 2 months of treatment for children who are HIV-uninfected, are living in an area of low prevalence of drug-resistant tuberculosis, and have no exposure to an individual from an area of high prevalence of drug-resistant tuberculosis. However, because the prevalence of and risk for drug-resistant tuberculosis can be difficult to ascertain, the American Academy of Pediatrics and most experts include EMB as part of the intensive-phase regimen for children with tuberculosis.

\textsuperscript{1} Clinicians experienced with using cycloserine suggest starting with 250 mg once daily and gradually increasing as tolerated. Serum concentrations often are useful in determining the appropriate dose for a given patient. Few patients tolerate 500 mg twice daily.

\textsuperscript{1} Ethionamide can be given at bedtime or with a main meal in an attempt to reduce nausea. Clinicians experienced with using ethionamide suggest starting with 250 mg once daily and gradually increasing as tolerated. Serum concentrations may be useful in determining the appropriate dose for a given patient. Few patients tolerate 500 mg twice daily.

\textsuperscript{1} Modified from adult intermittent dose of 25 mg/kg, and accounting for larger total body water content and faster clearance of injectable drugs in most children. Dosing can be guided by serum concentrations.

\textsuperscript{1} RIFAQUIN trial studied a 6-month regimen. Daily isoniazid was replaced by daily moxifloxacin 400 mg for the first 2 months, followed by once-weekly doses of moxifloxacin 400 mg and RPT 1200 mg for the remaining 4 months. Two hundred twelve patients were studied (each dose of RPT was preceded by a meal of 2 hard-boiled eggs and bread). This regimen was shown to be noninferior to a standard daily administered 6-month regimen \textsuperscript{164}.
DOSES* OF ANTITUBERCULOSIS DRUGS FOR ADULTS AND CHILDREN†
(Continued)

*Continued*

MMWR, June 20, 2003, p. 5

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**Table 4. Suggested pyrazinamide doses, using whole tablets, for adults weighing 40–90 kilograms**

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<th>40–55</th>
<th>56–75</th>
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<tr>
<td>Daily, mg (mg/kg)</td>
<td>1,000 (18.2–25.0)</td>
<td>1,500 (20.0–26.8)</td>
<td>2,000† (22.2–26.3)</td>
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<tr>
<td>Thrice weekly, mg (mg/kg)</td>
<td>1,500 (27.3–37.5)</td>
<td>2,500 (33.3–44.6)</td>
<td>3,000† (33.3–39.5)</td>
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<tr>
<td>Twice weekly, mg (mg/kg)</td>
<td>2,000 (36.4–50.0)</td>
<td>3,000 (40.0–53.6)</td>
<td>4,000† (44.4–52.6)</td>
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</table>

* Based on estimated lean body weight.
† Maximum dose regardless of weight.

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**Table 5. Suggested ethambutol doses, using whole tablets, for adults weighing 40–90 kilograms**

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<th>40–55</th>
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<tr>
<td>Daily, mg (mg/kg)</td>
<td>800 (14.5–20.0)</td>
<td>1,200 (16.0–21.4)</td>
<td>1,600† (17.8–21.1)</td>
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<tr>
<td>Thrice weekly, mg (mg/kg)</td>
<td>1,200 (21.8–30.0)</td>
<td>2,000 (26.7–35.7)</td>
<td>2,400† (26.7–31.6)</td>
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<tr>
<td>Twice weekly, mg (mg/kg)</td>
<td>2,000 (36.4–50.0)</td>
<td>2,800 (37.3–50.0)</td>
<td>4,000† (44.4–52.6)</td>
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</table>

* Based on estimated lean body weight.
† Maximum dose regardless of weight.

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*Centers for Disease Control and Prevention. Treatment of Tuberculosis, American Thoracic Society, CDC, and Infectious Diseases Society of America.
http://cid.oxfordjournals.org/content/63/7/e1 47
PYRIDOXINE (VITAMIN B6) SUPPLEMENTATION DURING TREATMENT OF LTBI OR ACTIVE TB DISEASE

Prevention of Peripheral Neuropathy and Central Nervous Symptom Effects of INH

Indications for pyridoxine when INH is ordered to treat LTBI or active TB disease:

**Adults:** Pyridoxine supplementation can be ordered for any adult being treated with INH, unless there is a medical contraindication. Pyridoxine (vitamin B6) supplementation is particularly recommended when INH is used for treatment of LTBI or active TB disease in some adults with medical conditions where peripheral neuropathy is common, such as:\textsuperscript{1, 2, 3}:

- Nutritional deficiencies
- Diabetes
- HIV infection
- Chronic renal failure
- Alcoholism
- Persons with seizure disorders
- Pregnant women
- Breastfeeding women

**Infants, children, and adolescents**\textsuperscript{1, 2, 3, 4, 5, 6}: Routine administration of pyridoxine is not recommended for most children and adolescents taking INH\textsuperscript{4}. Pyridoxine is recommended when INH is used for treatment of LTBI or active TB disease in some infants, children, and adolescents at increased risk for peripheral neuritis or other INH adverse effects, such as:

- Breastfed infants, particularly those who are exclusively breastfed
- Children and adolescents on meat- and milk-deficient diets
- Children and adolescents with nutritional deficiencies
- Children who experience paresthesias while taking isoniazid
- HIV infection, particularly symptomatic HIV-infected individuals
- Pregnant adolescents
- Breastfeeding adolescents

**Dose of pyridoxine when INH is ordered to treat LTBI or active TB disease:**

**Adults:**

- CDC guidelines – 25 mg/day\textsuperscript{1}
- Wisconsin TB Program guidelines – 10 to 50 mg/day\textsuperscript{2}
- The Harriet Lane Handbook\textsuperscript{5} – 25 to 100 mg/day
Infants, children, and adolescents:

- The Harriet Lane Handbook\(^5\): Child – 1-2 mg/kg/day. Pyridoxine injectable can be compounded with simple syrup to make an oral solution containing 1 mg/mL\(^6\).
- 10 mg/day to 25 mg/day\(^1\)

Prevention of Neurotoxic Effects of Cycloserine (A Second-line TB drug) in Adults:
Pyridoxine may help prevent and treat neurotoxic side effects of cycloserine in the treatment of active TB disease and is usually given in a dosage of 100–200 mg/day.\(^1\)

Recommended Daily Allowances and Recommended Maximum Daily Intake\(^7\):
“The daily recommended dietary allowances (RDAs) of vitamin B6 are: Infants 0-6 months, 0.1 mg; Infants 7-12 months, 0.3 mg; Children 1-3 years, 0.5 mg; Children 4-8 years, 0.6 mg; Children 9-13 years, 1 mg; Males 14-50 years, 1.3 mg; Males over 50 years, 1.7 mg; Females 14-18 years, 1.2 mg; Females 19-50 years, 1.3 mg; Females over 50 years, 1.5 mg; Pregnant women, 1.9 mg; and breast-feeding women, 2 mg. Some researchers think the RDA for women 19-50 years should be increased to 1.5-1.7 mg per day. The recommended maximum daily intake is: Children 1-3 years, 30 mg; Children 4-8 years, 40 mg; Children 9-13 years, 60 mg; Adults, pregnant and breast-feeding women, 14-18 years, 80 mg; and Adults, pregnant and breast-feeding women, over 18 years, 100 mg.”

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<table>
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<th>Weight in Pounds</th>
<th>Weight in Kilograms</th>
<th>Dosage at 5 mg/kg</th>
<th>Dosage at 10 mg/kg</th>
<th>Dosage at 15 mg/kg</th>
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<td>1293</td>
<td>1724</td>
<td>2155</td>
<td></td>
</tr>
<tr>
<td>195</td>
<td>88.5</td>
<td>442</td>
<td>885</td>
<td>1327</td>
<td>1769</td>
<td>2211</td>
<td></td>
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<tr>
<td>200</td>
<td>90.7</td>
<td>454</td>
<td>907</td>
<td>1361</td>
<td>1814</td>
<td>2268</td>
<td></td>
</tr>
<tr>
<td>205</td>
<td>93.0</td>
<td>465</td>
<td>930</td>
<td>1395</td>
<td>1860</td>
<td>2325</td>
<td></td>
</tr>
<tr>
<td>210</td>
<td>95.3</td>
<td>476</td>
<td>953</td>
<td>1429</td>
<td>1905</td>
<td>2381</td>
<td></td>
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<tr>
<td>215</td>
<td>97.5</td>
<td>488</td>
<td>975</td>
<td>1463</td>
<td>1950</td>
<td>2438</td>
<td></td>
</tr>
<tr>
<td>220</td>
<td>99.8</td>
<td>499</td>
<td>998</td>
<td>1497</td>
<td>1996</td>
<td>2495</td>
<td></td>
</tr>
<tr>
<td>225</td>
<td>102.1</td>
<td>510</td>
<td>1021</td>
<td>1531</td>
<td>2041</td>
<td>2551</td>
<td></td>
</tr>
<tr>
<td>230</td>
<td>104.3</td>
<td>522</td>
<td>1043</td>
<td>1565</td>
<td>2087</td>
<td>2608</td>
<td></td>
</tr>
<tr>
<td>235</td>
<td>106.6</td>
<td>533</td>
<td>1066</td>
<td>1599</td>
<td>2132</td>
<td>2665</td>
<td></td>
</tr>
<tr>
<td>240</td>
<td>108.9</td>
<td>544</td>
<td>1089</td>
<td>1633</td>
<td>2177</td>
<td>2722</td>
<td></td>
</tr>
<tr>
<td>245</td>
<td>111.1</td>
<td>556</td>
<td>1111</td>
<td>1667</td>
<td>2223</td>
<td>2778</td>
<td></td>
</tr>
<tr>
<td>250</td>
<td>113.4</td>
<td>567</td>
<td>1134</td>
<td>1701</td>
<td>2268</td>
<td>2835</td>
<td></td>
</tr>
</tbody>
</table>

*Dosage calculated may have to be adjusted in order not to exceed the maximum dose for any drug being used. Table recalculated in November 2010 with conversion factor of “1 pound = 0.45359237 kilograms.”*
Clinically Significant Drug-Drug Interactions Involving the Rifamycins

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Drugs Whose Concentrations Are Substantially Decreased by Rifamycins</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antiretroviral agents</td>
<td>HIV-1 protease inhibitors (lopinavir/ritonavir, darunavir/ritonavir, atazanavir/ritonavir)</td>
<td>RFB preferred with protease inhibitors. For ritonavir-boosted regimens, give RFB 150 mg daily. Double-dose lopinavir/ritonavir can be used with RIF but toxicity increased. Do not use RIF with other protease inhibitors.</td>
</tr>
<tr>
<td></td>
<td>NNRTIs: Nevirapine, Efavirenz, Rilpivirine</td>
<td>RIF decreases exposure to all NNRTIs. If nevirapine is used with RIF, lead-in nevirapine dose of 200 mg daily should be omitted and 400 mg daily nevirapine dosage given. With RIF, many experts advise that efavirenz be given at standard dosage of 600 mg daily, although FDA recommends increasing efavirenz to BOO mg daily in persons &gt;60 kg. In young children double-dose lopinavir/ritonavir given with RIF results in inadequate concentrations- super-boosted Lopinavir/ritonavir is advised (if available) by some experts. Rilpivirine and etravirine should not be given with RIF. RFB can be used with nevirapine and etravirine at usual dosing. Efavirenz and RFB user requires dose increase of RFB to 600 mg daily, as such RIF is preferred. Rilpivirine should not be given with RFB. Increase dose of raltegravir to BOO mg twice daily with RIF, although clinical trial data show similar efficacy using 400 mg twice daily. Dolutegravir dose should be increased to 50 mg every 12 h with RIF. Do not use RIF with elvitegravir. RFB can be used with all INSTIs.</td>
</tr>
<tr>
<td></td>
<td>Complera (fixed-dose combination tablet containing emtricitabine, rilpivirine, TDF)</td>
<td>RIF should not be used with maraviroc. RFB can be used with maraviroc.</td>
</tr>
<tr>
<td></td>
<td>Etravirine</td>
<td></td>
</tr>
<tr>
<td>INSTIs</td>
<td>Raltegravir, Dolutegravir, Elvitegravir (coformulated with cobicistat, tenofovir and emtricitabine as Stridil)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Genvoya (fixed-dose combination tablet containing elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide)</td>
<td></td>
</tr>
<tr>
<td>CCR5 inhibitors</td>
<td>Maraviroc</td>
<td></td>
</tr>
<tr>
<td>Anti-infectives</td>
<td>Macrolide antibiotics (azithromycin, clarithromycin, erythromycin)</td>
<td>Azithromycin has no significant interaction with rifamycins. Coadministration of clarithromycin and RFB results in significant bidirectional interactions that can increase RFB to toxic levels increasing the risk of uveitis. Erythromycin is a CYP3A4 substrate and clearance may increase insetting of rifamycin use. May require use of a drug other than doxycycline. Itraconazole, ketoconazole, and voriconazole concentrations may be subtherapeutic with any of the rifamycins. Fluconazole can be used with rifamycins, but the dose of fluconazole may have to be increased. Consider alternate form of <em>Pneumocystis jiroveci</em> treatment or prophylaxis. Consider an alternative antibiotic. Consider alternate form of malaria prophylaxis.</td>
</tr>
<tr>
<td></td>
<td>Doxycycline</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Azole antifungal agents (ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, isavuconazole)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Atovaquone</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chloramphenicol</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mefloquine</td>
<td></td>
</tr>
</tbody>
</table>
Clinically Significant Drug-Drug Interactions Involving the Rifamycins[^1] (Continued)

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Drugs Whose Concentrations Are Substantially Decreased by Rifamycins</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hormone therapy</td>
<td>Ethinylestradiol, norethindrone</td>
<td>Women of reproductive potential on oral contraceptives should be advised to add a barrier method of contraception when on a rifamycin.</td>
</tr>
<tr>
<td></td>
<td>Tamoxifen</td>
<td>May require alternate therapy or use of a non-rifamycin-containing regimen.</td>
</tr>
<tr>
<td></td>
<td>Levothyroxine</td>
<td>Monitoring of serum TSH recommended; may require increased dose of levothyroxine.</td>
</tr>
<tr>
<td>Narcotics</td>
<td>Methadone</td>
<td>RIF and RPT use may require methadone dose increase. RFB infrequently causes methadone withdrawal.</td>
</tr>
<tr>
<td>Anticoagulants</td>
<td>Warfarin</td>
<td>Monitor prothrombin time; may require 2- to 3-fold warfarin dose increase.</td>
</tr>
<tr>
<td>Immunosuppressive</td>
<td>Cyclosporine, tacrolimus</td>
<td>RFB may allow concomitant use of cyclosporine and a rifamycin; monitoring of cyclosporine and tacrolimus serum concentrations may assist with dosing.</td>
</tr>
<tr>
<td>agents</td>
<td>Corticosteroids</td>
<td>Monitor clinically; may require 2- to 3-fold increase in corticosteroid dose.</td>
</tr>
<tr>
<td>Anticonvulsants</td>
<td>Phenytoin, lamotrigine</td>
<td>TDM recommended; may require anticonvulsant dose increase.</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Verapamil, nifedipine, diltiazem (a similar interaction is also predicted for felodipine and nisoldipine)</td>
<td>Clinical monitoring recommended; may require change to an alternate cardiovascular agent.</td>
</tr>
<tr>
<td>agents</td>
<td>Propranolol, metoprolol</td>
<td>Clinical monitoring recommended; may require dose increase or change to an alternate cardiovascular drug.</td>
</tr>
<tr>
<td></td>
<td>Enalapril, losartan</td>
<td>Monitor clinically; may require a dose increase or use of an alternate cardiovascular drug.</td>
</tr>
<tr>
<td></td>
<td>Digoxin (among patients with renal insufficiency), digitoxin</td>
<td>TDM recommended; may require digoxin or digitoxin dose increase.</td>
</tr>
<tr>
<td></td>
<td>Quinidine</td>
<td>TDM recommended; may require quinidine dose increase.</td>
</tr>
<tr>
<td></td>
<td>Mexiletine, tocainide, propafenone</td>
<td>Clinical monitoring recommended; may require change to an alternate cardiovascular drug.</td>
</tr>
<tr>
<td></td>
<td>Theophylline</td>
<td>TDM recommended; may require theophylline dose increase.</td>
</tr>
<tr>
<td>Sulfonylurea</td>
<td>Tolbutamide, chlorpropamide, glyburide, glimepiride, regaplinide</td>
<td>Monitor blood glucose; may require dose increase or change to an alternate hypoglycemic drug.</td>
</tr>
<tr>
<td>hypoglycemics</td>
<td>Simvastatin, fluvastatin</td>
<td>Monitor hypolipidemic effect; may require use of an alternate anthyplipidemic drug.</td>
</tr>
</tbody>
</table>

[^1]: July 2019
Clinically Significant Drug-Drug Interactions Involving the Rifamycins a (Continued)

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Drugs Whose Concentrations Are Substantially Decreased by Rifamycins</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychotropic drugs</td>
<td>Nortriptyline</td>
<td>TDM recommended; may require dose increase or change to alternate psychotropic drug.</td>
</tr>
<tr>
<td></td>
<td>Haloperidol, quetiapine</td>
<td>Monitor clinically; may require a dose increase or use of an alternate psychotropic drug.</td>
</tr>
<tr>
<td></td>
<td>Benzodiazepines (eg, diazepam, triazolam), zolpidem, buspironel</td>
<td>Monitor clinically; may require a dose increase or use of an alternate psychotropic drug.</td>
</tr>
</tbody>
</table>

Abbreviations: CCR5, C chemokine receptor type 5; CYP, cytochrome P450; FDA, US Food and Drug Administration; HIV, human immunodeficiency virus; INSTI, integrase strand transfer inhibitor; NNRTI, nonnucleoside reverse transcriptase inhibitor; RFB, rifabutin; Rif, rifampin; RPT, rifapentine; TDF, tenofovir disoproxil fumarate; TDM, therapeutic drug monitoring; TSH, thyroid-stimulating hormone.

a See the following useful websites for updated information regarding drug interactions: AIDSinfo, Centers for Disease Control and Prevention, University of California San Francisco, University of Liverpool, Indiana University, and University of Maryland.
Dosing Recommendations for Adult Patients with Reduced Renal Function

<table>
<thead>
<tr>
<th>Drug</th>
<th>Change in Frequency</th>
<th>Recommended Dose and Frequency for Patients With Creatinine Clearance &lt;30 mL/min, or Patients Receiving Hemodialysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid</td>
<td>No</td>
<td>300 mg once daily, or 900 mg 3 times/wk</td>
</tr>
<tr>
<td>Rifampin</td>
<td>No</td>
<td>600 mg once daily, or 600 mg 3 times/wk</td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td>Yes</td>
<td>25–35 mg/kg/dose 3 times/wk (not daily)</td>
</tr>
<tr>
<td>Ethambutol</td>
<td>Yes</td>
<td>20–25 mg/kg/dose 3 times/wk (not daily)</td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>Yes</td>
<td>750–1000 mg/dose 3 times/wk (not daily)</td>
</tr>
<tr>
<td>Moxifloxacin</td>
<td>No</td>
<td>400 mg once daily</td>
</tr>
<tr>
<td>Cycloserine</td>
<td>Yes</td>
<td>250 mg once daily, or 500 mg/dose 3 times/wk</td>
</tr>
<tr>
<td>Ethionamide</td>
<td>No</td>
<td>250–500 mg/dose daily</td>
</tr>
<tr>
<td>Para-amino salicylic acid</td>
<td>No</td>
<td>4 g/dose twice daily</td>
</tr>
<tr>
<td>Streptomycin</td>
<td>Yes</td>
<td>15 mg/kg/dose 2-3 times/wk (not daily)</td>
</tr>
<tr>
<td>Capreomycin</td>
<td>Yes</td>
<td>15 mg/kg/dose 2-3 times/wk (not daily)</td>
</tr>
<tr>
<td>Kanamycin</td>
<td>Yes</td>
<td>15 mg/kg/dose 2-3 times/wk (not daily)</td>
</tr>
<tr>
<td>Amikacin</td>
<td>Yes</td>
<td>15 mg/kg/dose 2-3 times/wk (not daily)</td>
</tr>
</tbody>
</table>

- Standard doses are given unless there is intolerance.
- The medications should be given after hemodialysis on the day of hemodialysis.
- Monitoring of serum drug concentrations should be considered to ensure adequate drug absorption, without excessive accumulation, and to assist in avoiding toxicity.
- Data currently are not available for patients receiving peritoneal dialysis. Until data become available, begin with doses recommended for patients receiving hemodialysis and verify adequacy of dosing using serum concentration monitoring.
- In patients with 30–50 mL/min creatinine clearance, standard doses are used by experts, but measurement of serum concentrations 2 and 6 hours after timed administration can be used to assist with optimizing drug dosages.

\(^a\) Including adult patients receiving hemodialysis.

\(^b\) The appropriateness of 250-mg daily doses has not been established. There should be careful monitoring for evidence of neurotoxicity.
POTENTIAL REGIMENS FOR THE MANAGEMENT OF PATIENTS WITH DRUG-RESISTANT PULMONARY TUBERCULOSIS WHEN 2003 TREATMENT GUIDELINES ARE USED

MMWR, June 20, 2003, p. 69

<table>
<thead>
<tr>
<th>Pattern of drug resistance</th>
<th>Suggested regimen</th>
<th>Duration of treatment (mo)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>INH (± SM)</td>
<td>RIF, PZA, EMB (an FQN may strengthen the regimen for patients with extensive disease)</td>
<td>6</td>
<td>In BMRC trials, 6 mo regimens have yielded ≥95% success rates despite resistance to INH if four drugs were used in the initial phase and RIF plus EMB or SM was used throughout.* Additional studies suggested that results were best if PZA was also used throughout the 6 mo (Rating BII). Fluoroquinolones were not employed in BMRC studies, but may strengthen the regimen for patients with more extensive disease (Rating BII). INH should be stopped in cases of INH resistance (see text for additional discussion).</td>
</tr>
<tr>
<td>INH and RIF (± SM)</td>
<td>FQN, PZA, EMB, IA, ± alternative agent</td>
<td>18-24</td>
<td>In such cases, extended treatment is needed to lessen the risk of relapse. In cases with extensive disease, the use of an additional agent (alternative agents) may be prudent to lessen the risk of failure and additional acquired drug resistance. Resectional surgery may be appropriate (see text).</td>
</tr>
<tr>
<td>INH, RIF (± SM), and EMB or PZA</td>
<td>FQN (EMB or PZA if active), IA, and two alternative agents</td>
<td>24</td>
<td>Use the first-line agents to which there is susceptibility. Add two or more alternative agents in case of extensive disease. Surgery should be considered (see text).</td>
</tr>
<tr>
<td>RIF</td>
<td>INH, EMB, FQN, supplemented with PZA for the first 2 months (an IA may be included for the first 2-3 months for patients with extensive disease)</td>
<td>12-16</td>
<td>Daily and three times weekly regimens of INH, PZA, and SM given for 9 mo were effective in a BMRC trial (Rating BII). However, extended use of an injectable agent may not be feasible. It is not known if EMB would be as effective as SM in these regimens. An all-oral regimen for 12-18 mo should be effective (Rating BII). But for more extensive disease and/or to shorten duration (e.g., ≤12 months), an injectable agent may be added in the initial 2 mo of therapy (Rating BII).</td>
</tr>
</tbody>
</table>

Definition of abbreviations: BMRC = British Medical Research Council; EMB = ethambutol; FQN = fluoroquinolone; IA = injectable agent; INH = isoniazid; PZA = pyrazinamide; RIF = rifampin; SM = streptomycin.

FQN = Fluoroquinolone; most experience involves ofloxacin, levofloxacin, or ciprofloxacin.

IA = Injectable agent may include aminoglycosides (streptomycin, amikacin, or kanamycin) or the polypeptide capreomycin.

Alternative agents = Ethionamide, cycloserine, p-aminosalicylic acid, clindamycin, amoxicillin-clavulanate, linezolid.


http://cid.oxfordjournals.org/content/63/7/e1.47
TB TREATMENT IN SPECIAL SITUATIONS

Treating Culture-Negative Pulmonary TB

<table>
<thead>
<tr>
<th>Preferred Regimen:</th>
<th>Initial Phase:</th>
<th>Continuation Phase:</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIF/INH/PZA/EMB</td>
<td>RIPE x 2 months</td>
<td>RIPE x 2 months</td>
</tr>
<tr>
<td>(RIPE)</td>
<td>40 (M-F) doses</td>
<td>40 (M-F) doses</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Alternate Regimen:</th>
<th>Initial Phase:</th>
<th>Continuation Phase:</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIF/INH/PZA/EMB</td>
<td>RIPE x 2 months</td>
<td>RIF and INH x 2 months</td>
</tr>
<tr>
<td>(RIPE)</td>
<td>40 (M-F) doses</td>
<td>40 (M-F) doses</td>
</tr>
</tbody>
</table>

CONSULT TB EXPERTS AT SNTC (800-4TB-INFO) about treatment recommendations for drug-resistant tuberculosis.
BOX 3. Criteria for determining when, during therapy, a patient with pulmonary tuberculosis (TB) has become noninfectious*

* Patient has negligible likelihood of multidrug-resistant TB (no known exposure to multidrug-resistant tuberculosis and no history of prior episodes of TB with poor compliant during treatment).
* Patient has received standard multidrug anti-TB therapy for 2–3 weeks. (For patients with sputum acid-fast bacilli [AFB] smear results that are negative or rarely positive, threshold for treatment is 5–7 days.)
* Patient has demonstrated complete adherence to treatment (e.g., is receiving directly observed therapy).
* Patient has demonstrated evidence of clinical improvement (e.g., reduction in the frequency of cough or reduction of the grade of the sputum AFB smear result).
* All close contacts of patients have been identified, evaluated, advised, and, if indicated, started on treatment for latent TB infection. This criterion is critical, especially for children aged <4 years and persons of any age with immunocompromising health conditions (e.g., HIV infection).
* While in hospital for any reason, patients with pulmonary TB should remain in airborne infection isolation until they 1) are receiving standard multidrug anti-TB therapy; 2) have demonstrated clinical improvement; and 3) have had three consecutive AFB-negative smear results of sputum specimens collected 8–24 hours apart, with at least one being an early morning specimen. Hospitalized patients returning to a congregate setting (e.g., a homeless shelter or detention facility) should have three consecutive AFB-negative smear results of sputum specimens collected >8 hours apart before being considered noninfectious.

Source: [http://www.cdc.gov/MMWR/PDF/mm5412.pdf](http://www.cdc.gov/MMWR/PDF/mm5412.pdf) (Box 3, p 9)

* These criteria for absence of infectivity with treatment should be considered general guidelines. Decisions about infectivity of a person on treatment for TB should depend on the extent of illness and the specific nature and circumstances of the contact between the patient and exposed persons.
MANAGEMENT OF TREATMENT INTERRUPTIONS

## II. MANAGEMENT OF TB INFECTION

### BOX 1. Risk factors for *Mycobacterium tuberculosis* infection

Persons at increased risk* for *M. tuberculosis* infection

- close contacts of persons known or suspected to have active tuberculosis;
- foreign-born persons from areas that have a high incidence of active tuberculosis (e.g., Africa, Asia, Eastern Europe, Latin America, and Russia);
- persons who visit areas with a high prevalence of active tuberculosis, especially if visits are frequent or prolonged;
- residents and employees of congregate settings whose clients are at increased risk for active tuberculosis (e.g., correctional facilities, long-term care facilities, and homeless shelters);
- health-care workers who serve clients who are at increased risk for active tuberculosis [disease];
- populations defined locally as having an increased incidence of latent *M. tuberculosis* infection or active tuberculosis, possibly including medically underserved, low-income populations, or persons who abuse drugs or alcohol; and
- infants, children, and adolescents exposed to adults who are at increased risk for latent *M. tuberculosis* infection or active tuberculosis.

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**Source**: 2016 Clinical Practice Guidelines for Diagnosis of Tuberculosis in Adults and Children. [Based on](#)

* Persons with these characteristics have an increased risk for *M. tuberculosis* infection compared with persons without these characteristics.
DIRECTLY OBSERVED PREVENTIVE THERAPY (DOPT)
FOR LATENT TB INFECTION

A major step in controlling TB in a community is to make sure that a patient who is being treated for latent TB infection (LTBI) completes a course of treatment. DOPT is the only way to ensure that these patients are adherent (connected to or associated with) to the medication. As Kentucky is experiencing a decline in the number of TB cases, it is time to put a stronger focus on treating latent TB infection.

The Kentucky TB Control Program is advocating that the LHDs provide DOPT to higher risk patients, as well as to children. Children can be the most difficult clients when it comes to taking their medication. By providing DOPT, the health department not only prevents future cases of TB, but also provides a valuable service to families.

Members of the groups below are considered high-risk individuals when it comes to being adherent (connected to or associated with) to taking their medications. If found to have latent TB infection, members of these groups must be placed on DOPT:

- Children and adolescents
- Contacts to a case with active TB disease
- Homeless individuals
- Persons who abuse substances
- Persons with a history of treatment non-adherence
- Immunocompromised patients, especially HIV-infected
### Medications to Treat Latent Tuberculosis Infection: Doses, Toxicities, and Monitoring Requirements

**MMWR, June 9, 2000, pp. 28, 29**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Oral dose (mg/kg) (maximum dose)</th>
<th>Daily Adults</th>
<th>Children</th>
<th>Twice weekly Adults</th>
<th>Children</th>
<th>Adverse reactions</th>
<th>Monitoring</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Isoniazid</strong></td>
<td>(300 mg) (600 mg)</td>
<td>5</td>
<td>10-20</td>
<td>15</td>
<td>20-40</td>
<td>Rash</td>
<td>Clinical monitoring monthly</td>
<td>Hepatitis risk increases with age and alcohol consumption</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Hepatic enzyme elevation Hepatitis Peripheral neuropathy Mid-cerebral nervous system effects Drug interactions resulting in increased thymidine (didanosine or zidovudine) levels</td>
<td>Liver function tests at baseline in selected cases; and repeat measurements if Baseline results are abnormal Patient is pregnant, in the immediate postpartum period, or at high risk for adverse reactions Patient has symptoms of adverse reactions</td>
<td></td>
</tr>
<tr>
<td><strong>Rifampin</strong></td>
<td>10</td>
<td>10-20</td>
<td>10</td>
<td>600 mg</td>
<td>600 mg</td>
<td>—</td>
<td>Rash</td>
<td>Clinical monitoring at weeks 2, 4, and 8 when pyrazinamide given Complete blood count, platelets, and liver function tests at baseline in selected cases; and repeat measurements if Baseline results are abnormal Patient has symptoms of adverse reactions</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fever Thrombocytopenia Flu-like symptoms Orange-colored body fluids (sweat, urine, tears)</td>
<td>Rifampin is contraindicated or should be used with caution in human immunodeficiency virus (HIV)-infected patients taking protease inhibitors (PIs) or nonnucleoside reverse transcriptase inhibitors (NNRTIs) Decreases levels of many drugs (e.g., methadone, coumarin derivatives, glucocorticoids, hormonal contraceptives, estrogens, oral hypoglycemic agents, digitalis, anticonvulsants, dapsone, phenytoin, and digoxin) Might permanently discolor soft contact lenses</td>
<td></td>
</tr>
<tr>
<td><strong>Rifabutin</strong></td>
<td>5</td>
<td>5</td>
<td>—</td>
<td>(300 mg)</td>
<td>(300 mg)</td>
<td>—</td>
<td>Rash</td>
<td>Clinical monitoring at weeks 2, 4, and 8 when pyrazinamide given Complete blood count, platelets, and liver function tests at baseline in selected cases; and repeat measurements if Baseline results are abnormal Patient has symptoms of adverse reactions Use adjusted daily dose of rifabutin and monitor for decreased antiretroviral activity and for rifabutin toxicity if rifabutin taken concurrently with PIs or NNRTIs§</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fever Thrombocytopenia Orange-colored body fluids (sweat, urine, tears) With increased levels of rifabutin Severe arthralgias Uveitis Leukopenia</td>
<td>Rifabutin is contraindicated for HIV-infected patients taking hard-to-get saquinavir or delavirdine; caution is also advised if rifabutin is administered with soft-gel saquinavir Reduces levels of many drugs (e.g., PIs, NNRTIs, methadone, dapsone, ketocazole, coumarin derivatives, hormonal contraceptives, digitalis, sulfonylureas, diazepam, 5-blockers, anticonvulsants, and theophylline) Might permanently discolor contact lenses</td>
<td></td>
</tr>
<tr>
<td><strong>Pyrazinamide</strong></td>
<td>15–20</td>
<td>50</td>
<td>—</td>
<td>(2.0 g)</td>
<td>(4.0 g)</td>
<td>—</td>
<td>Gastrointestinal upset Hepatitis Rash Arthralgias Gout (rare)</td>
<td>Clinical monitoring at weeks 2, 4, and 8 Liver function tests at baseline in selected cases; and repeat measurements if Baseline results are abnormal Patient has symptoms of adverse reactions</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Treat hyperuricemia only if patient has symptoms Might make glucose control more difficult in persons with diabetes Should be avoided in pregnancy but can be given after first trimester</td>
</tr>
</tbody>
</table>

*All intermittent dosing should be administered by directly observed therapy.
† AST or ALT and serum bilirubin.
‡ HIV infection, history of liver disease, alcoholism, and pregnancy.

§ If nelfinavir, indinavir, ampranavir, or ritonavir is administered with rifabutin, blood concentrations of these protease inhibitors decrease. Thus, the dose of rifabutin is reduced from 300 mg to 150 mg/day when efavirenz is administered with rifabutin, blood concentrations of rifabutin decrease. Thus, when rifabutin is used concurrently with efavirenz, the daily dose of rifabutin should be increased from 300 mg to 450 mg or 600 mg. Pharmacokinetic studies suggest that rifabutin might be given at usual doses with nevirapine. It is not currently known whether dose adjustment of rifabutin is required when used concurrently with soft-gel saquinavir. For patients receiving multiple PIs or a PI in combination with an NNRTI, drug interactions with rifabutin are likely more complex; in such situations, the use of rifabutin is not recommended until additional data are available.

QuantiFERON®-TB Gold Plus Test
A blood test for latent tuberculosis infection (LTBI) has been licensed. At this time, the Kentucky State Laboratory is not conducting the test.

QuantiFERON®-TB Gold Plus and T-SPOT. TB
These two blood assays for Mycobacterium tuberculosis (BAMT) have been licensed by the FDA. At this time, the Kentucky State Laboratory is not performing BAMT tests with either assay.

2016 Clinical Practice Guidelines for Diagnosis of Tuberculosis in Adults and Children.
## Regimen Options for Treatment of Latent TB Infection in HIV-Negative Persons

<table>
<thead>
<tr>
<th>Drug</th>
<th>Daily</th>
<th>Twice Weekly</th>
<th>Weekly &amp; Injectable</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Children</td>
<td>Adults</td>
<td>Children</td>
<td>Adults</td>
</tr>
<tr>
<td>INH</td>
<td>9 months</td>
<td>9 months</td>
<td>9 months</td>
<td>9 months</td>
</tr>
<tr>
<td></td>
<td>Duration</td>
<td>Duration</td>
<td>Duration</td>
<td>Duration</td>
</tr>
<tr>
<td>INH and Rifampicin</td>
<td>Once Weekly for 3 months</td>
<td>Once Weekly for 3 months</td>
<td>Once Weekly for 3 months</td>
<td>Once Weekly for 3 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Minimum of 180 (M-F) or 270 (M-Sun) doses administered within 12 months.
- Twice-weekly regimens should consist of at least 76 doses administered within 12 months.
- Recommended regimen for pregnant women.
- Contraindicated for persons who have active hepatitis and end-stage liver disease.

Treatment for:
- Persons 2 years or older
- Must be given by directly observed preventive therapy
- Once weekly regimen should consist of at least 12 doses administered within 4 months.
- Not recommended for persons who are:
  - Younger than 2 years old
  - Living with HIV/AIDS taking antiretroviral treatment
  - Presumed infected with INH or RIF-resistant *M. tuberculosis*, and
  - Women who are pregnant or expect to become pregnant within the 12-week regimen.

*2016 Clinical Practice Guidelines for Diagnosis of Tuberculosis in Adults and Children.*
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>RIF</td>
<td>4 months</td>
<td>4 months</td>
<td>Not recommended</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**WARNING: Fatal and Severe Liver Injuries Have Been Associated With Rifampin (RIF) and Pyrazinamide (PZA) Treatment for LTBI**

- **RIF** and **PZA**: Not recommended 2 months Not recommended 2 or 3 months

**CONSULT TB EXPERTS AT SNTC (800-4TB-INFO) BEFORE USING.**

- Contraindicated for persons who have active hepatitis and end-stage liver disease. Avoid PZA for pregnant women because of the risk of adverse effects to the fetus.
- Minimum of 60 doses to be administered within 3 months. Twice-weekly regimens should consist of at least 16 doses to be administered for 2 months or 24 doses to be administered for 3 months.
- May be used for INH-intolerant patients. This regimen has not been evaluated in HIV-negative persons.

INH – isoniazid, RIF – rifampin, RFB – rifabutin, PZA – pyrazinamide, EMB – ethambutol

* Directly observed treatment of LTBI should be used.

Centers for Disease Control and Prevention, Core Curriculum on Tuberculosis (2013)

Morbidity and Mortality, August 31, 2009, Vol. 50 / No. 34

2016 Clinical Practice Guidelines for Diagnosis of Tuberculosis in Adults and Children.
### Regimen Options for Treatment of Latent TB Infection for Persons with HIV Infection

<table>
<thead>
<tr>
<th>Drug</th>
<th>Regimens</th>
<th>Comments</th>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Daily</td>
<td>Twice Weekly</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Children</td>
<td>Adults</td>
<td>Children</td>
</tr>
<tr>
<td></td>
<td>Duration</td>
<td>Duration</td>
<td>Duration</td>
</tr>
<tr>
<td>INH</td>
<td>9 months</td>
<td>9 months</td>
<td>9 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RIF and PZA*</td>
<td>Not recommended</td>
<td>2 months</td>
<td>Not recommended</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**WARNING:** Fatal and Severe Liver Injuries Have Been Associated With Rifampin (RIF) and Pyrazinamide (PZA) Treatment for LTBI

| RFB and PZA* | Not recommended | 2 months | Not recommended | 2-3 months | Dose adjustments, alternative therapies, or other precautions might be needed when rifamycins are used (e.g., patient using hormonal contraceptives must be advised to use barrier methods, and patients using methadone require dose adjustments). PIs or NNRTIs should generally not be administered concurrently with RIF; in this situation, an alternative is the use of RFB and PZA. |

INH – isoniazid; PZA- pyrazinamide; RFB- rifabutin; RIF- rifampin; DOPT- directly observed preventive therapy; PIs – protease inhibitors; NNRTIs – nonnucleoside reverse transcriptase inhibitors; NRTIs – nucleoside reverse transcriptase inhibitors.

*For patients with intolerance to PZA, some experts recommend the use of a rifamycin (RIF or RFB) alone for preventive treatment. Most experts agree that available data support the recommendation that this treatment can be administered for a short duration as 4 months, although some experts would treat for 6 months.

**2016 Clinical Practice Guidelines for Diagnosis of Tuberculosis in Adults and Children.**
PLANNING A CONTACT INVESTIGATION

**Confirmed TB Cases:**
A contact investigation is required for all confirmed cases that have infectious forms of TB disease (e.g., TB disease of the lungs, airways, or larynx).

**Suspected TB Cases:** For suspect cases with AFB-negative sputum smears or sputum smears not performed, the contact investigation process should be started if the case has abnormal chest x-ray findings consistent with TB disease.

For suspect cases with AFB-negative sputum smear results and no pulmonary cavities, a contact investigation should only be considered for certain circumstances, such as if the suspect was identified during an outbreak or source case investigation that included vulnerable or susceptible contacts.

**Extrapulmonary TB Disease:**
Persons with extrapulmonary TB disease are usually noninfectious unless they also have pulmonary TB disease, TB disease located in the oral cavity or the larynx, or extrapulmonary disease that includes an open abscess or lesion in which the concentration of organisms is high. **Pulmonary TB should always be ruled out when there is a diagnosis of extrapulmonary disease.**

**Initiating a Contact Investigation:**
The contact investigation process should be started for persons suspected of having infectious TB disease, even before confirmation (See “Initial Assessment of Contacts” in this section). Contact Investigations of persons with acid-fast bacilli (AFB)-positive sputum smears, and cavitary TB are assigned the highest priority. However, even if these conditions are not present, contact investigations should be considered if a chest radiograph is consistent with pulmonary TB. A positive result from an approved nucleic acid amplification (NAA) test supports a decision to initiate an investigation. **Because waiting for a sputum or respiratory culture result delays initiation of contact investigations, delay should be avoided if any contacts are especially vulnerable or susceptible to TB disease.** If it is later determined that the suspect case does not have infectious TB disease, the contact investigation should be stopped.

**The Goals of a Contact Investigation:**
The goals of a contact investigation are 1) rapid identification of individuals who are high priority contacts to a known or suspected case of pulmonary, laryngeal, or pleural TB; 2) timely initiation of appropriate treatment for those persons determined to be recently infected or exposed with a significant risk for progression to disease; and 3) identification and treatment of additional individuals found to have suspected TB disease in order to prevent further spread of disease.

Consult the State TB Program if you are planning a contact investigation for more than 10 people school, college, or large company). For complete guidelines on structuring a contact investigation see the “Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis,” MMWR 2005:54 (No. RR-14).
Determining the Infectious Period for a Patient with Active TB Disease

Determining the infectious period for a case with active TB disease focuses the investigation on those contacts most likely to be at risk for infection and sets the timeframe for testing contacts. Because the start of the infectious period cannot be determined with precision by available methods, a practical estimation is necessary. Per CDC guidelines, an assigned start date, that is **3 months before** symptom onset or first positive finding consistent with active TB disease, is recommended (Table, p. 50). In certain circumstances, an even earlier start date should be used. For example, a patient (or the patient's associates) might have been aware of protracted illness (in extreme cases, >1 year). Information from the patient interview and from other sources should be assembled to assist in estimating the infectious period. Helpful details are the approximate dates that TB symptoms were noticed, mycobacteriologic results, and extent of disease (especially the presence of large lung cavities, which imply prolonged illness).

The infectious period is closed when the following criteria are satisfied: 1) effective treatment (as demonstrated by *M. tuberculosis* susceptibility results) for ≥2 weeks; 2) diminished symptoms; and 3) mycobacteriologic response (e.g., decrease in grade of sputum smear positivity detected on sputum-smear microscopy). The exposure period for individual contacts is determined by how much time they spent with the index patient during the infectious period. Multidrug-resistant TB (MDR TB) can extend infectiousness if the treatment regimen is ineffective. Any index patient with signs of extended infectiousness should be continually reassessed for recent contacts.

Criteria that are more stringent should be applied for setting the end of the infectious period if particularly susceptible contacts are involved. A patient returning to a congregate living setting or to any setting in which susceptible persons might be exposed should have at least three consecutive negative sputum AFB smear results from sputum collected ≥8 hours apart (with one specimen collected during the early morning) before being considered noninfectious.

*MMWR Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis, Recommendations from the National Tuberculosis Controllers Association and CDC, December 16, 2005, Vol. 54, No. RR-15, p 12.*
Initial Assessment of Contacts

During the initial contact encounter, which should be accomplished within 3 working days of the contact having been listed in the investigation, the investigator gathers background health information and makes a face-to-face assessment of the person's health. Performing a TB Risk Assessment and administering a TST or drawing blood for a BAMT at this time accelerates the diagnostic evaluation.

The health department record should include:

- Previous *M. tuberculosis* infection or active TB disease and related treatment;
- Contact's verbal report and documentation of previous TST or BAMT results;
- Current symptoms of active TB disease (e.g., cough, chest pain, hemoptysis, fever, chills, night sweats, appetite loss, weight loss, malaise, or easy fatigability);
- Medical conditions or risk factors making active TB disease more likely
  - HIV infection
  - Infants and children aged less than five years;
  - Persons who are receiving immunosuppressive therapy such as tumor necrosis factor--alpha (TNF-α) antagonists, systemic corticosteroids equivalent to ≥15 mg of prednisone per day, or immune suppressive drug therapy following organ transplantation;
  - Persons recently infected with *Mycobacterium tuberculosis* (within the past two (2) years;
  - Persons with a history of inadequately treated active TB disease;
  - Persons with silicosis, diabetes mellitus, chronic renal failure, leukemia, lymphoma, cancer of the head, neck, or lung;
  - Persons who have had a gastrectomy, or jejunoileal bypass;
  - Persons with low body weight (BMI < 19);
  - Cigarette smokers and persons who abuse drugs or alcohol.
- Mental health disorders (e.g., psychiatric illnesses and substance abuse disorders)
- Type, duration, and intensity of TB exposure; and
- Sociodemographic factors (e.g., age, race or ethnicity, residence, and country of birth) (see Data Management and Evaluation of Contact Investigations).
Prioritization of Contacts Exposed to Persons with Acid-Fast Bacilli (AFB) Sputum Smear-Positive or Cavitary Tuberculosis (TB) Cases

Patient has pulmonary or pleural TB with cavitary lesion on chest radiograph or is AFB sputum smear positive

High-priority contact

Household contact

Yes

No

Contact aged ≥65 yrs

Yes

Contact with medical risk factor

No

Contact with exposure during medical procedure

Yes

Contact with exposure in congregate setting

No

Aged 5–15 yrs

Yes

Exposure exceeds duration/environment limits

No

Medium priority contact

Exposure exceeds duration/environment limits

Yes

Low-priority contact

Medium priority contact

Yes

Exposure exceeds duration/environment limits

No

Low-priority contact

*Human immunodeficiency virus or other medical risk factor.

bronchoscopy, sputum induction, or autopsy.

Exposure exceeds duration/environment limits per unit time established by the health department for high-priority contacts.

Exposure exceeds duration/environment limits per unit time established by the health department for medium-priority contacts.
Window-Period Prophylaxis

Primary prophylaxis of high-risk contacts:

Tuberculin skin test results might take 2-10 weeks to become positive after infection with *M. tuberculosis*. Thus, a contact's initial TST or BAMT result might be negative even if the person is infected. A second TST or BAMT should be performed 8-10 weeks after the contact's last exposure to the infectious patient, so the possibility of LTBI for those persons can be better evaluated. During the 8-10 week window period between a first and second skin test or BAMT, the following contacts with initially negative tuberculin skin test results or negative BAMT results should receive treatment for LTBI after active TB disease has been ruled out by clinical examination and chest radiograph:

- Contacts aged <5 years (with highest priority given to those aged <3 years) and
- Contacts with HIV infection or who are otherwise immunocompromised.

If the second TST result is negative (i.e. <5 mm) or the second BAMT is negative, the contact is immunocompetent (including immunocompetent young children) and no longer exposed to an infectious TB case, treatment for LTBI during the window period may be discontinued, and further follow-up is unnecessary.

If the second TST or BAMT result is negative but the contact is immunocompromised (e.g., with HIV infection), and an evaluation for active TB disease is negative, a full course of treatment for LTBI still should be completed.

If the second TST or BAMT result is negative but the person remains in close contact with an infectious TB case, treatment for LTBI should be continued if the contact is:

- Aged <5 years;
- Aged 5 through 15 years, at the clinician's discretion; or
- HIV-infected or otherwise immunocompromised.

The decision to treat individual contacts that have negative skin tests or negative BAMTs should take into consideration two factors:

- The frequency, duration, and intensity of exposure (even brief exposure to a highly infectious TB patient in a confined space probably warrants the same concern as extended exposure to less infectious TB cases); and
- Corroborative evidence of transmission from the index patient (e.g. a substantial fraction of contacts having TST or BAMT results classified as “positive” implies infectiousness).

*MMWR Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis, Recommendations from the National Tuberculosis Controllers Association and CDC, December 16, 2005, Vol. 54, No. RR-15, p 15.*
Evaluation, Treatment, and Follow-Up of Tuberculosis (TB) Contacts Aged < 5 Years

Evaluate with medical history, physical examination, chest radiograph and TST*.

Does the contact have symptoms consistent with TB disease?
   Yes → Fully evaluate for TB disease
   No → Is the chest radiograph abnormal?
      Yes → Complete full treatment course for LTBI
      No → Is the TST reaction ≥ 5 mm?
         Yes → Stop; no further evaluation or treatment required
         No → Have ≥ 12 weeks passed since last exposure?
            Yes → Begin treatment for LTBI; repeat TST 6–10 weeks post exposure
            No → Is TST reaction ≥ 5 mm?
               Yes → Complete full treatment course for LTBI
               No →

* Tuberculin skin test.
† Latent TB infection.

Evaluation, Treatment, and Follow-Up of Immunocompromised Contacts

Evaluation, Treatment, and Follow-Up of Contacts with a Documented Previously Positive Tuberculin Skin Test

Time Frames for Initial Follow-up of Contacts of Persons Exposed to Tuberculosis (TB)

<table>
<thead>
<tr>
<th>Type of contact</th>
<th>Business days from listing of a contact to initial encounter</th>
<th>Business days from initial encounter to completion of medical evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-priority contact: index case AFB$ sputum smear positive or cavitary disease on chest radiograph (see Figure 2)</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>High-priority contact: index case AFB sputum smear negative (see Figure 3)</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Medium-priority contact: regardless of AFB sputum smear or culture result (see Figures 2–4)</td>
<td>14</td>
<td>10</td>
</tr>
</tbody>
</table>


* A face-to-face meeting that allows the public-health worker to assess the overall health of the contact, administer a tuberculin skin test, and schedule further evaluation.

† The medical evaluation is complete when the contact's status with respect to *Mycobacterium tuberculosis* infection or TB disease has been determined. A normal exception to this schedule is the delay in waiting for final mycobacteriologic results, but this applies to relatively few contacts.

\$ Acid-fast bacilli.

* *MMWR Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis, Recommendations from the National Tuberculosis Controllers Association and CDC, December 16, 2005, Vol. 54, No. RR-15, p 9.*
## Guidelines for Estimating the Beginning of the Period of Infectiousness of Persons with Tuberculosis (TB), by Index Case Characteristic

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>AFB* sputum smear positive</th>
<th>Cavitary chest radiograph</th>
<th>Recommended minimum beginning of likely period of infectiousness</th>
</tr>
</thead>
<tbody>
<tr>
<td>TB symptoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>3 months before symptom onset or first positive finding (e.g., abnormal chest radiograph) consistent with TB disease, whichever is longer</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>3 months before symptom onset or first positive finding consistent with TB disease, whichever is longer</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>No</td>
<td>4 weeks before date of suspected diagnosis</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>3 months before first positive finding consistent with TB</td>
</tr>
</tbody>
</table>

**SOURCE:** California Department of Health Services Tuberculosis Control Branch; California Tuberculosis Controllers Association. Contact investigation guidelines. Berkeley, CA: California Department of Health Services; 1998.

*Acid-fast bacilli.*

*MMWR Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis, Recommendations from the National Tuberculosis Controllers Association and CDC, December 16, 2005, Vol. 54, No. RR-15, p 7.*
REFERENCES


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4. 2016 Clinical Practice Guidelines for Diagnosis of Tuberculosis in Adults and Children.

5. Tuberculosis Laws as found in the Kentucky Revised Statues, Chapter 215.511 – 600, http://chfs.ky.gov/dph/epi/tb

6. Tuberculosis Regulations: 902 KAR 2:020 – 090 (Surveillance, Control, Detection, Prevention); 902 KAR 20:016 – 200 (Hospital and Long-Term Care)

7. CDC. Treatment of Tuberculosis. MMWR 2003;52(No. RR-11)

8. CDC. Recommendations and Reports, Guidelines for Investigation of Contacts of Persons with Infectious TB. MMWR 2005; 54(No. RR-15)


12. NIOSH Website at: http://www.cdc.gov/niosh

13. CDC. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings 2005. MMWR 2005;54(No. RR-17)

14. CDC. Controlling Tuberculosis in the United States. MMWR 2005;54(No. RR-12)


15. HIPAA Privacy Rule and Public Health, MMWR, April 11, 2003 / 52;1-12


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**CDC TB Guidelines published in MMWR are available online,**

**World Health Organization Global TB Database Estimated Incidence**

This information is listed in the forms and teaching sheets listing of the CSG at http://chfs.ky.gov/dph/Local+Health+Department.htm.
Guidelines & Recommendation’s for Using Blood Assays
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Guidelines & Recommendations for Using Blood Assays .................................................................
  Recommendations for Use of IGRAs ..........................................................................................
  QuantiFERON-TB Gold Plus (QFT-Plus) .............................................................................
  T-SPOT.TB Test (T-SPOT) .................................................................................................
GUIDELINES AND RECOMMENDATIONS FOR USING BLOOD ASSAYS FOR *Mycobacterium tuberculosis* (BAMTs)

Before 2001, the tuberculin skin test (TST) was the only practical and commercially available immunologic test for *Mycobacterium tuberculosis* infection approved in the United States. Blood assay for M. tuberculosis (BAMT) is a general term to refer to recently developed in vitro diagnostic tests that assess for the presence of infection with *M. tuberculosis*. This term includes, but is not limited to, interferon-gamma (IFN-γ) release assays (IGRAs).

Since 2001, several IGRAs have been approved by FDA. In the United States, the currently available tests are the QuantiFERON®-TB Plus test (QFT-Plus) and the T-SPOT.TB test T). The following recommendations are from updated guidelines for using IGRAs in the June 25, 2010 MMWR: (Note that CDC guidelines describe the use of IGRAs instead of the more inclusive BAMT.)

**KEY POINTS FOR USING BAMTs**

- A BAMT may be used in place of (but not in addition to) a TST in all situations in which CDC recommends tuberculin skin testing as an aid in diagnosing *M. tuberculosis* infection.
- A BAMT is preferred for testing persons from groups that historically have low rates of returning to have TSTs read. For example, use of a BAMT might increase test completion rates for homeless persons and drug-users.
- A BAMT is preferred for testing persons who have received BCG (as a vaccine or for cancer therapy).
- A TST is preferred for testing children aged less than 5 years.
- Two-step testing is not required for BAMTS, because IGRA testing does not boost subsequent test results.
- Neither a BAMT nor TST can distinguish LTBI from active tuberculosis.
- As with TSTs, a negative BAMT result does not exclude LTBI or active TB disease.
Recommendations for Use of IGRAs

General Recommendations for Use of IGRAs

- TSTs and IGRAs (QFT-Plus, and T-SPOT) should be used as aids in diagnosing infection with *M. tuberculosis*. These tests may be used for surveillance purposes or to identify persons likely to benefit from treatment, including persons who are or will be at increased risk for *M. tuberculosis* infection (Box 1, below) or for progression to active tuberculosis if infected (Box 2, below).
- IGRAs should be performed and interpreted according to established protocols using FDA-approved test formats. They should be performed in compliance with Clinical Laboratory Improvement Amendment (CLIA) standards.
- Both the standard qualitative test interpretation and the quantitative assay measurements should be reported together with the criteria used for test interpretation. This will permit more refined assessment of results and promote understanding of the tests.
- Arrangement for IGRA testing should be made prior to blood collection to ensure that the blood specimen is collected in the proper tubes, and that testing can be performed within the required timeframe.
- Prior to implementing IGRAs, each institution and tuberculosis-control program should evaluate the availability, overall cost, and benefits of IGRAs for their own setting. In addition, programs should consider the characteristics of the population to be tested.
- As with the TST, IGRAs generally should not be used for testing persons who have a low risk for both infection and progression to active tuberculosis if infected (except for those likely to be at increased risk in the future). Screening such persons diverts resources from higher priority activities and increases the number of false-positive results. Even with a test specificity approaching 99%, when the prevalence of *M. tuberculosis* infection is ≤1%, the majority of positive results will be false positives. If persons at low risk for both infection and progression are to be tested, selection of the test with the greatest specificity will minimize false-positive results, reduce unnecessary evaluation and treatment, and minimize the potential for adverse events from unnecessary treatment.

Test Selection

- Selection of the most suitable test or combination of tests for detection of *M. tuberculosis* infection should be made on the basis of the reasons and the context for testing, test availability, and overall cost effectiveness of testing. Results of studies examining sensitivity, specificity, and agreement for IGRAs and TST vary with respect to which test is better. Although data on the accuracy of IGRAs and their ability to predict subsequent active tuberculosis are limited, to date, no major deficiencies have been reported in studies involving various populations. As use of these tests increases, greater understanding of their value and limitations will be gained.
- An IGRA may be used in place of (but not in addition to) a TST in all situations in which CDC recommends tuberculin skin testing as an aid in diagnosing *M. tuberculosis* infection, with preferences and special considerations noted below. Despite the indication of a preference in these instances, use of the alternative test (FDA-approved IGRA or TST) is acceptable medical and public health practice.

Situations in Which an IGRA Is Preferred But a TST Is Acceptable

- An IGRA is preferred for testing persons from groups that historically have low rates of returning to have TSTs read. For example, use of an IGRA might increase test completion rates for homeless
persons and drug-users. The use of IGRA for such persons can increase test completion rates, so control efforts can focus on those most likely to benefit from further evaluation and treatment.

- An IGRA is preferred for testing persons who have received BCG (as a vaccine or for cancer therapy). Use of IGRA in this population is expected to increase diagnostic specificity and improve acceptance of treatment for LTBI.

**Situations in Which a TST Is Preferred But an IGRA Is Acceptable**

- A TST is preferred for testing children aged <5 years. Use of an IGRA in conjunction with TST has been advocated by some experts to increase diagnostic sensitivity in this age group. Recommendations regarding use of IGRA in children have also been published by the American Academy of Pediatrics.

**Situations in Which Either a TST or an IGRA May Be Used Without Preference**

- An IGRA or a TST may be used without preference to test recent contacts of persons known or suspected to have active tuberculosis with special considerations for follow-up testing. IGRA offer the possibility of detecting *M. tuberculosis* infection with greater specificity than with a TST. Also, unlike TSTs, IGRA do not boost subsequent test results and can be completed following a single patient visit. However, data on the ability of IGRA to predict subsequent active tuberculosis are limited. If IGRA are to be used in contact investigations, negative results obtained prior to 8 weeks after the end of exposure typically should be confirmed by repeat testing 8--10 weeks after the end of exposure. This recommendation is similar to one used for TST, because data on the timing of IGRA conversion after a new infection are not currently available. Use of the same test format for repeat testing will minimize the number of conversions that occur as a result of test differences.

- An IGRA or a TST may be used without preference for periodic screening of persons who might have occupational exposure to *M. tuberculosis* (e.g., surveillance programs for health-care workers) with special considerations regarding conversions and reversions. For serial and periodic screening, IGRA offer technical, logistic, and possible economic advantages compared with TST but also have potential disadvantages. Advantages include the ability to get results following a single visit. Two-step testing is not required for IGRA, because IGRA testing does not boost subsequent test results. Disadvantages of IGRA in this setting include a greater risk of test conversion due to false-positive IGRA results with follow-up testing of low-risk health-care workers who have tested negative at prior screening. CDC has published criteria for identifying conversions for TSTs and IGRA. TST conversion is defined as a change from negative to positive with an increase of ≥10 mm in induration within 2 years. TST conversion is associated with an increased risk for active tuberculosis. An IGRA conversion is defined as a change from negative to positive within 2 years without any consideration of the magnitude of the change in TB Response. Using this lenient criterion to define IGRA conversion might produce more conversions than are observed with the more stringent criteria applied to TSTs. Furthermore, an association between an IGRA conversion and subsequent disease risk has not been demonstrated. The criteria for interpreting changes in an IGRA that identify new infections remain uncertain. CDC encourages institutions and programs in which IGRA are used to publish their experiences, particularly in regard to rates of conversion, reversion, and progression to active tuberculosis over time.
Situations in Which Testing with Both an IGRA and a TST May Be Considered

- Although routine testing with both a TST and an IGRA is not generally recommended, results from both tests might be useful when the initial test (TST or IGRA) is negative in the following situations: 1) when the risk for infection, the risk for progression, and the risk for a poor outcome are increased (e.g., when persons with HIV infection or children aged <5 years are at increased risk for *M. tuberculosis* infection) or 2) when clinical suspicion exists for active tuberculosis (such as in persons with symptoms, signs, and/or radiographic evidence suggestive of active tuberculosis) and confirmation of *M. tuberculosis* infection is desired. In such patients with an initial test that is negative, taking a positive result from a second test as evidence of infection increases detection sensitivity. However, multiple negative results from any combination of these tests cannot exclude *M. tuberculosis* infection.

- Using both a TST and an IGRA also might be useful when the initial test is positive in the following situations: 1) when additional evidence of infection is required to encourage compliance (e.g., in foreign-born health-care workers who believe their positive TST result is attributable to BCG) or 2) in healthy persons who have a low risk for both infection and progression. In the first situation, a positive IGRA might prompt greater acceptance of treatment for LTBI as compared with a positive TST alone. In the latter situation, requiring a positive result from the second test as evidence of infection increases the likelihood that the test result reflects infection. For the second situation, an alternative is to assume, without additional testing, that the initial result is a false positive or that the risk for disease does not warrant additional evaluation or treatment, regardless of test results. Steps should be taken to minimize unnecessary and misleading testing of persons at low risk.

- Repeating an IGRA or performing a TST might be useful when the initial IGRA result is indeterminate, borderline, or invalid and a reason for testing persists. A second test also might be useful when assay measurements from the initial test are unusual, such as when the Nil value is higher than typical for the population being tested (e.g., IFN-γ concentration for Nil by QFT-G or QFT-GIT >0.7 IU/mL for most of the U.S. populations), the Nil value is appreciably greater than the value obtained with *M. tuberculosis* antigen stimulation (e.g. when IFN-γ concentration for Nil by QFT-G is 0.35 IU/mL greater than the concentration obtained with either ESAT-6 or CFP-10 stimulation, or when the number of spots for Nil by T-SPOT is four spots greater than the number with either ESAT-6 or CFP-10 stimulation), or the Mitogen value is lower than is expected for the population being tested (e.g., the Mitogen Response by QFT-G or QFT-GIT is <0.5 IU/mL, or the number of spots in the mitogen well by T-SPOT is <20). If an IGRA is to be repeated, a new blood sample should be used. In such situations, repeat testing with another blood sample usually provides interpretable results.
Medical Management After Testing

- Diagnoses of *M. tuberculosis* infection and decisions about medical or public health management should not be based on IGRA or TST results alone, but should include consideration of epidemiologic and medical history as well as other clinical information.

- Persons with a positive TST or IGRA result should be evaluated for the likelihood of *M. tuberculosis* infection, for risks for progression to active tuberculosis if infected, and for symptoms and signs of active tuberculosis. If risks, symptoms, or signs are present, additional evaluation is indicated to determine if the person has LTBI or active tuberculosis.

- A diagnosis of LTBI requires that active tuberculosis be excluded by medical evaluation, which should include taking a medical history and a physical examination to check for suggestive symptoms and signs, a chest radiograph, and, when indicated, testing of sputum or other clinical samples for the presence of *M. tuberculosis*. Neither an IGRA nor TST can distinguish LTBI from active tuberculosis.

- In persons who have symptoms, signs, or radiographic evidence of active tuberculosis or who are at increased risk for progression to active tuberculosis if infected, a positive result with either an IGRA or TST should be taken as evidence of *M. tuberculosis* infection. However, negative IGRA or TST results are not sufficient to exclude infection in these persons, especially in those at increased risk for a poor outcome if disease develops, and clinical judgment dictates when and if further diagnostic evaluation and treatment are indicated.

- In healthy persons who have a low likelihood both of *M. tuberculosis* infection and of progression to active tuberculosis if infected, a single positive IGRA or TST result should not be taken as reliable evidence of *M. tuberculosis* infection. Because of the low probability of infection, a false-positive result is more likely. In such situations, the likelihood of *M. tuberculosis* infection and of disease progression should be reassessed, and the initial test results should be confirmed. Repeat testing, with either the initial test or a different test, may be considered on a case-by-case basis. For such persons, an alternative is to assume, without additional testing, that the initial result is a false positive.

- In persons with discordant test results (i.e., one positive and the other negative), decisions about medical or public health management require individualized judgment in assessing the quality and magnitude of each test result (e.g., size of induration and presence of blistering for a TST; and the TB Response, Nil, and Mitogen values for an IGRA), the probability of infection, the risk for disease if infected, and the risk for a poor outcome if disease occurs.

- Taking a positive result from either of two tests as evidence of infection is reasonable when 1) clinical suspicion exists for active tuberculosis (e.g., in persons with symptoms, signs, and/or radiographic evidence of active tuberculosis) or 2) the risks for infection, progression, and a poor outcome are increased (e.g., when persons with HIV infection or children aged <5 years are at increased risk for *M. tuberculosis* infection).

- For healthy persons who have a low risk for both infection and progression, discounting an isolated positive result as a false positive is reasonable. This will increase detection specificity and decrease unnecessary treatment.

- For persons who have received BCG and who are not at increased risk for a poor outcome if infected (Box 2, below), TST reactions of <15 mm in size may reasonably be discounted as false positives when an IGRA is clearly negative.

- In other situations, inadequate evidence exists on which to base recommendations for dealing with discordant results. However, in the absence of convincing evidence of infection, diagnostic decisions may reasonably be deferred unless an increased risk exists for progression if infected and/or a high risk exists for a poor outcome if disease develops.”
Table 1. Interpretation of QFT-Plus test results

<table>
<thead>
<tr>
<th>Nil (IU/ml)</th>
<th>TB1 minus Nil (IU/ml)</th>
<th>TB2 minus Nil (IU/ml)</th>
<th>Mitogen minus Nil (IU/ml)*</th>
<th>QFT-Plus Result</th>
<th>Report/interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤8.0</td>
<td>≥0.35 and ≥25% of Nil</td>
<td>Any</td>
<td>Any</td>
<td>Positive†</td>
<td>M. tuberculosis infection likely</td>
</tr>
<tr>
<td></td>
<td>Any</td>
<td>≥0.35 and ≥25% of Nil</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;0.35 or ≥0.35 and &lt;25% of Nil</td>
<td>&lt;0.35 or ≥0.35 and &lt;25% of Nil</td>
<td>≥0.50</td>
<td>Negative</td>
<td>M. tuberculosis Infection NOT likely</td>
</tr>
<tr>
<td></td>
<td>&lt;0.35 or ≥0.35 and &lt;25% of Nil</td>
<td>&lt;0.35 or ≥0.35 and &lt;25% of Nil</td>
<td>&lt;0.50</td>
<td>Indeterminate‡</td>
<td>Likelihood of M. tuberculosis Infection cannot be determined</td>
</tr>
<tr>
<td>&gt;8.0†</td>
<td>Any</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Responses to the Mitogen positive control (and occasionally TB Antigen) can be outside the range of the microplate reader. This has no impact on test results. Values >10 IU/ml are reported by the QFT-Plus software as >10 IU/ml.
† Where M. tuberculosis infection is not suspected, initially positive results can be confirmed by retesting the original plasma samples in duplicate in the QFT-Plus ELISA. If repeat testing of one or both replicates is positive, the test result is considered positive.
‡ Refer to “Troubleshooting Guide”, page 58 for possible causes.
§ In clinical studies, less than 0.25% of subjects had IFN-γ levels of >8.0 IU/ml for the Nil value.
TABLE 2. Interpretation criteria for the T-SPOT.TB Test (T-SPOT)

<table>
<thead>
<tr>
<th>Interpretation</th>
<th>Nil*</th>
<th>TB Response†</th>
<th>Mitogen§</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive¶</td>
<td>≤10 spots</td>
<td>≥8 spots</td>
<td>Any</td>
</tr>
<tr>
<td>Borderline**</td>
<td>≤10 spots</td>
<td>5, 6, or 7 spots</td>
<td>Any</td>
</tr>
<tr>
<td>Negative††</td>
<td>≤10 spots</td>
<td>≤4 spots</td>
<td></td>
</tr>
<tr>
<td>Indeterminate**</td>
<td>&gt;10 spots</td>
<td>Any</td>
<td>Any</td>
</tr>
<tr>
<td></td>
<td>≤10 spots</td>
<td>&lt;5 spots</td>
<td>&lt;20 spots</td>
</tr>
</tbody>
</table>


* The number of spots resulting from incubation of PBMCs in culture media without antigens.
† The greater number of spots resulting from stimulation of peripheral blood mononuclear cells (PBMCs) with two separate cocktails of peptides representing early secretory antigenic target-6 (ESAT-6) or culture filtrate protein-10 (CFP-10) minus Nil.
§ The number of spots resulting from stimulation of PBMCs with mitogen without adjustment for the number of spots resulting from incubation of PBMCs without antigens.
¶ Interpretation indicating that *Mycobacterium tuberculosis* infection is likely.
** Interpretation indicating an uncertain likelihood of *M. tuberculosis* infection.
†† Interpretation indicating that *M. tuberculosis* infection is not likely.

References:

CDC. Recommendations and Reports. Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection. MMWR 2010; 59(No. RR-5)
TB Evaluation of Immigrants & Refugees

Table of Contents

CASE MANAGEMENT

Procedure for LHD TB Staff

TB Follow-up Recommendations for Arrivals with a TB Class Condition

Instructions for Completing the TB Class Follow-up Worksheet

World Health Organization Global TB Database Estimated Incidence
Evaluation of Immigrants and Refugees for Tuberculosis

The Local Health Department Tuberculosis (TB) Coordinator or TB Nurse will assure that an immigrant and/or a refugee referred to the Kentucky TB Prevention and Control Program (KY TB Program) by the Centers for Disease Control and the U.S. Department of State (DOS) receives an evaluation for active TB disease. This process of completing the evaluation of an immigrant or a refugee is collaborative with roles for the Centers for Disease Control and Prevention Electronic Disease Notification (EDN) system, the KY TB Program, and the LDH TB staff.

PROCEDURE FOR LHD TB STAFF:

1. The LHD TB Coordinator or TB nurse must contact the immigrant or refugee designated as B1 or B2 within three working days of receiving the DOS documents (DS-2053: Medical Examination for Immigrant or Refugee Applicant; DS-3024: Chest X-ray and Classification Worksheet; DS-3025: Vaccination Documentation Worksheet; and DS-3026: Medical History and Physical Examination Worksheet) forwarded by the KY TB Program.

2. Follow the instructions on the TB Class Follow-up Worksheet.

3. A medical evaluation must be initiated within 30 days of the notification date for immigrants and refugees with abnormal chest x-rays overseas that were consistent with TB.

4. A complete medical evaluation must be completed within 90 days of the notification date for immigrants and refugees with abnormal chest x-rays read overseas that were consistent with TB.

5. All immigrants and refugees with abnormal chest x-rays read overseas consistent with TB and diagnosed with latent TB infection (LTBI) should be evaluated as per Section C, diagnosed as per Section D, and treated as per Section E on the TB Follow-up Worksheet (see below).

6. All immigrants and refugees with abnormal chest x-rays read overseas consistent with TB, diagnosed with LTBI and started on treatment should complete LTBI treatment.

7. All refugees from high-prevalence countries (see Appendix) must be evaluated for tuberculosis with the work-up described below.

8. The LHD TB Coordinator or TB nurse must notify the KY TB Program if an immigrant and/or a refugee cannot be located within 14 working days of receipt of the DOS documents.
PROCEDURE:

KY TB Program staff will:

1. Review the medical and contact information contained within the DOS documents to determine the immigrant or refugee’s demographics and TB classification.
2. Notify the LHD by phone or fax of immigrant or refugee’s notification.
3. Complete the demographic information in the CDC Electronic Disease Notification System and attach it to the DOS documents.

LHD TB Coordinator or TB nurse will:

1. Contact the refugee or immigrant, if they have been designated as TB Class B1 or B2, within 3 days of receiving the forwarded DOS documents and request that the individual immediately contact the county health department to schedule an appointment for evaluation. This can be accomplished by the following methods:
   a. Step 1 – Make a telephone call within 24 hours of receipt of documents.
   b. Step 2 – Send a letter within 7 working days if no response to phone call.
   c. Step 3 – Make a home visit within 10 working days if no response to call or letter.
2. Conduct an assessment work-up:
   a. Assess for signs and symptoms of TB using the TB Risk Assessment.
   b. Repeat tuberculin skin test (TST) and/or administer a tuberculin skin test (TST) or perform a blood assay for *Mycobacterium tuberculosis* (BAMT).
   c. Obtain a chest x-ray (CXR) or repeat the CXR if the previous CXR was obtained outside of the United States.
3. Assure that a diagnostic work-up is completed by the TB Medical Clinician to determine if treatment for LTBI or active TB disease is indicated.
4. Forward all completed TB Follow-up Worksheets to the KY TB Program within 90 days.
<table>
<thead>
<tr>
<th>Arrival's Class Status</th>
<th>TB Follow-up Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TB Class A – active TB disease</strong></td>
<td>□ Consider this patient to have active TB disease (suspected or confirmed).</td>
</tr>
<tr>
<td></td>
<td>□ Review overseas medical exam and treatment documentation.</td>
</tr>
<tr>
<td></td>
<td>□ Assess the patient clinically and do additional diagnostic testing, such as repeat chest x-ray (CXR), sputum collection, and other tests, if indicated.</td>
</tr>
<tr>
<td></td>
<td>□ Provide HIV counseling, testing, and referral. If HIV test is refused, reoffer HIV testing monthly while on treatment for active TB disease</td>
</tr>
<tr>
<td></td>
<td>□ Continue or revise treatment regimen, as indicated.</td>
</tr>
<tr>
<td></td>
<td>□ Report a case of active TB disease to the Kentucky TB Program by calling 502-564-4276 within one business day.</td>
</tr>
<tr>
<td></td>
<td>□ Directly observed therapy (DOT) is the standard of practice for treating persons with active TB.</td>
</tr>
<tr>
<td><strong>TB Class B1 –</strong></td>
<td>□ Evaluate for signs and symptoms of TB disease that may have developed since their overseas exam.</td>
</tr>
<tr>
<td></td>
<td>□ Administer a tuberculin skin test (TST) or blood assay for <em>Mycobacterium tuberculosis</em> (BAMT) such as a QuantIFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.TB regardless of BCG history, unless the patient has reliable documentation of a previous positive TST or positive BAMT test done in the United States.</td>
</tr>
<tr>
<td></td>
<td>□ Obtain a chest x-ray (CXR) regardless of TST/BAMT result. Repeat the CXR if done previously outside the United States.</td>
</tr>
<tr>
<td></td>
<td>□ Do additional tests (e.g., sputa for AFB, etc.), as indicated, to determine TB diagnosis (i.e., latent TB infection [LTBI] or active TB disease).</td>
</tr>
<tr>
<td></td>
<td>□ Provide HIV counseling, testing, and referral. If HIV test is refused, reoffer HIV testing monthly while on treatment for active TB disease or while on treatment for LTBI</td>
</tr>
<tr>
<td>Arrival's Class Status</td>
<td>TB Follow-up Recommendations</td>
</tr>
<tr>
<td>------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td><strong>TB Class B2 – LTBI</strong></td>
<td>Consider this patient to have latent TB infection (LTBI). Evaluate for signs and symptoms of active TB disease that may have developed since their overseas exam.</td>
</tr>
<tr>
<td>• (TST ≥ 10 mm induration)</td>
<td>Repeat TST or BAMT to confirm or rule-out an overseas diagnosis of LTBI.</td>
</tr>
<tr>
<td></td>
<td>Obtain a chest x-ray (CXR) unless the patient had repeated CXRs overseas showing improvement or stability and the most recent CXR was less than 3 months ago and was done in the United States. If HIV infected, repeat CXR regardless of overseas CXR results.</td>
</tr>
<tr>
<td></td>
<td>Obtain a CXR for those who have signs or symptoms compatible with TB disease, regardless of previous results.</td>
</tr>
<tr>
<td></td>
<td>Provide HIV counseling, testing, and referral. If HIV test is refused, reoffer HIV testing monthly while on LTBI treatment.</td>
</tr>
<tr>
<td></td>
<td>It is a standard of practice in the United States to offer treatment for LTBI. A stateside medical evaluation must be done before initiating LTBI treatment. LTBI treatment for this class should preferably be done by Directly Observed Preventive Therapy (DOPT).</td>
</tr>
</tbody>
</table>

| **TB Class B3 – TB Contact** | This person is a contact overseas to a confirmed case of active TB. Evaluate for signs and symptoms of active TB disease that may have developed since their overseas exam. |
| • Contact overseas to a confirmed case of TB | Administer a TST or BAMT, regardless of BCG history. |
| | Obtain a chest x-ray (CXR) for individuals with a positive TST or positive BAMT, and anyone with symptoms compatible with TB disease, regardless of the TST or BAMT result. |
| | If more information is needed about the source case, call the Kentucky TB Program Refugee and Immigrant Coordinator, Tammy Hall, at 502-564-4276. |
## TB Follow-up Recommendations for Arrivals with a TB Class Condition – October 2010

<table>
<thead>
<tr>
<th>Arrival’s Class Status</th>
<th>TB Follow-up Recommendations</th>
</tr>
</thead>
</table>

### NOTE:
- Pregnancy is not a medical contraindication for administration of a TST, for treatment of LTBI, or for treatment of active TB disease.
- A BAMT may be used in place of (but not in addition to) a TST in all situations in which CDC recommends tuberculin skin testing as an aid in diagnosing *M. tuberculosis* infection.
- A BAMT is preferred for testing persons who have received BCG (as a vaccine or for cancer therapy).
- A TST is preferred for testing children aged less than 5 years.
- A TST administered prior to 6 months of age may yield a false negative result.
- Complete the TB Class Follow-up Worksheet for ALL TB Class B1 arrivals, and Immigrant arrivals with TB Class B2 and Class B3.

Return form by mail or fax to:  **Tammy Hall, Administrative Specialist II**  
Kentucky Department for Public Health  
TB Prevention and Control Program  
275 East Main Street  
Frankfort, KY 40621  
Fax# 502-564-3772  
Phone# 502-564-4276
### Instructions for Completing the TB Class Follow-up Worksheet – October 2010

The TB Follow-up Worksheet is used to document the initial evaluation of an arrival with a TB Class Condition.

A complete evaluation requires a diagnosis and, when indicated, a treatment start date.

<table>
<thead>
<tr>
<th>Sections A &amp; B</th>
<th>Demographic &amp; Jurisdictional</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Pre-populated</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section C</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Evaluation</td>
</tr>
<tr>
<td>• Record date of the initial evaluation.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>TST and/or BAMT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Administer a tuberculin skin test (TST) or draw blood for BAMT.</td>
<td></td>
</tr>
<tr>
<td>• Record the TST date, mm induration (not redness), and interpretation.</td>
<td></td>
</tr>
<tr>
<td>• For persons with TB Class B1 Conditions or TB-related abnormalities on CXR, a TST reading of &gt;5 mm is considered positive.</td>
<td></td>
</tr>
<tr>
<td>• Record date and results of BAMT, if used. BAMTs (i.e., IGRAs) are not widely available in KY.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Review of Overseas CXR</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Arrivals should bring their overseas CXR film(s) with them to their exam. Record your (or your radiologist’s) interpretation of the overseas CXR.</td>
<td></td>
</tr>
<tr>
<td><strong>NOTE:</strong> Call Tammy Hall in the KY TB Program if overseas CXR is not available.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Domestic CXR</th>
</tr>
</thead>
<tbody>
<tr>
<td>• For Class B1 TB - Repeat CXR, regardless of TST or BAMT results.</td>
<td></td>
</tr>
<tr>
<td>• For Class B2 or B3 - Perform a CXR if positive TST or positive BAMT.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>CXR Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Compare overseas to U.S. CXR and document the results.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Microscopy/ Bacteriology</th>
</tr>
</thead>
<tbody>
<tr>
<td>• If active TB disease cannot be ruled out by TST/BAMT and CXR, collect specimen/sputum for AFB smear and culture. Document results.</td>
<td></td>
</tr>
<tr>
<td><strong>Report suspected pulmonary or extrapulmonary TB disease to Kentucky TB Program within one working day. Call 502-564-4276. Do not wait for culture confirmation.</strong></td>
<td></td>
</tr>
</tbody>
</table>
# Instructions for Completing the TB Class Follow-up Worksheet – October 2010

The TB Follow-up Worksheet is used to document the initial evaluation of an arrival with a TB Class Condition. A complete evaluation requires a diagnosis and, when indicated, a treatment start date.

## Section C - U.S. Evaluation (Continued)

### U.S. Review of Overseas Treatment

- Record your interpretation of overseas TB treatment based on review of overseas documents and information provided by the patient.
  - C13-C15 refer to TB treatment recommended or administered during the most current overseas exam (by a panel physician) prior to departure.
  - C16 includes recent or any previous TB treatment.

## Section D

### Disposition

- Record “disposition date” when the evaluation has concluded or you cannot complete the evaluation for one of the reasons listed.
  - When the evaluation is complete, document whether or not treatment is recommended.
  - If unable to complete or initiate the evaluation, indicate the reason.
- Indicate diagnosis as described on the form.

*Leave D4 blank – for KY TB Program use only.*

## Section E

### U.S. Treatment

- Check appropriate box for treatment and document start date.
- Use CDC treatment recommendations:
  - No treatment indicated for Classes 0 and 1.
  - Strongly consider treatment of Class 2 (LTBI) and Class 4 (old, healed TB) unless previously treated.
  - Class 3 (active TB disease) patients should be treated using directly observed therapy (DOT); arranged through the local health department.

*Leave E3-E4 blank – for KY TB Program use only.*

*KY TB Program will track treatment completion data for those who start therapy.*
**Instructions for Completing the TB Class Follow-up Worksheet – October 2010**

The TB Follow-up Worksheet is used to document the initial evaluation of an arrival with a TB Class Condition.

A complete evaluation requires a diagnosis and, when indicated, a treatment start date.

| Please mail or fax the form to: Tammy Hall, Administrative Specialist II |
| Kentucky Department for Public Health |
| TB Prevention and Control Program | Fax# 502-564-3772 |
| 275 East Main Street, HS2E-B | Phone# 502-564-4276 |
| Frankfort, KY 40621 | |
Vital Signs

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Blood Pressure ...............................................................................................

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VITAL SIGNS

When reviewing vital signs in each of the age groups, be alert for significant changes and compare with normal values for each of the signs. For best results, when taking vital signs of infants, respirations are counted first before the infant is disturbed, the pulse next and the temperature last. When taking temperatures, the use of non-mercury thermometers is recommended.

<table>
<thead>
<tr>
<th>TEMPERATURE (Birth to Adult)</th>
<th>NORMAL RESTING PULSE (Birth to Adult)</th>
<th>RESPIRATIONS (Birth to Adult)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Birth to 10)</td>
<td>Newborn ------------------ 100–170</td>
<td>The procedure for measuring a child's respiratory rate is essentially the same as for an adult. However, keep in mind these points.</td>
</tr>
<tr>
<td>Temperature between 99.8–100.8 F is considered low-grade fever. If the temperature is taken rectally, a temperature is not considered a fever until it is above 100.4</td>
<td>6 months–1 year ------- 90–130</td>
<td>• Since a child’s respiration rate is diaphragmatic, observe abdominal movement to count the respiration rate.</td>
</tr>
<tr>
<td>• Temperature between 101–102 is considered a mild fever.</td>
<td>2–3 years -------------- 80–120</td>
<td>• Abdominal movement in a child will be irregular.</td>
</tr>
<tr>
<td>• Temperature between 102–103 is considered a moderate fever.</td>
<td>4–5 years -------------- 70–110</td>
<td>• Count for one full minute.</td>
</tr>
<tr>
<td>• Temperature around 104 or above is considered a high fever, and delirium or convulsions may occur. (11 Years to Adult)</td>
<td>10 years–Adult --------- 60–100</td>
<td>Normal Respiration Rate (Birth through Adult)</td>
</tr>
<tr>
<td>• Temperature above 100.4 is considered a fever.</td>
<td>Management The apical heart rate is preferred in children. To count the rate, place stethoscope on the anterior chest at the fifth intercostal space in a midclavicular position. Each “lub-dub” sound is one beat. Count the beats for one full minute. While counting the rate, note whether the rhythm is regular or irregular.</td>
<td>Newborn ------------- 30–60</td>
</tr>
<tr>
<td>• If temperature is taken rectally, it would register one degree higher and a reading of 101 would be considered a fever.</td>
<td>Pulse rates may be checked at sites other than the apex, for example, the carotid, brachial, radial, femoral, and dorsalis pedis sites. Compare the distal and proximal pulses for</td>
<td>6 months ------------- 24–36</td>
</tr>
<tr>
<td>• Temperature between 101–102 is considered a mild fever.</td>
<td></td>
<td>1 year -------------- 20–40</td>
</tr>
<tr>
<td>• Temperature between 102–103 is considered a high fever, and delirium or convulsions may occur.</td>
<td></td>
<td>2–3 years ------------- 20–30</td>
</tr>
</tbody>
</table>
Management
Assess the patient to determine if other signs or symptoms are present (i.e., flushed face, hot, dry skin, low output and highly concentrated urine, disinterest in eating, constipation, diarrhea, or vomiting. Older children or adolescents may complain of sore throat, headaches, aching all over, nausea, constipation, or diarrhea). Determine if elevated temperature could be post immunization (see Immunization Section), or related to underlying condition, being treated at the LHD. If not, seek medical consultation and/or refer for medical evaluation.

Fever in an infant 3 months and younger is of greater significance and medical consultation or referral should occur.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Normal Pulse Rate</th>
<th>Normal Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>4–6 years</td>
<td>16–22</td>
<td></td>
</tr>
<tr>
<td>6–10 years</td>
<td>16–20</td>
<td></td>
</tr>
<tr>
<td>11–20 years</td>
<td>12–20</td>
<td></td>
</tr>
</tbody>
</table>

Management
Assess the patient to determine if other signs or symptoms of respiratory or cardiac distress are present. If a child has any acute distress (retractions, cyanosis, wheezing, irritability), refer immediately for a medical evaluation.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Normal Pulse Rate</th>
<th>Normal Temperature</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

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Management
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Fever in an infant 3 months and younger is of greater significance and medical consultation or referral should occur.

Management
Assess the patient to determine if other signs or symptoms of respiratory or cardiac distress are present. If a child has any acute distress (retractions, cyanosis, wheezing, irritability), refer immediately for a medical evaluation.
BLOOD PRESSURE READINGS IN CHILDREN & ADOLESCENTS

Blood pressure measurement for a child is basically the same as for an adult. The size of the blood pressure cuff is extremely important. Whether manual or electronic equipment is being used, the size of the blood pressure cuff is determined by the size of the child’s arm or leg. Generally, the width of the bladder cuff is two thirds of the length of the long bone of the extremity on which the blood pressure is taken. The length of the bladder cuff should be about three-fourths the circumference of the extremity and should not overlap. If the bladder of the cuff is too small, the pressure will read extremely high; if it is too large, the pressure will be falsely low.

<table>
<thead>
<tr>
<th>Age</th>
<th>*Normal</th>
<th>**Stage I Mild Hypertension</th>
<th>**Stage II Moderate Hypertension</th>
<th>**Stage III Severe Hypertension</th>
</tr>
</thead>
<tbody>
<tr>
<td>3–5 Years</td>
<td>For results above normal, follow Stage II guidelines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>107–111</td>
<td>112</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diastolic</td>
<td>61–70</td>
<td>71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6–9 years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>111–115</td>
<td>116–121</td>
<td>122–129</td>
<td>&gt;129</td>
</tr>
<tr>
<td>Diastolic</td>
<td>61–70</td>
<td>71–77</td>
<td>78–85</td>
<td>&gt;85</td>
</tr>
<tr>
<td>10–12 Years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>112–116</td>
<td>117–125</td>
<td>126–133</td>
<td>&gt;133</td>
</tr>
<tr>
<td>Diastolic</td>
<td>64–75</td>
<td>76–81</td>
<td>82–89</td>
<td>&gt;89</td>
</tr>
<tr>
<td>13–15 Years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>116–123</td>
<td>124–135</td>
<td>136–143</td>
<td>&gt;143</td>
</tr>
<tr>
<td>Diastolic</td>
<td>65–76</td>
<td>77–85</td>
<td>86–89</td>
<td>&gt;91</td>
</tr>
<tr>
<td>16–18 Years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>118–126</td>
<td>127–141</td>
<td>142–149</td>
<td>&gt;149</td>
</tr>
<tr>
<td>Diastolic</td>
<td>70–79</td>
<td>80–91</td>
<td>92–97</td>
<td>&gt;97</td>
</tr>
</tbody>
</table>

*Source: modified from National Heart, Lung & Blood Institute–Bethesda, MD

**Source: modified from the American Academy of Pediatrics
Management for Abnormal Blood Pressure Readings

Stage I (Mild Hypertension)
1. Repeat to confirm
2. Assess for obesity and anxiety
3. Review for underlying causes, including medications, underlying illnesses, pain, etc.
4. Health education to include:
   a. Basic nutrition
   b. Exercise for older children and adolescents
   c. Monitor weekly at 3 different times within 1 month to confirm baseline values; then monitor
      at routine visits.

Stage II and III (Moderate to Severe Hypertension)
1. Repeat to confirm
2. Health and nutrition education
3. Refer for medical evaluation
## Classification and Management of Blood Pressure for Adults

### Ages 18 and Older

<table>
<thead>
<tr>
<th>BP Classification</th>
<th>SBP mmHg</th>
<th>DBP mmHg</th>
<th>Management*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;120</td>
<td>And &lt;80</td>
<td>1. Encourage lifestyle modifications (i.e., weight reduction, dietary sodium reduction, aerobic physical activity, moderation of alcohol consumption, and smoking cessation).&lt;br&gt;2. Recheck BP every year</td>
</tr>
<tr>
<td>Prehypertension</td>
<td>120–139</td>
<td>Or 80–89</td>
<td>1. Prescribe lifestyle modifications.&lt;br&gt;2. Confirm BP in contralateral arm.&lt;br&gt;3. Refer for medical evaluation.</td>
</tr>
<tr>
<td>Stage 1 Hypertension</td>
<td>140–159</td>
<td>Or 90–99</td>
<td>1. Prescribe lifestyle modifications.&lt;br&gt;2. Confirm hypertension in contralateral arm.&lt;br&gt;3. Assess risk factors.&lt;br&gt;4. Refer for medical evaluation.&lt;br&gt;5. Provide or refer for medical nutrition therapy.</td>
</tr>
<tr>
<td>Stage 2 Hypertension</td>
<td>≥160</td>
<td>Or ≥100</td>
<td>1. Prescribe lifestyle modifications.&lt;br&gt;2. Confirm hypertension in contralateral arm.&lt;br&gt;3. Assess risk factors.&lt;br&gt;4. Refer for medical evaluation.&lt;br&gt;5. Provide or refer for medical nutrition therapy.</td>
</tr>
</tbody>
</table>

**Source:** Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7).

*Any hypertension in a pregnant woman could signal the onset of pregnancy-induced hypertension or other complications and should be immediately brought to the attention of the clinical provider.*
APPENDICES:


KENTUCKY DEPARTMENT FOR PUBLIC HEALTH
CLINICAL PROTOCOL FOR EPINEPHRINE AUTO-INJECTORS IN THE SCHOOL SETTING

Background

2013 HB 172, an amendment to KRS 158.836, makes provisions for students with life-threatening allergies to have access to an epinephrine auto-injector in school. Changes to KRS 158.836 include:

- A student who has a documented life-threatening allergy shall have:
  a) An epinephrine auto-injector provided by his or her parent or guardian in his or her possession or in the possession of the school nurse, school administrator, or his or her designee in all school environments that the student may be in.
  b) A written individual health care plan in place for the prevention and proactive management for the student in all school environments that the student may be in. The individual health care plan may be incorporated in the student’s individualized education program or student’s 504 plan.
- Each school is encouraged to keep an epinephrine auto-injector in a minimum of two (2) locations in the school so that epinephrine may be administered to any student believed to be having a life-threatening allergic or anaphylactic reactions.
- Schools electing to keep epinephrine auto-injectors shall maintain them in a secure, accessible, but unlocked location. This shall apply to the extent that the epinephrine auto-injectors are donated to a school or a school has sufficient funding to purchase the epinephrine auto-injectors. Epinephrine auto-injectors may only be purchased with a prescription from a medical provider.
- Each school electing to keep epinephrine auto-injectors shall implement policies and procedures for managing student’s life-threatening allergic reaction or anaphylactic reaction developed and approved by the local school board.
- Clinical protocols shall be developed by the Kentucky Department for Public Health to address epinephrine auto-injectors kept by schools and to advise on clinical administration of epinephrine auto-injectors.


Anaphylaxis is a life threatening allergic reaction that can occur quickly and can cause death within minutes. In some instances, signs and symptoms of anaphylaxis can occur up to a few hours after exposure to the allergen.

Common triggers for an anaphylaxis include: food (particularly peanuts, tree nuts, shellfish, soy, milk, wheat or eggs); stinging insects (such as wasps or bees); medications, latex, animal dander or exercise.
**Signs and Symptoms of Anaphylaxis**

Signs and Symptoms of anaphylaxis may include, but are not limited to:

- **Mouth:** tingling, itching, swelling of the tongue, lips or mouth; blue/gray color of the lips
- **Throat:** tightening of throat, tickling feeling in back of throat, hoarseness or change in voice
- **Nose/Eyes/Ears:** runny, itchy nose; redness and/or swelling of eyes; throbbing in ears
- **Lung:** shortness of breath, repetitive shallow cough, wheezing
- **Stomach:** abdominal cramps, nausea, vomiting, diarrhea
- **Skin:** itchy rash, hives, swelling of face or extremities, facial flushing, sweating
- **Heart:** weak pulse; rapid pulse; palpitations; fainting; blueness of lips, face or nail beds; paleness; lightheadedness; sense of impending doom or loss of consciousness

It is important to note that not all signs and symptoms may be present during anaphylaxis.

Since the severity of an allergic reaction is difficult to predict, the allergic response may rapidly progress to anaphylaxis. It is important for students with known severe allergies who are at risk of anaphylaxis to have an Allergy or Anaphylaxis Emergency Action Plan of Care. **Epinephrine should be administered promptly at the first sign of anaphylaxis. It is safer to administer epinephrine than to delay treatment for anaphylaxis.**

Epinephrine should be stored at room temperature (between 59-86 degrees F) in a dark area. The epinephrine should be checked monthly to ensure proper storage, expiration date, and medication stability. Expired auto-injectors or those with discolored solution or solid particles should not be used. Discard them in a sharps container. Personnel should be familiar with the type of epinephrine auto injector maintained by the school and its use.
**Responding to Anaphylaxis**

*This is a life and death decision. Act promptly.*

Go to the student. Never send a student to the health room alone or leave a student alone. Do not move a student who is in severe distress.

A. **For a student with specific orders on file (written individual health plan), follow the student’s individually prescribed emergency action plan as it relates to a known life-threatening allergy and/or known history of anaphylaxis.** Note: For some students with known potential for life-threatening allergic reactions, the individual health plan may call for administration of epinephrine by auto-injector after exposure to a known allergen and before symptoms of anaphylaxis may be present.

B. **For a student without specific orders on file:**

1. Based on symptoms observed, determine that an anaphylactic reaction is occurring.
2. Act quickly. Only a few symptoms may be present. Severity of symptoms can change rapidly.
3. Place student on his/her back if possible. Do not give anything by mouth if the individual is unconscious or unable to swallow.
4. Determine the proper dose of epinephrine.
   Dosages for epinephrine auto-injection:
   a. If the child weighs 33 (15 kg) to 66 pounds (30kg), administer 0.15 mg of epinephrine (junior size auto-injector.)

   b. If the child is 66 pounds (30kg) or over, administer 0.30 mg of epinephrine (regular size auto-injector.)

5. **Remove colored safety cap and INJECT EPINEPHRINE IMMEDIATELY into outside of mid-thigh (through clothing if necessary), press firmly and hold for 10 seconds for most brands of auto-injectors, such as the EpiPen Auto-Injector, but only 5 seconds for the Auvi-Q auto-injector.** Note the time that the epinephrine is administered. For questions regarding dosage or timing of the auto-injector brand being used, please see product instructions developed by the manufacturer.

6. **Call 911 or direct someone to call 911 to request immediate medical assistance.** Advise the 911 operator that anaphylaxis is suspected and that epinephrine has been given or is being given.

7. Direct someone to call the school nurse or front-office.
8. Direct someone to notify the child’s parents.
9. Begin monitoring airway and breathing. For a severe reaction consider keeping student lying on back with legs raised.
10. Remain with student and reassure him or her as needed.
11. A second dose of auto-injectable epinephrine may be given 5 minutes or more after the first if symptoms persist or recur.
12. Administer CPR if needed.
13. Document student’s name, date and time epinephrine was administered on the used epinephrine auto-injector and give to Emergency Medical Services (EMS), when EMS arrives, so that the information will accompany the student to the emergency department.

14. Even if symptoms subside or go away, EMS must still be summoned to respond, and the student must be evaluated by a physician. A delayed or secondary reaction may occur up to several hours later.

15. Document the incident and complete school incident report.

16. Replace epinephrine stock medication as appropriate.

**References and Additional Resources**

- KY TRAIN Course # 1029214. Medication Administration Training for Unlicensed School Personnel –EpiPen only. [https://ky.train.org](https://ky.train.org)
- KDE Medication Administration Training Manual for Non-Licensed School Personnel, Chapter 3, Emergency Medications
- National Association for School Nurses (NASN) NASN Tool Kit, Food Allergy and Anaphylaxis [http://www.nasn.org/ToolsResources/FoodAllergyandAnaphylaxis](http://www.nasn.org/ToolsResources/FoodAllergyandAnaphylaxis)
- American Academy of Allergy Asthma & Immunology [https://www.aaaai.org/conditions-and-treatments/conditions-a-to-z-search/anaphylaxis.aspx](https://www.aaaai.org/conditions-and-treatments/conditions-a-to-z-search/anaphylaxis.aspx)
- Food Allergy and Anaphylaxis Network (FAAN) [http://www.foodallergy.org/resources/schools](http://www.foodallergy.org/resources/schools)
APPENDIX B:

- NALOXONE AUTO INJECTOR PROTOCOL IN THE SCHOOL SETTING – JULY 2017

KENTUCKY DEPARTMENT FOR PUBLIC HEALTH
CLINICAL PROTOCOL FOR NALOXONE AUTO-INJECTORS IN THE SCHOOL SETTING

Background

2015 SB 192, section 8, an amendment to KRS 217.186 makes provisions for individuals with life-threatening symptoms of opioid overdose to have access to naloxone auto-injector by the board of each local public school district and the governing body of each private or parochial school or school district that chooses to keep naloxone on the premises and regulate its administration. Changes to KRS 217.186 include:

1. A person or agency, including a school employee authorized to administer medication under KRS 156.502 may:
   a) Receive a prescription for the drug naloxone;
   b) Possess naloxone pursuant to this subsection and any equipment needed for its administration; and
   c) Administer naloxone to an individual suffering from an apparent opiate-related overdose.

2. A person acting in good faith who administers naloxone received under KRS 217.186 shall be immune from criminal and civil liability for the administration, unless personal injury results from the gross negligence or willful or wanton misconduct of the person administering the drug.

- Opioid overdose-related deaths can be prevented when naloxone is administered in a timely manner. As a narcotic antagonist, naloxone displaces opiates from receptor sites in the brain and reverses respiratory depression that usually is the cause of overdose deaths. During the period of time when an overdose can become fatal, respiratory depression can be reversed by giving the individual naloxone¹. **Naloxone should be administered promptly at the first sign of opioid overdoses. It is safer to administer naloxone than to delay treatment for opioid overdose.**

- Each school is encouraged to ensure ready access to naloxone and keep it in a minimum of two (2) locations in the school so that it may be administered to any individual believed to be having a life-threatening opioid overdose.

- Schools electing to keep naloxone shall maintain the drug in a secure, accessible, but unlocked location. Naloxone may only be purchased with a prescription from a medical provider.
• Each school electing to keep naloxone shall implement policies and procedures for managing opioid overdose, developed and approved by the local school board.
• Administration of appropriate CPR measures may be needed if the individual does not have respirations or a heartbeat.


WHAT ARE OPIOIDS?¹

Opioids include illegal drugs such as heroin, as well as prescription medications used to treat pain such as morphine, codeine, methadone, oxycodone (OxyContin®, Percodan®, Percocet®), hydrocodone (Vicodin®, Lortab®, Norco®), fentanyl (Duragesic®, Fentora®), hydromorphone (Dilaudid®, Exalgo®), and buprenorphine (Subutex®, Suboxone®). Opioids work by binding to specific receptors in the brain, spinal cord and gastrointestinal tract. In doing so, they minimize the body’s perception of pain. However, stimulating the opioid receptors or “reward centers” in the brain also can trigger other systems of the body, such as those responsible for regulating mood, breathing and blood pressure.

HOW DOES OVERDOSE OCCUR?
A variety of effects can occur after a person takes opioids, ranging from pleasure to nausea, vomiting, severe allergic reactions (anaphylaxis) and overdose, in which breathing and heartbeat slow or even stop.¹

Since the onset and severity of an opioid overdose is difficult to predict, the overdose may rapidly progress to respiratory depression. In some instances signs and symptoms of an opioid overdose may appear as an individual experiencing extreme sleepiness or having breathing difficulties. Naloxone should be administered promptly at the first sign of an opioid overdose.

WHO MAY BE AT RISK

The following clinical factors may increase a patient's risk for overdose when taking an opioid ¹, ³–¹⁰
• Anyone who uses opioids for long-term management of chronic cancer or non-cancer pain is at risk for opioid overdose
• Substance abuse, dependence and/or addiction, as are persons who use heroin
• Accidental exposure and unintentional opioid misuse
  ➢ Includes members of a patient’s household who may discover and use the prescribed opioid inappropriately
• A morphine-equivalent dose (MED) ≥20 mg per day
• Switching to another opioid
• Chronic pulmonary disease
• Sleep apnea
• Asthma
• Chronic kidney and/or liver impairment
• Use of CNS depressants, including benzodiazepines and alcohol
• Use of certain medications for depression, including monoamine oxidase inhibitors (MAOIs)
SIGNs AND SYMPTOMS OF OPIoid OVERDOSE

All school staff, including those in extracurricular programs should be trained on how to recognize the signs and symptoms of an opioid overdose requiring the use of a naloxone. Symptoms of an opioid overdose requiring the use of naloxone may include but are not limited to the following: extreme sleepiness (inability to awaken verbally or upon sternal rub); breathing problems which can range from slow to shallow breathing in a patient that cannot be awakened; fingernails or lips turning blue/purple; extremely small “pinpoint” pupils; slow heartbeat and/or low blood pressure. Signs of overmedication which may progress to overdose include: unusual sleepiness; drowsiness; or difficulty staying awake despite loud verbal stimulus or vigorous sternal rub; mental confusion; slurred speech; intoxicated behavior; slow or shallow breathing; extremely small “pinpoint” pupils, although normal size pupils do not exclude opioid overdose; slow heartbeat; low blood pressure; and difficulty waking the person from sleep.¹

It is important to note that not all signs and symptoms may be present during an opioid overdose. If the individual is not responsive to shaking, yelling or vigorously rubbing their sternum, ACT PROMPTLY!!

- CALL FOR HELP!
- CHECK FOR BREATHING!
- CALL 911 IMMEDIATELY!
- GET THE NALOXONE!

Differentiating between overdose and an opioid high
Sometimes it is difficult to tell if someone is overdosing or if they are just really high. The table below offers clues on how a responder might be able to tell the difference.⁴

<table>
<thead>
<tr>
<th>REALLY HIGH</th>
<th>OVERDOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Muscles become relaxed</td>
<td>Pale, clammy skin</td>
</tr>
<tr>
<td>Speech is slowed/slurred</td>
<td>Very infrequent or no breathing</td>
</tr>
<tr>
<td>Sleepy looking</td>
<td>Deep snoring or gurgling (death rattle)</td>
</tr>
<tr>
<td>Responsive to stimuli (such as shaking, yelling, vigorous sternal rub, etc...)</td>
<td>Not responsive to stimuli (such as shaking, yelling, vigorous sternal rub, etc...)</td>
</tr>
<tr>
<td>Normal heart beat/pulse</td>
<td>Slow heart beat/pulse</td>
</tr>
<tr>
<td>Normal skin tone/color</td>
<td>Blue lips and/ or fingertips</td>
</tr>
</tbody>
</table>

Because opioids depress respiratory function and breathing, one telltale sign of a person in a critical medical state is the “death rattle.” If a person emits a “death rattle” an exhaled breath with a very distinct, labored sound coming from the throat, emergency resuscitation will be necessary immediately, as it almost always is a sign that the individual is near death.¹
RESPONDING TO AN OPIOID OVERDOSE

IF YOU SUSPECT AN OVERDOSE

ACT PROMPTLY!! Always go a distressed individual. Never send the individual to the health room/school nurse alone or leave them alone. Do not move an individual who is in severe distress.

AN OPIOID OVERDOSE NEEDS IMMEDIATE MEDICAL ATTENTION. An essential step is to get someone with medical expertise to see the patient as soon as possible, CALL 911 immediately to activate emergency medical services (EMS).

1. **CALL 911 immediately**
   - If you suspect an opioid overdose or if someone is showing signs of respiratory distress (infrequent or no breathing, deep snoring or gurgling), call 911 or direct someone to call 911 to request immediate medical assistance. Advise the 911 operator that an opioid overdose is suspected and that naloxone has been given or is being given.

2. **PROVIDE RESCUE BREATHING if necessary**

   For a person who is not breathing or who is unresponsive with shallow, infrequent breathing, rescue breathing is the quickest way to get oxygen to the brain and is an important step in preventing an overdose death.

   **Steps for rescue breathing are:**
   a) Place the person on his or her back and pinch their nose.
   b) Open the person’s airway by tilting the chin up and gently pushing down on the forehead. Look into the mouth to see if there is anything blocking the airway. If so, remove it.
   c) Create an air tight mouth to mouth seal on the victim’s mouth.
   d) Take a regular (not deep) breath, and give a breath over 1 second.
   e) Blow enough air into the lungs to make the chest rise. If the chest is not rising, tilt the head back more and try again.
   f) Give a second rescue breath over 1 second.
   g) Breathe again every 5 seconds until the patient is breathing on their own, or EMS arrive and take over.

3. **ADMINISTERNALOXONE**

   There are multiple routes of administration for FDA approved naloxone: intramuscular, subcutaneous and intravenous. Schools may choose to use
administration methods that are more cost effective such as syringe/needle and naloxone vial method. For the purposes of this guidance, the use of the FDA approved naloxone via prefilled syringe as well as the auto-injector will be reviewed.

Most patients respond by returning to spontaneous breathing, with minimal withdrawal symptoms. The response generally occurs within 3 to 5 minutes of naloxone administration. Rescue breathing should continue while waiting for the naloxone to take effect.¹

<table>
<thead>
<tr>
<th>Preparing naloxone in a pre-filled syringe</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Quickly open the box and pull out the pre-filled 1 milliliter syringe</td>
</tr>
<tr>
<td>b) Attach the 1-1 ½ inch needle to the syringe</td>
</tr>
<tr>
<td>c) Remove the safety cap on the needle</td>
</tr>
<tr>
<td>d) Quickly push the needle straight down into the outer mid-thigh muscle, through the clothes if necessary and push down on the plunger</td>
</tr>
<tr>
<td>e) Put the needle/syringe in a sharps container</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Use of the naloxone auto injector</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Pull auto injector from the outer case</td>
</tr>
<tr>
<td>b) Quickly visually inspect the naloxone auto injector through the viewing window for particulate matter and discoloration prior to administration. Do not administer unless the solution is clear and the glass container is undamaged.</td>
</tr>
<tr>
<td>c) Remove the safety cap, pull firmly.</td>
</tr>
<tr>
<td>d) Immediately place the auto injector against the outer mid-thigh, (see above) through the clothes if necessary, and press firmly and hold for 5 seconds. You may hear a normal clicking sound. <strong>To reduce the chance of an accidental injection to yourself, do not touch the base of the auto-injector, which is where the needle comes out. If an accidental injection happens, get medical help right away.</strong></td>
</tr>
</tbody>
</table>

Naloxone will continue to work for as long as 30 to 90 minutes, but after that time, overdose symptoms may return.¹ **ASSURE 911 HAS BEEN CALLED** and that EMS has been activated. If no one has yet called 911, **IMMEDIATELY CALL 911.**

4. **Direct someone to call and notify the front office and the school nurse.**
**If the individual is breathing on their own, place them in the recovery position.**

After giving naloxone, stay with the individual. If they are breathing on their own, to decrease the individual’s chance of choking on their vomit, place them in the recovery position, on their side and support the body with one bent knee with the face turned to the side.

5. **STAY WITH THE PERSON AND MONITOR FOR RESPIRATORY DISTRESS.**

Provide rescue breathing as necessary. It is necessary to seek immediate emergency medical assistance (911) after delivering the first dose of naloxone, keep the patient under continued surveillance, and repeat doses of naloxone as necessary.

6. **REPEATNALOXONE ADMINISTRATION IF SYMPTOMS CONTINUE.**

The duration of action of most opioids is likely to exceed the 30-90 minutes that naloxone will be effective, resulting in a return of respiratory and/or central nervous system depression, even after an initial improvement in symptoms. If the desired response is not obtained after 2 or 3 minutes, another dose of naloxone may be administered if available.

If after 1-2 doses of naloxone there is no breathing or breathing continues to be shallow, lay the person on their back and continue to perform rescue breathing while waiting for the naloxone to take effect, they breathe for themselves or EMS arrives.

7. **DOCUMENT** the individual’s name, date and time naloxone was administered and give this information to EMS, so that the information will accompany the individual to the hospital's emergency department.

8. Document the incident and complete school incident report.

9. Replace naloxone in-stock medication as appropriate as soon as possible.

**NALOXONE**

Generic Name: naloxone (nah LOX own) Brand Names: Evzio, Narcan

**INDICATIONS AND USAGE**

Naloxone is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Naloxone is intended for immediate administration as emergency therapy in settings where opioids may be present. Naloxone is not a substitute for emergency medical care. When in doubt, if an individual is unresponsive and an opioid overdose is suspected, administer naloxone as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death. Call 911 to activate EMS immediately after administering the first dose of naloxone.
HOW NALOXONE IS SUPPLIED

Naloxone is supplied in a carton containing two pre-filled naloxone hydrochloride injections, USP 0.4 mg auto-injectors and a single black and white trainer that can be used for practice.

For questions regarding dosage or timing of the brand being used, please see product package insert instructions developed by the manufacturer.

STORAGE AND HANDLING OF NALOXONE AUTO INJECTOR

Store naloxone at controlled room temperature 15°C to 25°C (59°F to 77°F) and in a dark area.

The naloxone should be checked monthly to ensure proper storage, expiration date, and medication stability. Expired naloxone or those with discolored solution or solid particles should not be used. Discard them in a sharps container.

Personnel should be familiar with the type of naloxone maintained by the school and its use.

Schools should refer to the package insert and store naloxone hydrochloride according to the individual manufacturer’s direction.
RESPONDING TO AN OPIOID OVERDOSE WITH NALOXONE FLOW CHART

The following flow-chart illustrates the steps that are taken depending on the victim’s responsiveness.

Assess for responsiveness and breathing

- **Responsive**
  - **Stay and observe until alert**

- **Not Responsive**
  - **Provide Stimuli (e.g. vigorous sternal rub)**
    - **Responsive**
    - **Not Responsive**
      - **CALL FOR HELP!! CALL 911!!**
      - **Breathing**
      - **Not Breathing**
        - **Monitor**
        - **Start Rescue Breathing**

      - **GIVE NALOXONE**
        - **Assess Breathing**
          - **Breathing**
          - **Not Breathing**
            - **Monitor**
            - **Start Rescue Breathing**
            - **Repeat Naloxone if available**
            - **If no one has responded, CALL FOR HELP!! CALL 911!!**
REFERENCES AND SOURCES
16. EVZIO Naloxone Auto Injector FDA Package Insert: http://evzio.com/pdfs/Evzio%20PI.PDF
22. Opana® (oxymorphone hydrochloride tablet) [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc; 2013.

Additional Resources
32. EVZIO Naloxone Administration Training: http://evzio.com/pdfs/Evzio-Trainer-Information.pdf
33. FDA approves new hand-held auto-injector to reverse opioid overdose: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm391465.htm

We would like to acknowledge and thank the Massachusetts Department for Public Health for the use of any information from the Massachusetts Department for Public Health Opioid Overdose Education and Naloxone Distribution, in developing these protocols.
APPENDIX B (continued):

- **NALOXONE INTRANASAL PROTOCOL IN THE SCHOOL SETTING – JULY 2017**

KENTUCKY DEPARTMENT FOR PUBLIC HEALTH
CLINICAL PROTOCOL FOR INTRANASAL
NALOXONE IN THE SCHOOL SETTING

**Background**

In 2015, SB 192, section 8, an amendment to KRS 217.186 (http://www.lrc.ky.gov/Statutes/statute.aspx?id=44004) made provisions for individuals with life-threatening symptoms of opioid overdose to have access to naloxone by the board of each local public school district and the governing body of each private or parochial school or school district that chooses to keep naloxone on the premises and regulate its administration. Changes to KRS 217.186 include:

3. A person or agency, including a school employee authorized to administer medication under KRS 156.502 may:
   - d) Receive a prescription for the drug naloxone;
   - e) Possess naloxone pursuant to this subsection and any equipment needed for its administration; and
   - f) Administer naloxone to an individual suffering from an apparent opiate-related overdose.

4. A person acting in good faith who administers naloxone received under KRS 217.186 shall be immune from criminal and civil liability for the administration, unless personal injury results from the gross negligence or willful or wanton misconduct of the person administering the drug.

- Opioid overdose-related deaths can be prevented when naloxone is administered in a timely manner. As a narcotic antagonist, naloxone displaces opiates from receptor sites in the brain and reverses respiratory depression that usually is the cause of overdose deaths. During the period of time when an overdose can become fatal, respiratory depression can be reversed by giving the individual naloxone\(^1\). **Naloxone should be administered promptly at the first sign of opioid overdoses. It is safer to administer naloxone than to delay treatment for opioid overdose.**

- Each school is encouraged to ensure ready access to naloxone and keep it in a minimum of two (2) locations in the school so that it may be administered to any individual believed to be having a life-threatening opioid overdose.

- Schools electing to keep naloxone shall maintain the drug in a secure, accessible, but unlocked location. Naloxone may only be purchased with a prescription from a medical provider.
• Each school electing to keep naloxone shall implement policies and procedures for managing opioid overdose, developed and approved by the local school board.
• Administration of appropriate CPR measures may be needed if the individual does not have respirations or a heartbeat.

WHAT ARE OPIOIDS? ¹
Opioids include illegal drugs such as heroin, as well as prescription medications used to treat pain such as morphine, codeine, methadone, oxycodone (OxyContin®, Percodan®, Percocet®), hydrocodone (Vicodin®, Lortab®, Norco®), fentanyl (Duragesic®, Fentora®), hydromorphone (Dilauidid®, Exalgo®), and buprenorphine (Subutex®, Suboxone®). Opioids work by binding to specific receptors in the brain, spinal cord and gastrointestinal tract. In doing so, they minimize the body’s perception of pain. However, stimulating the opioid receptors or “reward centers” in the brain also can trigger other systems of the body, such as those responsible for regulating mood, breathing and blood pressure.

HOW DOES OVERDOSE OCCUR?
A variety of effects can occur after a person takes opioids, ranging from pleasure to nausea, vomiting, severe allergic reactions (anaphylaxis) and overdose, in which breathing and heartbeat slow or even stop.¹

Since the onset and severity of an opioid overdose is difficult to predict, the overdose may rapidly progress to respiratory depression. In some instances signs and symptoms of an opioid overdose may appear as an individual experiencing extreme sleepiness or having breathing difficulties. **Naloxone should be administered promptly at the first sign of an opioid overdose.**

WHO MAY BE AT RISK
The following clinical factors may increase a patient's risk for overdose when taking an opioid ¹, 3–10
• Anyone who uses opioids for long-term management of chronic cancer or non-cancer pain is at risk for opioid overdose
• Substance abuse, dependence and/or addiction, as are persons who use heroin
• Accidental exposure and unintentional opioid misuse
  ➢ Includes members of a patient’s household who may discover and use the prescribed opioid inappropriately
• A morphine-equivalent dose (MED) ≥20 mg per day
• Switching to another opioid
• Chronic pulmonary disease
• Sleep apnea
• Asthma
• Chronic kidney and/or liver impairment
• Use of CNS depressants, including benzodiazepines and alcohol
• Use of certain medications for depression, including monoamine oxidase inhibitors (MAOIs)
**SIGNS AND SYMPTOMS OF OPIOID OVERDOSE**

All school staff, including those in extracurricular programs should be trained on how to recognize the signs and symptoms of an opioid overdose requiring the use of naloxone. Symptoms of an opioid overdose requiring the use of naloxone may include but are not limited to the following: extreme sleepiness (inability to awaken verbally or upon sternal rub); breathing problems which can range from slow to shallow breathing in a patient that cannot be awakened; fingernails or lips turning blue/purple; extremely small “pinpoint” pupils; slow heartbeat and/or low blood pressure. Signs of overmedication which may progress to overdose include: unusual sleepiness; drowsiness; or difficulty staying awake despite loud verbal stimulus or vigorous sternal rub; mental confusion; slurred speech; intoxicated behavior; slow or shallow breathing; extremely small “pinpoint” pupils, although normal size pupils do not exclude opioid overdose; slow heartbeat; low blood pressure; and difficulty waking the person from sleep.¹

**It is important to note that not all signs and symptoms may be present during an opioid overdose.** If the individual is not responsive to shaking, yelling or vigorously rubbing their sternum, **ACT PROMPTLY!!**

- CALL FOR HELP!
- CHECK FOR BREATHING!
- CALL 911 IMMEDIATELY!
- GET THE NALOXONE!

**Differentiating between overdose and an opioid high**

Sometimes it is difficult to tell if someone is overdosing or if they are just really high. The table below offers clues on how a responder might be able to tell the difference.⁴

<table>
<thead>
<tr>
<th>REALLY HIGH</th>
<th>OVERDOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Muscles become relaxed</td>
<td>Pale, clammy skin</td>
</tr>
<tr>
<td>Speech is slowed/slurred</td>
<td>Very infrequent or no breathing</td>
</tr>
<tr>
<td>Sleepy looking</td>
<td>Deep snoring or gurgling (death rattle)</td>
</tr>
<tr>
<td>Responsive to stimuli (such as shaking, yelling, vigorous sternal rub, etc...)</td>
<td>Not responsive to stimuli (such as shaking, yelling, vigorous sternal rub, etc...)</td>
</tr>
<tr>
<td>Normal heart beat/pulse</td>
<td>Slow heart beat/pulse</td>
</tr>
<tr>
<td>Normal skin tone/color</td>
<td>Blue lips and/or fingertips</td>
</tr>
</tbody>
</table>

Because opioids depress respiratory function and breathing, one telltale sign of a person in a critical medical state is the “death rattle.” If a person emits a “death rattle” an exhaled breath with a very distinct, labored sound coming from the throat, emergency resuscitation will be necessary immediately, as it almost always is a sign that the individual is near death¹.
RESPONDING TO AN OPIOID OVERDOSE

IF YOU SUSPECT AN OVERDOSE

ACT PROMPTLY!! Always go a distressed individual. Never send the individual to the health room/school nurse alone or leave them alone. Do not move an individual who is in severe distress.

AN OPIOID OVERDOSE NEEDS IMMEDIATE MEDICAL ATTENTION. An essential step is to get someone with medical expertise to see the patient as soon as possible, CALL 911 immediately to activate emergency medical services (EMS).

10. **CALL 911 immediately**
   If you suspect an opioid overdose or if someone is showing signs of respiratory distress (infrequent or no breathing, deep snoring or gurgling), call 911 or direct someone to call 911 to request immediate medical assistance. Advise the 911 operator that an opioid overdose is suspected and that naloxone has been given or is being given.

11. **PROVIDE RESCUE BREATHING if necessary**

   For a person who is not breathing or who is unresponsive with shallow, infrequent breathing, rescue breathing is the quickest way to get oxygen to the brain and is an important step in preventing an overdose death.

   **Steps for rescue breathing are:**
   a) Place the person on his or her back and pinch their nose.
   h) Open the person’s airway by tilting the chin up and gently pushing down on the forehead. Look into the mouth to see if there is anything blocking the airway. If so, remove it.
   i) Create an air tight mouth to mouth seal on the victim’s mouth.
   j) Take a regular (not deep) breath, and give a breath over 1 second.
   k) Blow enough air into the lungs to make the chest rise. If the chest is not rising, tilt the head back more and try again.
   l) Give a second rescue breath over 1 second.
   m) Breathe again every 5 seconds until the patient is breathing on their own, or EMS arrive and take over.
12. **ADMINISTER NALOXONE**

There are multiple routes of administration for FDA approved naloxone: intramuscular, subcutaneous, intranasal and intravenous. Schools may choose to use administration methods that are more cost effective such as syringe/needle and naloxone vial method. For the purposes of this guidance, the use of the FDA approved intranasal naloxone will be reviewed.

Most patients respond by returning to spontaneous breathing, with minimal withdrawal symptoms. The response generally occurs within 3 to 5 minutes of naloxone administration. Rescue breathing should continue while waiting for the naloxone to take effect.¹

**Important:** Intranasal naloxone is for use in the nose only.
- Do not remove or test the NARCAN Nasal Spray until ready to use.
- Each NARCAN Nasal Spray has 1 dose and cannot be reused.
- You do not need to prime NARCAN Nasal Spray.
How to use NARCAN nasal spray:

Step 1. Lay the person on their back to receive a dose of NARCAN Nasal Spray.

Step 2. Remove NARCAN Nasal Spray from the box. Peel back the tab with the circle to open the NARCAN Nasal Spray.

Step 3. Hold the NARCAN Nasal Spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.

Step 4. Tilt the person’s head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril until your fingers on either side of the nozzle are against the bottom of the person’s nose.

Step 5. Press the plunger firmly to give the dose of NARCAN Nasal Spray.

Step 6. Remove the NARCAN Nasal Spray from the

Step 7. Get emergency medical help right away.

- Move the person on their side (recovery position) after giving NARCAN Nasal Spray.
- Watch the person closely.
- If the person does not respond by waking up, to voice or touch, or breathing normally another dose may be given. NARCAN Nasal Spray may be dosed every 2 to 3 minutes, if available.
- Repeat Steps 2 through 6 using a new NARCAN Nasal Spray to give another dose in the other nostril. If additional NARCAN Nasal Sprays are available, Steps 2 through 5 may be repeated every 2 to 3 minutes until the person responds or emergency medical help is received.

Step 8. Put the used NARCAN Nasal Spray back into its box.

Step 9. Throw away (dispose of) the used NARCAN Nasal Spray in a place that is away from children.
Naloxone will continue to work for as long as 30 to 90 minutes, but after that time, overdose symptoms may return.\(^1\)**ASSURE 911 HAS BEEN CALLED** and that EMS was activated. If no one has yet called 911, **IMMEDIATELY CALL 911.**

4. **DIRECT SOMEONE TO CALL AND NOTIFY THE FRONT OFFICE AND THE SCHOOL NURSE**

   If the individual is breathing on their own, place them in the recovery position.

   After giving naloxone, stay with the individual. If they are breathing on their own, to decrease the individual's chance of choking on their vomit, place them in the recovery position, on their side and support the body with one bent knee with the face turned to the side.

5. **STAY WITH THE PERSON AND MONITOR FOR RESPIRATORY DISTRESS.**

   Provide rescue breathing as necessary. It is necessary to seek immediate emergency medical assistance (911) after delivering the first dose of naloxone, keep the patient under continued surveillance, and repeat doses of naloxone as necessary.

6. **REPEAT NALOXONE ADMINISTRATION IF SYMPTOMS CONTINUE.**

   The duration of action of most opioids is likely to exceed the 30-90 minutes that naloxone will be effective, resulting in a return of respiratory and/or central nervous system depression, even after an initial improvement in symptoms. If the desired response is not obtained after 2 or 3 minutes, another dose of naloxone may be administered if available.

   If after 1-2 doses of naloxone there is no breathing or breathing continues to be shallow, lay the person on their back and continue to perform rescue breathing while waiting for the naloxone to take effect, they breathe for themselves or EMS arrives.

13. **DOCUMENT** the individual's name, date, time and route the naloxone was administered and give this information to EMS, so that the information will accompany the individual to the hospital's emergency department.


15. Replace naloxone in-stock medication as appropriate as soon as possible.
**NALOXONE**
Generic Name: naloxone (nah LOX own) Brand Names: *Narcan*

**INDICATIONS AND USAGE**
Naloxone is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Naloxone is intended for immediate administration as emergency therapy in settings where opioids may be present. **Naloxone is not a substitute for emergency medical care.** When in doubt, if an individual is unresponsive and an opioid overdose is suspected, administer naloxone as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death. Call 911 to activate EMS immediately after administering the first dose of naloxone.

**HOW NALOXONE IS SUPPLIED**
Intranasal naloxone is supplied in a carton containing two blister packages each with a single NARCAN Nasal Spray (single 4 mg dose of naloxone hydrochloride intranasal spray).

For questions regarding dosage or timing of the brand being used, please see product package insert instructions developed by the manufacturer.

**STORAGE AND HANDLING OF INTRANASAL NALOXONE**
Store NARCAN Nasal Spray in the blister and cartons provided in a controlled room temperature 15°C to 25°C (59°F to 77°F) and in a dry, dark area. The naloxone should be checked monthly to ensure proper storage, expiration date, and medication stability. Personnel should be familiar with the type of naloxone maintained by the school and its use. Schools should refer to the package insert and store naloxone hydrochloride according to the individual manufacturer’s direction.
RESPONDING TO AN OPIOID OVERDOSE WITH NALOXONE FLOW CHART

The following flow-chart illustrates the steps that are taken depending on the victim’s responsiveness.

1. Assess for responsiveness and breathing
   - Responsive
     - Stay and observe until alert
   - Not Responsive
     - Provide Stimuli (e.g. vigorous sternal rub)
       - Responsive
         - Not Responsive
           - CALL FOR HELP!! CALL 911!!
             - Breathing
               - Monitor
             - Not Breathing
               - Start Rescue Breathing
                 - GIVE NALOXONE
                   - Assess Breathing
                     - Breathing
                       - Monitor
                     - Not Breathing
                       - Start Rescue Breathing
                         - Repeat Naloxone if available
                           - If no one has responded, CALL FOR HELP!! CALL 911!!
REFERENCES AND SOURCES
35. http://www.narcannasalspray.com/ Intranasal Naloxone FDA Package Insert:
38. Duragesic® (fentanyl transdermal system) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; 2013.
39. Percocet® (oxycodeone hydrochloride and acetaminophen tablets) [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc; 2013.
40. Opana® (oxymorphone hydrochloride tablet) [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc; 2013.
42. Data on file. kaleo, Inc.

Additional Resources

We would like to acknowledge and thank the Massachusetts Department for Public Health for the use of any information from the Massachusetts Department for Public Health Opioid Overdose Education and Naloxone Distribution in developing these protocols.
PUBLIC HEALTH NURSING ORAL HEALTH PROTOCOLS

Sections of this document contain guidelines, (recommendations for patient management) and protocols, (authoritative statements requiring a physician’s or dentist’s signature.) Both are contained in the specific sections. It is the local agency’s responsibility to obtain appropriate signatures ANNUALLY on each of the protocols.

The following table is a list of Protocols by Section to facilitate identification of those items requiring a physician’s and/or dentist’s signature.

<table>
<thead>
<tr>
<th>Section</th>
<th>Protocols</th>
</tr>
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<tbody>
<tr>
<td>Oral Health (Nurse-Based)</td>
<td>Fluoride Supplement Protocol</td>
</tr>
<tr>
<td></td>
<td>Fluoride Varnish Protocol</td>
</tr>
</tbody>
</table>
FLUORIDE SUPPLEMENT PROGRAM
GUIDELINES

1. The program is primarily for pre-school children (6 months–6 years), but may be provided up to age 16 (targeting children who do not attend a school with fluoridated water), who are not presently receiving fluoridated drinking water, other fluoride supplements, or vitamins with fluoride.

2. Whether or not a child is receiving fluoride can be determined by the answers to questions on the questionnaire and consent form (OH-9). A copy of the form is included in this section.

3. When bottled water is being used as the primary source of drinking water, the fluoride content of the water should be determined. If the child’s legal representative is unaware of the fluoride content of the bottled water, there are several sources of information, which can be helpful in learning the fluoride content of different brands of bottled water. Generally, bottled water has a toll-free phone number printed on the label, or a product website, which can be accessed to learn the fluoride content of the bottled water. Additional sources for learning the fluoride content of bottled water can be found at International Bottled Water Association (IBWA) Information Hotline: 1-800-WATER-11 or the International Bottled Water Association Website http://www.bottledwater.org/default.htm. **Do not submit** a sample of bottled water for testing, without first attempting to determine the fluoride content of the bottled water.

4. If the child is not receiving fluoride in the water supply, an analysis of the natural fluoride content of the home water supply must be performed prior to prescribing fluoride supplementation. Instructions for taking and submitting a water sample are provided on the reverse side of “Information for Parents or Guardians”.

5. The maximum amount of fluoride a child under six should receive is 0.5 mg. fluoride ion per day.

6. Fluoride drops (8 drops–1 mg. fluoride ion) are packaged in plastic bottles containing one ounce liquid with about 500 drops (62.5 mg. fluoride ion) per bottle.

7. Fluoride chewable tablets (0.5 mg. fluoride ion) are packaged in plastic bottles containing 120 tablets (60 mg. fluoride ion) per bottle.

8. Dosage levels of fluoride drops or tablets depend on the age of the child and the amount of fluoride in the drinking water (from fluoride water sample tests). The dosage schedule for fluoride drops or tablets is included in the fluoride supplement protocols. For patients with abnormal fluoride test results of water samples submitted to the State Lab, issuing of fluoride supplements (drops or tablets) and follow-up should be followed per protocol.
9. If the test results from the water sample are:
   - Equal to or greater than 2.00 ppm fluoride concentration, submit another sample of the water source to the State Lab for confirmation testing.
     - If both water samples are equal to or greater than 2.00 ppm up to 4.00 ppm fluoride concentration, recommend to the parent or guardian that children equal to or less than 8 years of age should consume another source of water.
   - Equal to or greater than 4.00 ppm fluoride concentration, recommend that both children and adults should consume another source of water.
     - The Environmental Protection Agency classifies water with equal to or greater than 2.00 ppm fluoride concentration as the Secondary Containment Level and water with equal to or greater than 4.00 ppm fluoride concentration as the Maximum Containment Level for fluoride in water.
     - When both water samples are equal to or greater than 4.00 ppm fluoride concentration, the nurse working with the Fluoride Supplement Program in the local health department should contact the local health department environmentalists and request an investigation of the water source.
   - If the second water samples, comes back less than 2.00 ppm, submit a third water sample to the State Lab for testing.
     - If fluoride concentration in two of the three samples is less than 2.00 ppm, follow the Fluoride Supplements Protocols for water samples with fluoride concentrations less than 2.00 ppm. If the fluoride concentration in two of the three samples is equal to or greater than 2.00 ppm, follow Fluoride Supplement Protocols for water samples with fluoride concentrations equal to or greater than 2.00 ppm.
   - For further clarifications and directions, call the Oral Health Program at 502-564-3246, extension 4421.

10. Orders for fluoride supplement drops or tablets must be signed by the health officer, another physician, a dentist, or another health professional with prescriptive authority. Protocols may be used—one copy will cover all children in the program. A sample copy is included in this section. If prescription blanks are used, a signed prescription for fluoride must be in each child’s folder.

11. Parents or guardians must be advised concerning the importance of giving their child no more than the prescribed amounts of fluoride. It should be called to the attention of the parent or guardian that excessive amounts (i.e., more than 2 mg. per day) over an extended period of time (two or three months) may cause tooth discoloration during their development; with white spots appearing on the child’s permanent teeth. In addition, they need to be told of the potentially toxic nature of fluoride when ingested in large doses at a single time.

    If, for example, a 22 pound child takes 264 mg. of sodium fluoride (120 mg. fluoride ion) at any single time, symptoms of acute toxicity can occur (stomach upset, vomiting). The minimum lethal dose for a 22-pound child is 480 mg. of sodium fluoride.
12. If it is determined that a child will participate in a preventive dental program, a questionnaire and consent form, the fluoride analysis of home water supply report, and a record of the amount of fluoride to be provided, if needed, shall be made a part of the child’s permanent health record. (Each participating child in the family must have a signed questionnaire and consent form and a record of the amount of fluoride to be taken.)

13. If more than one child in a family is to receive the fluoride supplement, written instructions for each child must be given to the parent.

14. A 3-month supply of supplements may be provided for each child in a family. Empty containers should be returned before providing a replacement. At this time, a determination should be made whether circumstances affecting the amount of fluoride supplement to be provided have changed, such as change in address, change in water source or the ‘aging out’ of the impacted children.

Questions to Ask Parents

a. Have you moved?
b. Have you changed your water supply? (Hint: even redrilling a well may impact the fluoride intake of the family.)
c. Has the child been placed on a vitamin supplement with fluoride?

Fluoride Supplementation Recommendations are based on the current guidelines of the American Dental Association, http://www.ada.org/2684.aspx#dosschedule

For additional information, please call the Oral Health Administrator at 502-564-3246, ext 4421.
Water Samples Tested for Fluoride Concentration

Results of Initial Water Sample Test

Fluoride Concentration

Less than 2.00 ppm
Follow Fluoride Supplement Protocols

Equal to or greater than 2.00 ppm
Submit another sample of the water source to the State Lab for testing

Equal or greater than 2.00 ppm to 4.00 ppm
Recommend children 8 years of age and younger consume another source of water

Equal to or greater than 4.00 ppm
Recommend children and adults consume another source of water
RN/RDH responsible for Fluoride Supplement Program at LHD should contact LHD environmentalist and request an investigation of the water source

Less than 2.00 ppm
Submit another sample of the water source to the State Lab for testing

2 water samples less than 2.00 ppm
Follow Fluoride Supplement Protocols

2 water samples equal to or greater than 2.00 ppm
Follow chart for readings equal to or greater than 2.00 ppm

For further information or directions, contact the Oral Health Program
502-564-3246 x 4421
# FLUORIDE SUPPLEMENT PROTOCOL

Infants and preschool children who are not drinking fluoridated water or who are not taking vitamins with fluoride should be given this essential nutrient. A laboratory test done on a sample of the drinking water supply will tell how much fluoride is in the water and the amount of the supplement that may be needed.

Call the Oral Health Program at 502-564-3246 to order forms, fluoride supplements, water sample, and collection kits or if further information is needed.

<table>
<thead>
<tr>
<th>HEALTH RISK OR CONDITION</th>
<th>TREATMENT/ INTERVENTION</th>
<th>EDUCATION/ COUNSELING</th>
<th>FOLLOW-UP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unfluoridated drinking water source may be:</td>
<td>Distribute one (1) bottle of fluoride drops and/or one (1) bottle of fluoride tablets to each child with individualized doses as follows:</td>
<td>NaFrisne Drops – 1 bottle has about 500 drops fluoride. NaFrisne Tablets – 1 bottle contains 120 tablets. Children under 3 are not issued tablets. Dosage depends on age of child and amount of fluoride in drinking water.</td>
<td>At each preventive visit ask: 1. Have you moved? 2. Has the source of your child’s drinking water changed? 3. Is child taking vitamin with fluoride supplement? Yes response to #1 and 2— assess new water supply, if indicated Yes response to #3— discontinue fluoride supplement</td>
</tr>
</tbody>
</table>

## DOSAGE

<table>
<thead>
<tr>
<th>Age of child</th>
<th>Fluoride in water 0 to 0.3 ppm</th>
<th>Fluoride in water 0.3 to 0.6 ppm</th>
<th>Fluoride in water 0.6 ppm and above</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age birth – 6 months</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Age 6 months – 3 yrs</td>
<td>2 drops – .25 mg 1 time per day (8 month supply)</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Age 3 – 6 yrs</td>
<td>4 drops – .50 mg 1 time per day (4 month supply) or 1 tablet – .50 mg 1 time per day (About a 4 month supply)</td>
<td>2 drops – .25 mg 1 time per day (8 month supply) Must give drops. There are no .25 mg tablets.</td>
<td>None</td>
</tr>
<tr>
<td>Age 6 – 16 yrs *</td>
<td>8 drops – 1.0 mg 1 time per day (2 month supply) or 2 tablets – .50 mg 1 time per day (2 month supply)</td>
<td>4 drops – .50 mg 1 time per day (4 month supply) or 1 tablet – .50 mg 1 time per day (4 month supply)</td>
<td>None</td>
</tr>
</tbody>
</table>

*Children who do not attend school with a fluoridated water supply may continue in the program.

Dispose of unused drops or tablets by:
- Returning any unused liquid or tablets to LHD
- Flushing unused liquid or tablet down toilet
- Placing unused liquid or tablets in disposable trash container

Source: American Dental Association’s Council on Scientific Affairs: Fluoride Supplement Dosage Schedule: 2010

| Physician, Dentist, Other | Date |
KIDS SMILE PROGRAM
FLUORIDE VARNISH PROGRAM

1. The Kentucky Oral Health Program has provided funding for fluoride varnish programs in local health departments. The Kentucky Oral Health Program offers training to local health department nurses in the areas of oral health screening, fluoride varnish application, oral health prevention messages, and procedures to determine when and how to make proper referrals to oral health professionals.

2. Fluoride varnishes are primarily used as a decay prevention therapy for pediatric patients and persons at a high-risk for tooth decay. Individuals who benefit the most from fluoride varnish include children, ages 0 through 5 years who have a family history of decay, low levels of fluoride in their drinking water or limited access to dental care. At the minimum, the fluoride varnish should be applied 2 times a year and those children who are at higher risk for decay may require more frequent applications. Because of recent studies showing positive results, children through the fifth grade may receive fluoride varnish, using the same protocol as those services for children less than six years of age.

3. Criteria for the use of fluoride varnish include the presence of factors that put a child at risk for decay. Clinical criteria include: visible plaque on the front teeth, decayed teeth, white-spot lesions or a family history of decay. Other criteria include: socioeconomic status and dental value of the primary caregiver.

4. Instructions for applying cavity varnish for decay reduction vary among the brands of products, always read and follow manufacturer’s instructions for any product.

5. Equipment and materials: non-latex gloves, toothbrush, fluoride varnish and applicator, mouth mirror, 2x2 gauze squares (in kit supplied by KDPH) and post-procedure instructions.

6. Apply fluoride varnish:
   a) Order the materials for application of fluoride varnish from the University of Kentucky College of Dentistry. Order blank provided by the Kentucky Oral Health Program and found in each KIDS Smile Training Manual.
   b) The Oral Health Program has reverted to the original varnish product is being reintroduced. 3M’s formulation of Vanish includes the same new technology as previous products: free calcium and phosphate that is available for immediate uptake into vulnerable surfaces.
   c) Position the child. Use the "knee-to-knee" technique for positioning. The child should sit in the caregivers lap, facing the caregiver. Then, have the caregiver lower the child's head into your lap.
   d) Brush the child’s teeth with the toothbrush included in the kit. This removes current plaque so the varnish can reach the at-risk areas without impediment. It also creates an opportunity for correct hygiene instruction with the patient or the attending parent/guardian.
   e) Prepare the fluoride varnish for single-dose containers. The supplies used to apply the varnish include a 0.50 ml unit dose package of fluoride varnish and applicator brush. For the primary dentition, the entire contents of the 0.50 ml unit of fluoride varnish do not have to be used – about half is usually sufficient to coat all the baby teeth.

Instructions for use:
1) Dispense the entire contents of the unit-dose package onto the gloved hand opposite the hand that will apply the varnish to the teeth.
2) Thoroughly mix the varnish with the applicator brush, keeping the material inside the circle.
3) Remove excess saliva from around teeth with the 2x2 gauze sponge.
4) Apply varnish evenly over all tooth surfaces particularly the buccal (cheek side) and facial (toward the lips) aspects of the upper and lower baby (primary) teeth with an emphasis on the high-risk areas: upper front teeth, lip side near the gumline.

5) A thin coating of the white-colored varnish may be visible on the teeth. The child may be able to feel the coating with rubbing the teeth with their tongue.

7. The provider should offer a small drink of water to the patient immediately after the application procedure is finished.

8. Instructions to give caregivers or older children without parent at visit (i.e., school) for after-care treatment include:
   a) Do not remove the varnish by brushing or flossing for the remainder of the day. Wait until the next morning to resume normal oral hygiene.
   b) The child should eat a soft diet for the remainder of the day. Avoid hot liquids, hard and sticky foods for the rest of the day.
   c) To receive the maximum decay prevention benefit, multiple applications of fluoride varnish are needed. The varnish needs to be reapplied at least every 6 months, depending on child’s risk for developing decay.

9. Document procedures for the day in the personal medical record provided by the Kentucky Oral Health Program.

10. For additional information, please call the Oral Health Administrator at 502-564-3246, extension 4421.

References


**KIDS’ SMILE PROGRAM: FLUORIDE VARNISH PROTOCOL**

The Kentucky Oral Health Program has provided funding for fluoride varnish programs in local health departments. The Kentucky Oral Health Program will offer training to local health department nurses in the areas of oral health screening, fluoride varnish application, oral health prevention messages, and procedures to determine when and how to make proper referrals to oral health professionals. Fluoride varnishes are primarily used as a decay prevention therapy for pediatric patients and persons at a high-risk for tooth decay.

Call the Oral Health Program at 502-564-3246, ext 4421 for additional information and to order fluoride varnish supplies.

<table>
<thead>
<tr>
<th>HEALTH RISK OR CONDITION</th>
<th>TREATMENT/INTERVENTION</th>
<th>FLUORIDE VARNISH/DOSAGE APPLIED</th>
<th>EDUCATION/COUNSELING</th>
<th>FOLLOW-UP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Ages 0 (eruption of first tooth) through 12 years</td>
<td>• Oral screening or assessment</td>
<td>• 0.25 ml for primary dentition</td>
<td>• Discuss the procedure with the child and obtain consent from caregiver</td>
<td>1) If no decay, repeat oral screening exam and fluoride varnish application in six months.</td>
</tr>
<tr>
<td>• Decayed teeth</td>
<td>• Apply fluoride varnish</td>
<td>• 0.40 ml for mixed dentition</td>
<td>• To preserve the varnish coating as long as possible do not brush the teeth until the next day. The varnish can be brushed off the next morning, when they resume their normal oral care routine.</td>
<td>2) a. If any white spots or untreated dental decay are noted, refer to a dentist.</td>
</tr>
<tr>
<td>• Family history of tooth decay</td>
<td>• Referral to dentist for observed urgent care needs.</td>
<td>• 0.50 ml for permanent dentition</td>
<td>• The child should eat a soft diet for the remainder of the day. Avoid hot liquids, hard and sticky foods for the rest of the day.</td>
<td>b. Repeat oral screening exam and fluoride varnish application in six months.</td>
</tr>
<tr>
<td>• Low levels of fluoride in their drinking water</td>
<td></td>
<td></td>
<td>• Do not take a fluoride supplement the day of treatment. Do not provide any other at-home fluoride treatment that day (i.e., toothpaste, mouthrinse).</td>
<td></td>
</tr>
<tr>
<td>• Limited access to dental care</td>
<td></td>
<td></td>
<td>• To receive the maximum decay prevention benefit, multiple applications of fluoride varnish are needed. The varnish needs to be reapplied at least twice a year, depending on child’s risk for developing decay.</td>
<td></td>
</tr>
<tr>
<td>• Visible plaque on the front teeth</td>
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<tr>
<td>• White-spot lesions</td>
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</tr>
</tbody>
</table>

Physician, Dentist, Other __________________________  Date __________________________
Fluoride References

American Dental Association. Fluoridation Facts. 1999; J120; 1-56


Centers for Disease Control and Prevention. Recommendations for using fluoride to prevent and control dental caries in the Unites States. MMWR 2001; 50(No. RR-14): 1-42


